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Adverse drug event reporting by pharmacists: a systematic literature review

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Abstract

Background Adverse drug event (ADE) reporting enhances early detection of risks associated with drug use. Pharmacists are uniquely suited to detect and report ADEs, but their contribution is diminished by under-reporting.

Objectives To assess pharmacists' knowledge and perceptions towards ADE reporting and to determine factors that improve or impede reporting using data from published survey articles using PRISMA.

Methods A systematic review was conducted to identify published survey articles that assess pharmacists' knowledge of and attitudes towards ADE reporting. PubMed, CINAHL and Web of Science databases were searched. The following information was extracted from eligible articles: demographic factors, sample size, response rate, survey delivery, pharmacists' working setting, barriers and facilitators of ADE reporting.

Results Only 68 survey articles were eligible to be included in the review (out of 820). The number of respondents ranges from 10 to 1870, and response rate varied between 10.5% and 100%. Pharmacists working in hospital settings and clinical pharmacists were more likely to report, to have better knowledge, favourable attitudes and familiarity with ADE reporting systems compared to pharmacists working in community settings. The main barrier towards reporting (recorded in >70% of the studies) was lack of confidence/basic knowledge of pharmacovigilance systems/concepts and ADE reporting process. Providing special training and education programmes related to pharmacovigilance concept was the most commonly mentioned factor to enhance reporting.

Conclusion To improve ADE reporting by pharmacists, it is recommended to design and integrate educational interventions related to pharmacovigilance within the pharmacy curriculum or continuous education courses.

Keywords adverse drug events; attitudes; knowledge; pharmacists; pharmacovigilance; reporting

Introduction

Adverse drug events (ADEs) account for substantial morbidity^[1–3] and mortality^[2] along with considerable economic burden.^[2,4,5] ADEs increase the risk of hospital admission,^[6] emergency department visits^[7] and prolongation of hospital stay (up to 20 days).^[8] It is estimated that the cost of managing ADEs in the United States may reach up to 30.1 billion dollars annually.^[9] Postmarketing drug surveillance systems are necessary to detect ADEs once a drug has been marketed and used by patients.^[10] Worldwide, reporting suspected adverse events is implemented via various spontaneous reporting systems.^[11,12] Both healthcare professionals and patients can directly report ADEs to these systems or through reporting to pharmaceutical manufacturers.^[13–15] Reporting ADEs to the respective regulatory authority enhances the early detection of signals and risks associated with drug use.^[15] Pharmacists, as drug experts and the most accessible healthcare providers, are uniquely suited to detect and report ADEs.^[16] However, the contribution of pharmacists is diminished by under-reporting; it is estimated that no more than 10% of all potential ADEs are eventually reported.^[17] Under-reporting of ADEs delays the identification of drugs with triggering alert signals and thus imposes a threat on the public health.^[15,17]

Factors that influence under-reporting included but not limited to insufficient knowledge of ADE detection and reporting, time constraints and lack of incentives.^[13,18–21]

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The number of cross-sectional studies that examined the determinants of under-reporting by healthcare professionals has risen overtime with a special emphasis on pharmacists.^[18] To our knowledge, no known systematic literature review has collectively investigated published studies that evaluated barriers and facilitators of ADE reporting specifically by pharmacists. The aim of this systematic review is to assess pharmacists' knowledge and perceptions towards ADE reporting and to determine factors that improve or impede reporting by pharmacists.

Methods

PubMed, CINAHL and Web of Science databases were searched to locate studies that meet the objectives of this systematic review. Additional articles were included by manual search of the references cited by eligible articles located by the database search. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for conducting this literature review.^[22]

The following search terms were used for identification of eligible articles: “adverse drug reaction”, “ADR”, “adverse drug event”, “ADE”, “attitude”, “barriers”, “factors”, “knowledge”, “spontaneous reporting” and “pharmacovigilance”. The search included all articles that appeared in the literature until October 2019. The resulting studies were then screened initially based on their respective titles and abstracts. Some studies were excluded because of the following reasons: (i) pharmacists were not among the surveyed healthcare professionals; (ii) an analysis/ summary of ADE case reports of certain drugs; (iii) an expert opinion, commentary or literature review; (iv) models to improve signal detection of ADEs; (v) research restricted to pharmacy students; and (vi) qualitative studies. In the eligibility stage, the selected articles were (i) written in English and published in a peer-reviewed journal, (ii) have a sufficient sample size ($n \geq 10$) and (iii) included a primary analysis of pharmacists' knowledge, attitudes, experiences and/or perceptions towards ADE reporting. Extraction of the eligible articles was performed by two independent authors using predefined criteria. The extracted fields were then compared, and incompatible data were investigated.

The following information was extracted from each eligible study: author, publication year, objective of the study, country of occurrence, national pharmacovigilance centre (year of establishment), survey period, study population, pharmacist work setting, number of respondents and response rate, survey/study delivery (mail, face-to-face, self-administrative, e-mail/web), scale or type of questions [yes or no questions, multiple-choice questions (MCQS), Likert scale, visual analogue scale (VAS) and open-ended questions], percentage of ADE reporting among respondents, the use of theoretical framework (if any), facilitators and barriers of ADE reporting as perceived by pharmacists and demographic factors that might impact reporting (age, sex, work settings/professional title, workload/years of experience and years since graduation). Factors that were found to be statistically significant in the original studies were included in the tables, if p-

values were not calculated in the included studies; we only considered the top three most frequently reported barriers and facilitators. We also extracted data from studies that conducted comparison between pharmacists and other HCPs with regard to attitudes and knowledge about ADE reporting.

Results

Characteristics of the eligible studies

A total of 802 studies were identified through the initial electronic database search (403 via PubMed, 324 via Web of Science and 75 via CINAHL). Additional 18 articles were identified through reference citations and manual search. The total number of screened articles was 820, and after initial screening of titles and abstract, 738 articles were excluded. Of the 94 articles that were eligible, only 68 were included (Figure 1).

Analysis according to the country of occurrence showed that 59% of the studies had been conducted in Asia (40/68), twelve studies came from European Union, seven studies came from Africa, six from North America, two from Australia and one study from South America (Venezuela). Tables 1 and 2 demonstrate studies that were included in the systematic review, listed by year of publication. As shown in the tables, the number of papers investigating factors that impact reporting of ADEs by pharmacist increased overtime. The year with the largest number of publication was 2018 (11 publications).

The number of pharmacist respondents in the eligible studies ranged from 10^[23] to 1870^[24] with a median of 179 (25th percentile = 87.8; 75th percentile = 331.25). Response rate ranges from as low as 10.5%^[25] to more than 90%.^[26–34] Most of the studies included in this review surveyed pharmacists working in hospital settings (either alone (27 studies) or with pharmacists working in community settings (19 studies)). Some of the studies surveyed only pharmacists working in community settings (18 studies).

Self-administered questionnaires were used in 41 studies (60%), mail surveys in 13 studies (19%), online surveys in nine studies (13%) and face-to-face delivery in five (8%) studies. Likert scale was used in 38 and VAS in two studies.^[33,35] In addition to Likert and VAS, most studies included other scales such as yes/no, multiple-choice and open-ended questions. Web surveys delivered via e-mail or social media were used more frequently in recent studies.^[24,36–38] Many studies included in this review lacked a theoretical framework. In papers in which a theoretical framework was utilized, Inmans' seven deadly sins for not reporting ADEs^[32,33,35,39,40]; Knowledge-Attitude-Practice Model (KAP)^[29–31,34,41–56]; and theory of planned behaviour were the most frequently used theories to understand pharmacists' reporting of ADEs.^[57]

Demographic factors that impact reporting of ADEs by pharmacists

Older age was found to be significantly associated with reporting in one study^[32] and negatively associated with

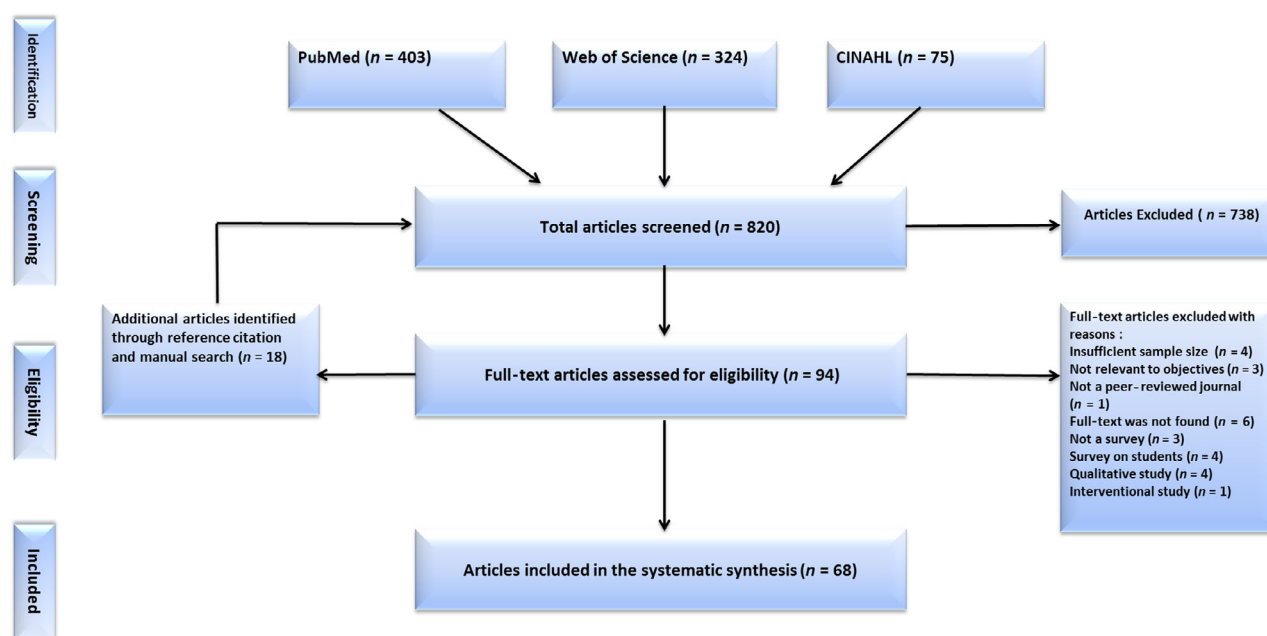


Figure 1 PRISMA flow chart for the included studies.

reporting^[58] and knowledge^[59] of ADEs in two studies. A recent study by Yu *et al.*^[51] indicated that pharmacists aged 60 years and older were less likely to report ADE compared with younger pharmacists ($P < 0.001$). However, other studies found no significant association between different age groups and tendency to report ADE by pharmacist.^[39,41,47] Recent pharmacy graduates were found to be significantly less familiar with reporting system than pharmacists who had graduated for at least 15 years.^[60] There was no significant difference between the two genders in attitude^[54,61] or reporting rate of ADEs.^[39,47] However, recent studies by Williams *et al.*^[38] and Hajj *et al.*^[26] showed that female pharmacists have significantly stronger intentions to report ADEs and a higher mean knowledge of ADE reporting compared to male pharmacists.

More working experience as a pharmacist was found to increase the odds of reporting in three studies^[32,38,39] but was not significant in other studies^[47,62] and was associated with better knowledge and attitude towards ADE and ADE reporting in one study^[63] and with reduced knowledge in other two studies^[56,59]. Increasing years of experience (10–14 years) increased the awareness about the presence of the national ADE reporting system.^[28] However, a recent study from Lebanon showed that younger pharmacists (staff pharmacists) have better training on reporting and higher reporting rates compared to chief pharmacists.^[30] Workload and number of hours worked per week were found to have significant impact on willingness to report, though there was no consensus upon the specific number of hours.^[39,40,60,64]

Pharmacists working in hospital settings and clinical pharmacists were more likely to report,^[21,24,29,36,40,49] to have better knowledge, favourable attitude and familiarity with ADE reporting system compared to pharmacists working in community/retail settings or dispensary

pharmacists.^[21,40,47,59] Perez Garcia *et al.*^[65] did not find that workplace to have an influence on pharmacovigilance knowledge. Higher levels of education and earning a post-graduate degree were found to increase reporting knowledge^[26] and frequency.^[66]

Reporting of ADEs by pharmacists compared to other HCPs

Most studies indicate poor knowledge and practices with regard to ADE reporting among all healthcare professionals. However, some studies show statistically significant differences between the healthcare professionals. Among studies that included other healthcare professionals, pharmacists were more likely to see an ADE and more likely to be aware about the existence of pharmacovigilance centres and reporting forms compared to doctors and nurses.^[25,28,42,46,67–70] No difference in the mean knowledge/attitudes was found between the three healthcare professional in some studies^[27,33,71,72] or reporting rate.^[67] However, other studies found that pharmacists have better knowledge of ADEs than nurses^[50,73] and pharmacists have better mean knowledge score compared to physicians.^[46,53,70] One study found that pharmacist prescribers were more likely to report ADE than nurse prescribers.^[36] A recent study found that physicians reported significantly more ADEs compared to pharmacists.^[53] More pharmacists than physicians would hesitate to report an ADE because of uncertainty over who is responsible for reporting. On the other hand, more physicians than pharmacists hesitate to report an ADE due to concerns over liability.^[40] Compared to pharmacy technicians, pharmacist found to have better knowledge of and attitudes towards ADE reporting.^[74] In a study conducted among HCPs in South Wales teaching

Table 1 Summary of the studies that investigate factors which impact reporting of adverse drug events (ADEs) among pharmacists

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
Lee <i>et al.</i> (1994) ^[87]	1994	Hong Kong	Pharmacovigilance and Risk Management Division/Department of Health (1986)	To study the attitudes and knowledge of pharmacists in Hong Kong towards the reporting of adverse drug reactions (ADRs)	Pharmacists	Retail shops, hospitals and outpatient clinics	Cross-sectional
Generali <i>et al.</i> (1995) ^[60]	1995	United States	Food and Drug Administration/MedWatch programme	To survey pharmacists' knowledge of the adverse drug reaction (ADR) reporting process, as well as the nature and seriousness of ADRs observed by pharmacists, and to determine how pharmacists perceive their role in monitoring and reporting suspected reactions	Pharmacists	Hospital and community pharmacists (others include HMO and nursing homes)	Cross-sectional
Wallace <i>et al.</i> (1995) ^[40]	1995	Canada	The Canadian Adverse Drug Reaction Monitoring Program (CADRMP)(1965)	To evaluate the awareness and understanding of adverse drug reaction (ADR) reporting by pharmacists and physicians in the province of Saskatchewan	Pharmacists and physicians	Hospital and community pharmacists	Cross-sectional
Sweis and Wong (2000) ^[39]	2000	UK	Yellow Card Scheme (YCS)(1964)	(i) To analyse the extent to which hospital pharmacists think that specified factors could affect reporting ADRs; (ii) to identify any additional factors that could hinder reporting; and (iii) to recommend possible methods to improve reporting.	Pharmacists	Hospital pharmacists	Cross-sectional
Green <i>et al.</i> (2001) ^[88]	2001	UK	Yellow Card Scheme (YCS)(1964)	To investigate the attitudes of UK hospital pharmacists towards, and their understanding of, adverse drug reaction (ADR) reporting	Pharmacists	Hospital pharmacists	Cross-sectional
Kelly <i>et al.</i> (2004) ^[70]	2004	Australia	Adverse Drug Reactions Advisory Committee (ADRAC)	To identify predisposing and enabling factors which influence adverse drug reaction reporting by medical, nursing and pharmacy staff in New South Wales teaching hospitals	HCPs (physicians, nurses and pharmacists)	Hospital pharmacists	Cross-sectional
Bawazir (2006) ^[89]	2006	Saudi Arabia	Ministry of Health, Post Marketing Program (1998)	To assess the attitude and behaviour of community pharmacists in Saudi Arabia regarding the reporting of adverse drug reactions (ADRs)	Pharmacists	Community pharmacists	Cross-sectional
Herdade <i>et al.</i> (2006) ^[35]	2006	Portugal	Pharmacovigilance Center (1992)	To identify (i) professional or demographic characteristics; and (ii) attitudes associated with pharmacists' ADR reporting in northern Portugal	Pharmacists	Hospital and community pharmacists	Case-control
Granås <i>et al.</i> (2007) ^[90]	2007	Norway	Regional Medicines Information Centers (RELIS), (2003)	To explore pharmacists' attitudes towards pharmacovigilance and their experiences with ADR reporting, to evaluate the effect of an educational programme and to compare these findings to the attitudes in a control group	Pharmacists	Community pharmacists	Prospective controlled study
Irujo <i>et al.</i> (2007) ^[32]	2007	Spain	Yellow Card System	To identify the factors that influence community pharmacists' ADR under-reporting in Navarra, a northern Spanish region	Pharmacists	Community pharmacists	Case-control

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
Toklu and Uysal (2008) ^[91]	2008	Turkey	National Pharmacovigilance Center (TUFAM)	To investigate the knowledge and attitudes of community pharmacists towards pharmacovigilance and adverse drug reactions (ADRs) in Kadıköy district of Istanbul (Turkey)	Pharmacists	Community pharmacists	Cross-sectional
Elhour et al. (2009) ^[92]	2009	Sudan	Pharmacovigilance Center at the Ministry of Health (2008)	To determine baseline data for healthcare leaders' and policymakers' knowledge, attitudes and policies related to ADRs at eight hospitals in Wad Madani, Sudan	HCPs (physicians, pharmacists and nurses)	Community, hospital, marketing and administrative pharmacists	Cross-sectional
Jarensiripornkul et al. (2009) ^[93]	2009	Thailand	Thai FDA Safety Monitoring Programme (1989)	To determine the knowledge, attitudes and practices of Thai hospital pharmacists concerning the safety monitoring programme and reporting of adverse drug reactions to the Thai Food and Drug Administration	Pharmacists	Hospital pharmacists	Cross-sectional
Vessal et al. (2009) ^[94]	2009	Iran	Iranian Pharmacovigilance Center (1998)	To investigate the role of pharmacists in reporting ADRs in Iran	Pharmacists	Hospital and community pharmacists	Cross-sectional
Xu et al. (2009) ^[25]	2009	China	National Center for ADE Monitoring (1989)	To investigate the awareness of pharmacovigilance by healthcare professionals in Jiangsu, China	HCPs (physicians, pharmacists, nurses, administrator and medical technology)	Hospital pharmacists	Cross-sectional
Su et al. (2010) ^[38]	2010	China	National Center (1989)	To investigate the knowledge and opinions of hospital pharmacists about the spontaneous reporting of adverse drug reactions (ADRs) in Inner Mongolia, a northern region of China.	Pharmacists	Hospital pharmacists: dispensary administration and clinical pharmacy	Cross-sectional
García and Figueras (2011) ^[65]	2011	Venezuela	Yellow Card Scheme (YCS) (1995)	To measure the knowledge level on the suspected ADR voluntary reporting system among physicians and pharmacists in Venezuela and to study its relationship with different variables	HCPs	NM	Cross-sectional
Gavaza et al. (2011) ^[75]	2011	United States	Food and Drug Administration/ MedWatch programme (1993)	To investigate the influence of pharmacists' attitudes on intention to report serious adverse drug events (ADEs) to the Food and Drug Administration (FDA)	Pharmacists	Hospital and community pharmacists	Cross-sectional
Gavaza et al. (2011) ^[57]	2011	United States	Food and Drug Administration/ MedWatch (1993)	This study explored the utility of the theory of planned behaviour (TPB) model in predicting Texas pharmacists' intention to report serious ADEs to the FDA	Pharmacists	Hospital and community pharmacists	Cross-sectional
Gavaza et al. (2011) ^[95]	2011	United States	Food and Drug Administration/ MedWatch programme (1993)	To assess Texas pharmacists' knowledge of adverse drug event (ADE) reporting to the Food and Drug Administration (FDA) and to determine demographic and practice characteristics associated with this knowledge	Pharmacists	Hospital and community pharmacists	Cross-sectional

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
Oreagba <i>et al.</i> (2011) ^[96]	2011	Nigeria	National Pharmacovigilance Center (NPC) (2004)	To investigate the knowledge, perceptions and practice of pharmacovigilance among community pharmacists in Lagos State, south-west Nigeria	Pharmacists	Community pharmacists	Cross-sectional
Vrublevska <i>et al.</i> (2011) ^[97]	2011	Latvia	WHO Pharmacovigilance System (2004)	To estimate the awareness of Latvian pharmacy practitioners about pharmacovigilance and to identify the main reasons for their reluctance to report adverse drug reactions (ADRs)	Pharmacists and pharmacy assistant	Community pharmacists	Cross-sectional
Dos Santos Pernas <i>et al.</i> (2012) ^[33]	2012	Portugal	Portugal Pharmacovigilance Center (1992)	To assess the reproducibility of a self-administered questionnaire and to identify health professionals' (physicians, pharmacists and nurses) knowledge of and attitudes to spontaneous ADR reporting	HCPs (physicians, pharmacists and nurses)	Hospital and community pharmacists	Cross-sectional
Gavaza <i>et al.</i> (2012) ^[77]	2012	United States	Food and Drug Administration/MedWatch (1993)	1 To identify the groups or individuals that influence pharmacists' decision-making to report adverse drug events (ADEs) 2 To determine the differences in social influence or subjective norm between intenders and non-intenders and 3 To determine the relationship between subjective norm towards reporting serious ADEs and practice and demographic characteristics	Pharmacists	Hospital and community pharmacists	Cross-sectional
Prakasam <i>et al.</i> (2012) ^[98]	2012	India	National Pharmacovigilance Program (NPP) of the Ministry of Health and Family Welfare (2010)	The aim of our study was to evaluate the knowledge, perception and practice of pharmacovigilance among registered community pharmacists in Hyderabad, India	Pharmacists	Community pharmacists	Cross-sectional
Ahmad <i>et al.</i> (2013) ^[48]	2013	India	National Pharmacovigilance Program (NPP) of the Ministry of Health and Family Welfare (2010)	To assess the knowledge, attitude and practice of pharmacists in India with the aim of identifying reasons for under-reporting of ADRs and determining the steps that could be adopted to increase reporting rates	Pharmacists	Pharmacists from all fields (community, hospital, industry and academia)	Cross-sectional
Hadi <i>et al.</i> (2013) ^[62]	2013	Malaysia	Malaysian Adverse Drug Reactions Advisory Committee (MADRAC)	To evaluate knowledge, facilitators and barriers towards adverse drug reaction (ADR) reporting among hospital pharmacists in Malaysia	Pharmacists	Hospital pharmacists	Cross-sectional study
Jose <i>et al.</i> (2013) ^[63]	2013	Oman	Drug Control Department, Directorate General of Pharmacy Affairs and Drugs Control, Sultanate of Oman	To assess the knowledge, attitude and behaviour of community pharmacists to ADR-related aspects in the Sultanate of Oman	Pharmacists	Community pharmacists	Cross-sectional

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
KC <i>et al.</i> (2013) ^[99]	2013	Nepal	National Pharmacovigilance Centre (NPC) (2004)	To investigate the knowledge about ADRs and ADR reporting among healthcare professionals working at four Regional Pharmacovigilance Centers (RPCs) of Nepal	HCPs (physicians, pharmacists and nurses)	Hospital pharmacists	Cross-sectional
Khan (2013) ^[76]	2013	Saudi Arabia	Saudi National Pharmacovigilance Center (2009)	To analyse community pharmacists' current knowledge and perceived barriers to adverse drug reaction (ADR) reporting systems in the eastern region, Al-Ahsa, Saudi Arabia	Pharmacists	Community pharmacists	Cross-sectional
Santosh <i>et al.</i> (2013) ^[67]	2013	Nepal	National Pharmacovigilance Centre (NPC) and Regional Pharmacovigilance Centre (RPC)	To investigate the attitudes towards and ways to improve adverse drug reaction (ADR) reporting among healthcare professionals working at four Regional Pharmacovigilance Centers (RPCs) of Nepal	HCPs (physicians, pharmacists and nurses)	Hospital pharmacists	Cross-sectional
Stewart <i>et al.</i> (2013) ^[36]	2013	UK	Yellow Card Scheme (YCS)(1964)	To determine UK non-medical prescribers' (NMPs) (supplementary or independent) current participation and self-reported competence in pharmacovigilance, and their perceptions of training and future needs	Non-medical prescribers (nurses and pharmacists)	Hospital and community pharmacists	Cross-sectional
Wilbur (2013) ^[49]	2013	Qatar	NA	To describe pharmacists' knowledge, experiences, attitudes and perceived barriers to ADR reporting in Qatar	Pharmacists	Hospital and community pharmacists	Cross-sectional
Affi <i>et al.</i> (2014) ^[100]	2014	Iran	Yellow Card System (1998)	1 To find methods to improve Iranian pharmacovigilance system and to determine reasons for under-reporting 2 To investigate the role of pharmacist in ADR reporting in Shiraz, Iran	Pharmacists	Hospital and community pharmacists	Cross-sectional
Qassim <i>et al.</i> (2014) ^[44]	2014	UAE	Health Authority of Abu Dhabi (HAAD) Pharmacovigilance Program (2007)	To determine the knowledge, attitudes among UAE Community Pharmacists towards an adverse drug reaction reporting and factors associated with reporting in Ajman and Sharjah, UAE	Pharmacists	Community pharmacist	Cross-sectional
Mahmoud <i>et al.</i> (2014) ^[43]	2014	Saudi Arabia	Saudi National Pharmacovigilance Center (2009)	To assess community pharmacists' knowledge, behaviours and experiences relating to adverse drug reaction (ADR) reporting in Saudi Arabia	Pharmacists	Community pharmacist	Cross-sectional
Mulatu and Worku (2014) ^[41]	2014	Ethiopia	Food, Medicine, and Health Care Administration and Control Authority (2002)	To assess the knowledge, attitude and practice of health professionals towards an adverse drug reaction reporting and factors associated with reporting	HCPs (physicians, pharmacists and nurses)	Hospital pharmacist	Cross-sectional

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
Abdel-Latif & Abdel-Wahab (2014) ^[68]	2015	Saudi Arabia	Saudi National Pharmacovigilance Center	To assess the knowledge and awareness of ADR reporting and pharmacovigilance system among healthcare professionals in Al-Madinah Al-Munawwarah hospitals, Kingdom of Saudi Arabia	HCPs (physicians, pharmacists, pharmacy technicians and nurses)	Hospital pharmacists	Cross-sectional
Alshammari <i>et al.</i> (2015) ^[71]	2015	Saudi Arabia	Saudi National Pharmacovigilance Center (2009)	To investigate the Knowledge, attitude and awareness of Saudi healthcare professionals working in hospitals towards the concept of pharmacovigilance	HCPs (physicians, pharmacists, nurses and others)	Hospital pharmacists	Cross-sectional
Liu <i>et al.</i> (2015) ^[29]	2015	China	National Center for ADR Monitoring (1989)	1 identify factors that affect hospital pharmacist ADR reporting in the Xi'an region using the pharmacist ADR reporting in the Xi'an 2 obtain suggestions from pharmacists about how to improve the current ADR reporting system	Pharmacists	Hospital pharmacists	Cross-sectional
Suyagh <i>et al.</i> (2015) ^[31]	2015	Jordan	The Jordanian Pharmacovigilance Center (2001)	To evaluate pharmacist's knowledge, practice and attitudes towards ADRs reporting after establishing the national ADR reporting centre in Jordan	Pharmacists	Hospital and community pharmacists	Cross-sectional
Williams <i>et al.</i> (2015) ^[38]	2015	England	Yellow Card Scheme (YCS)(1964)	To assess the effect of factors within hospital pharmacists' practice on the likelihood of their reporting a medication safety incident	Pharmacists	Hospital pharmacists	Cross-sectional
Almandil (2016) ^[69]	2016	Saudi Arabia	Saudi National Pharmacovigilance Center (2009)	To document the knowledge and awareness of ADR reporting and pharmacovigilance systems among healthcare professionals working at King Fahd Hospital	HCPs (physicians, pharmacists, pharmacy technicians and nurses)	Hospital pharmacists	Cross-sectional
Amin <i>et al.</i> (2016) ^[79]	2016	Bangladesh	Directorate General of Drug Administration (1996)	To assess community pharmacists' and pharmacy technicians' knowledge and perceptions about ADRs and the barriers towards the reporting of these reactions in Dhaka, Bangladesh	Pharmacists/pharmacy technicians	Community pharmacists	Cross-sectional
Bule <i>et al.</i> (2016) ^[23]	2016	Ethiopia	Food, Medicine, and Health Care Administration and Control Authority Bhutan National Pharmacovigilance Centre (2007)	To assess the knowledge, attitude and practices of adverse drug reaction reporting among health professionals in Adama Hospital Medical College	HCPs (physicians, pharmacists and nurses)	Hospital pharmacists	Cross-sectional
Dorji <i>et al.</i> (2016) ^[50]	2016	Bhutan	Bhutan National Pharmacovigilance Centre (2007)	To investigate the level of knowledge of both ADRs and ADR reporting among HCPs, including traditional medicine practitioners	HCPs (physicians, pharmacists, technicians and nurses)	Hospital pharmacists	Cross-sectional

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
MM <i>et al.</i> (2016) ^[46]	2016	Malaysia	Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) 2007	To investigate the KAP towards ADR reporting among HCPs working at primary outpatient care in Kuala Muda District Health Office, Kedah, Malaysia	Physicians and pharmacists	Hospital pharmacist	Cross-sectional
Shamim <i>et al.</i> (2016) ^[42]	2016	Pakistan	Drug Regulatory Authority of Pakistan 2012	To measure awareness about adverse drug reaction (ADRs) reporting among doctors, pharmacists and nurses and to determine reasons of ADR under-reporting in Pakistan	HCPs (physicians, nurses and pharmacists)	Hospital pharmacists	Cross-sectional
Umar <i>et al.</i> (2016) ^[27]	2016	Nigeria	National Pharmacovigilance Center (2004)	To assess the attitude of nurses and pharmacists towards adverse drug reaction (ADR) reporting	Pharmacists and nurses	Hospital pharmacists	Cross-sectional
Yu <i>et al.</i> (2016) ^[51]	2016	Korea	Regional Pharmacovigilance Centers and Regional Pharmacovigilance Centers in Korea (2009)	To evaluate the association between spontaneous reporting (SR) and the knowledge, attitude and needs of community pharmacists	Pharmacists	Community pharmacists	Cross-sectional
AlSaleh <i>et al.</i> (2017) ^[45]	2017	Kuwait	Kuwait Drug and Food Control (2016)	To document knowledge, attitude and practices (KAP) among pharmacists working in the government hospitals in Kuwait and to explore barriers to implementing a fully functional PV programme in Kuwait	Pharmacists	Hospital pharmacists	Cross-sectional
Al-Worafi <i>et al.</i> (2017) ^[74]	2017	Yemen	The Yemeni Pharmacovigilance Centre (2011)	To compare the knowledge, attitude and barriers of pharmacy technicians and pharmacists towards pharmacovigilance, adverse drug reactions (ADRs) and ADR reporting in community pharmacists in Yemen	Pharmacists and pharmacy technicians	Community pharmacists	Cross-sectional
Cheema <i>et al.</i> (2017) ^[37]	2017	UK	The United Kingdom (UK)'s Yellow Card Scheme (YCS) (opened to pharmacists in 1997)	To identify the barriers to ADR reporting among community pharmacists practicing in the UK	Pharmacists	Community pharmacists	Cross-sectional
Said & Hussain (2017) ^[72]	2017	UAE	Health Authority of Abu Dhabi (HAAD) Pharmacovigilance Program (2007)	To assess knowledge, attitude and practice (KAP) of ADR reporting among United Arab Emirates (UAE) healthcare professionals to clarify their present strategies and identify steps to avoid under-reporting	Physicians and pharmacists	Hospital and community pharmacists	Cross-sectional
Ali <i>et al.</i> (2018) ^[101]	2018	Saudi Arabia	Saudi National Pharmacovigilance Center	To assess knowledge, practice and attitudes towards pharmacovigilance and adverse drug reaction reporting process among healthcare providers in Dammam, KSA	HCPs (physicians, pharmacists, nurses and others)	Hospital pharmacists	Cross-sectional
Bahnassi & Al Harbi (2018) ^[54]	2018	Syria		To describe Syrian pharmacists' knowledge, attitudes, practices and perceived barriers to	Pharmacists		Cross-sectional study

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
Hajj <i>et al.</i> (2018) ^[26]	2018	Lebanon	The Syrian pharmacovigilance (PV) system National Pharmacovigilance Center (2004)	reporting of adverse drug reactions (ADR), and to evaluate the sociodemographic effects within Damascus and rural Damascus To assess the knowledge, attitudes and practices (KAP) among community pharmacists in Lebanon in relevance to potential pharmacovigilance and adverse drug reactions reporting in Lebanon To evaluate the knowledge, attitude and practice, among hospital pharmacists in Lebanon concerning ADRs and pharmacovigilance concepts	Pharmacists	Hospital and community pharmacists Community pharmacists	Cross-sectional
Hallit <i>et al.</i> (2018) ^[30]	2018	Lebanon	The National Pharmacovigilance Center	To assess the knowledge, contribution and perception of German pharmacy professionals regarding pharmacovigilance activities, in order to identify their needs to report better on the issue To investigate and compare the knowledge, attitude and practices regarding pharmacovigilance (PV) and reporting of adverse drug reactions (ADRs) among physicians and pharmacists in primary care settings.	Pharmacists	Hospital pharmacists	Cross-sectional study
Laven <i>et al.</i> (2018) ^[52]	2018	Germany		To measure community pharmacists' knowledge and perspectives towards ADR reporting	Pharmacists	Hospital and community pharmacists	Cross-sectional study
Lemay <i>et al.</i> (2018) ^[53]	2018	Kuwait	Kuwait Drug and Food Control		Physicians and pharmacists in primary care settings	Pharmacists in primary care settings	Cross-sectional
Li <i>et al.</i> (2018) ^[64]	2018	Australia	Adverse Drug Reactions Advisory Committee (ADRAC)		Pharmacists	Community pharmacist	Cross-sectional study
Moinuddin <i>et al.</i> (2018) ^[55]	2018	Saudi Arabia	National Pharmacovigilance Center (NPC)	To investigate the knowledge of ADRs and attitude of healthcare professionals towards ADRs reporting	HCPs (physicians, nurses and pharmacists)	Hospital pharmacists	Cross-sectional study
Nisa <i>et al.</i> (2018) ^[34]	2018	Pakistan	NA	To assess the knowledge, attitude, practice and factors associated with ADR reporting by healthcare professionals (physicians and pharmacists) in secondary and tertiary hospitals of Islamabad	HCPs (physicians and pharmacists)	Hospital pharmacists	Cross-sectional study
Seid <i>et al.</i> (2018) ^[73]	2018	Ethiopia	Food, Medicines and Health Care Administration and Control Authority (FMHACA) (2002)	To assess the knowledge, attitudes and practices of healthcare professionals towards adverse drug reaction reporting	HCPs (nurses, health officers and pharmacists)	Health centre	Cross-sectional study
Shanko & Abdela (2018) ^[28]	2018	Ethiopia	Food, Medicine, and Health Care Administration and Control Authority (2002)	To assess knowledge, attitude and practices of adverse drug reaction reporting among healthcare professionals in Hiwot Fana Specialized University Hospital	HCPs (physicians, nurses and pharmacists)	Hospital pharmacists	Cross-sectional

1 (continued)

Reference (publication year)	Year	Country	Pharmacovigilance centre (established year)	Objective	Study population	Pharmacists employment	Study design
Aldryhim <i>et al.</i> (2019) ^[24]	2019	Saudi Arabia	The Saudi National Pharmacovigilance Center	To identify potential factors that facilitate pharmacists in community and hospital settings to report ADR	Pharmacists	Hospital and community pharmacists	Cross-sectional
Al Rabayah <i>et al.</i> (2019) ^[47]	2019	Jordan	Jordan Food and Drug Administration	To determine the knowledge, attitude and practice of healthcare providers towards pharmacovigilance and ADR reporting, barriers to ADR reporting and the association between the demographics of healthcare providers and their knowledge and attitude towards reporting	HCPs (physicians, nurses and pharmacists)	Hospital pharmacists	Cross-sectional
Kopciuch <i>et al.</i> (2019) ^[56]	2019	Poland	NA	To evaluate the pharmacists' attitudes to and knowledge on spontaneous ADR reporting in Poland and to identify the reasons for under-reporting of ADRs	Pharmacists	NM	Cross-sectional

HCPs, health care professionals; NA, not available; NM, not mentioned.

hospitals, the majority of doctors and nurses indicated that the ward pharmacists are their main source of information about ADRs.^[70] However, a recent study from Ethiopia found that less than 7% of the surveyed HCPs used pharmacists as a source of information about ADRs.^[73]

Factors that negatively influence reporting of ADEs by pharmacists

The factors most frequently associated with not reporting ADEs by pharmacists were as follows: lack of confidence/basic knowledge of pharmacovigilance concepts, systems and ADE reporting process in 75% (51/68); lack of time, interest or reporting forms in 74% (50/68); ADE is too trivial or well known to report in 26% (18/68); uncertainty that a specific drug is responsible for a particular ADE in 25% (17/68); fear of legal liabilities in 12% (8/68); and lack of monetary compensation in 7% (5/68) of studies (Figure 2).

Other factors that negatively impact reporting of ADEs by pharmacist were lack of patient complete medical history^[40,57], disturbance of normal workflow^[75], fear of breaching patient confidentiality^[39,45,69], uncertainty over who is responsible for reporting^[36,40], and deficient of professional environment.^[45,76]

Factors positively influence reporting of ADEs by pharmacists

The most frequently mentioned or recommended factors to enhance reporting of ADEs by pharmacists were as follows: providing special training or education programmes related to pharmacovigilance concepts and ADE reporting in 49% (33/68); reporting serious reaction to a new product or unusual reaction to an existing product in 18% (12/68); feedback about the reported ADE association in 13% (9/68); having a positive or favourable attitude towards reporting in 12% (8/68); considering reporting ADE as a professional obligation in 9% (6/68); making ADE reporting compulsory in 7% (5/68); and the presence of onsite pharmacist dedicated for reporting or local pharmacovigilance centre in 4% (3/68) of studies (Figure 3).

Other factors that positively impact reporting of ADEs by pharmacists were as follows: the impact and opinion of other pharmacists about ADE reporting (social influence),^[77] patient complaint or request to report,^[48,78,79] having a hospital written policy,^[39] providing a toll-free number by the relevant authorities^[79] and establishing incentive mechanisms.^[29]

Discussion

The role of pharmacists within the healthcare system has evolved over time from the traditional dispensing responsibilities towards more involvement in patient therapy by providing pharmaceutical care.^[80] Reporting of ADEs is essential to maintain the safe use of medications by patients. Countries worldwide depend mainly on spontaneous reporting of adverse drug events to national pharmacovigilance systems. This is because these systems provide the main

Table 2 Description of survey articles that investigate factors which impact reporting of adverse drug events (ADEs) among pharmacists

Reference (publication year)	Year	Survey period	No. of respondents pharmacists (response rate %)*	Survey delivery	Scale	% Reporters of ADEs*	Theory used
Lee <i>et al.</i> (1994) ^[87]	1994	December 1993	129 (45.1%)	Mail	Yes/no and MCQs	14.7%	NA
Generali <i>et al.</i> (1995) ^[60]	1995	May 1989	318 (40%)	Mail	MCQs	NM	NA
Wallace <i>et al.</i> (1995) ^[40]	1995	May 1990	643 (73%)	Mail	MCQs and Likert	20%	Inman's seven deadly sins
Sweis and Wong (2000) ^[39]	2000	July 1998	346 (63%)	Mail	Likert	14.1%	Inman's seven deadly sins
Green <i>et al.</i> (2001) ^[88]	2001	March 1999	322 (53.7%)	Mail	Yes/no questions	25.60%	NA
Kelly <i>et al.</i> (2004) ^[70]	2004	April–May 1998	56 (23%)	Self-administered	Yes/no questions	38 (68%)	Predisposing-enabling-reinforcing factors model
Bawazir (2006) ^[89]	2006	December 2004–February 2005	172 (71.7%)	Self-administered	Yes/no, MCQs, Likert scale and open-ended questions	4%	NA
Herdade <i>et al.</i> (2006) ^[35]	2006	June 2003	256 (86.6%)	Mail	VAS	NA	Inman's seven deadly sins
Granas <i>et al.</i> (2007) ^[90]	2007	September–December 2004	105 (68%)	Web survey	Yes/no and MCQs	<10%	NA
Irujo <i>et al.</i> (2007) ^[32]	2007	January–February 2006	78 (97.5%)	Face to face	Likert scale	23.30%	Inman's seven deadly sins
Toklu and Uysal (2008) ^[91]	2008	December 2005–June 2006	219 (53.3%)	Face to face	Yes/no, MCQs, Likert scale and open-ended questions	7%	NA
Elhour <i>et al.</i> (2009) ^[92]	2009	August 2006–January 2007	100 (21.1%)	Self-administered	Closed and/or open-ended questions	NM	NA
Jarensiripomkul <i>et al.</i> (2009) ^[93]	2009	NM	262 (63%)	Self-administered	Likert scale	5.7%	NA
Vessal <i>et al.</i> (2009) ^[94]	2009	May 2007	100 (55%)	Mail	NM	25%	NA
Xu <i>et al.</i> (2009) ^[25]	2009	May–August 2007	222 (10.5%)	Self-administered	Yes/no and MCQs	NM	NA
Su <i>et al.</i> (2012) ^[58]	2010	July–December 2007	246 (85.4%)	Face to face	MCQs	14.60%	NA
García and Figueras (2011) ^[65]	2011	April–June 2007	78 (48.7%)	Self-administered	Yes/no, MCQs, Likert scale and open-ended questions	14%	Theory of planned behaviour
Gavaza <i>et al.</i> (2011) ^[75]	2011	June–July 2009	377 (26.4%)	Mail	Yes/no, MCQs, Likert scale and open-ended questions	32.10%	Theory of planned behaviour
Gavaza <i>et al.</i> (2011) ^[57]	2011	June–July 2009	377 (26.4%)	Mail	Yes/no, MCQs, Likert scale and open-ended questions	32.10%	Theory of planned behaviour
Gavaza <i>et al.</i> (2011) ^[95]	2011	June–July 2009	377 (26.4%)	Mail	Yes/no, MCQs, Likert scale and open-ended questions	32.10%	Theory of planned behaviour
Oreaga <i>et al.</i> (2011) ^[96]	2011	February–July 2011	332 (83%)	Face to face	Likert and yes/no	3.00%	NA
Vrublevska <i>et al.</i> (2011) ^[97]	2011	October–December 2008	479 (71%)	Self-administered	Likert scale	2%	NA
Dos Santos Pernas <i>et al.</i> (2012) ^[33]	2012	NM	20 (100%)	Mail	VAS	NM	Inman's seven deadly sins

Table 2 (continued)

Reference (publication year)	Year	Survey period	No. of respondents (response rate %)*	Survey delivery	Scale	% Reporters of ADEs*	Theory used
Gavaza <i>et al.</i> (2012)	2012	June–July 2009	377 (26.4%)	Mail	Likert scale	32.10%	Theory of planned behaviour
Prakasam <i>et al.</i> (2012) ^[98]	2012	August 2011–April 2012	347 (53.3%)	Face to face	Yes/no and Likert scale	11.80%	NA
Ahmad <i>et al.</i> (2013) ^[48]	2013	May 2012–July 2012	400 (67%)	E-mail, social networking sites	Yes/no and MCQs	37%	Knowledge-Attitude-Practice Model
Hadi <i>et al.</i> (2013) ^[62]	2013	July–August 2009	163 (54.3%)	Self-administered	Yes/no and MCQs	89.60%	NA
Jose <i>et al.</i> (2013) ^[63]	2013	April–June 2012	107 (72.3%)	Self-administered	Yes/no, MCQs and Likert scale	70%	NA
KC <i>et al.</i> (2013) ^[99]	2013	NM	32 (74%)	Self-administered	Likert	25.00%	NA
Khan (2013) ^[76]	2013	June–July 2012	50 (71.43%)	Self-administered	Yes/no, MCQs and Likert scale	NM	NA
Santosh <i>et al.</i> (2013) ^[67]	2013	2013	32 (74%)	Self-administered	Yes/no, MCQs and Likert scale	25.00%	NA
Stewart <i>et al.</i> (2013) ^[56]	2013	January–May 2011	320 (13.1%)	E-mail	Yes/no, MCQs, Likert scale and open-ended questions	58.60%	NA
Wilbur (2013) ^[49]	2013	April–June 2011	142 (25%)	Electronic survey	Yes/no and MCQs	34 (23.9%)	Knowledge-Attitude-Practice Model
Afifi <i>et al.</i> (2014) ^[100]	2014	January–June 2013	100 (83.3%)	Self-administered	Yes/no, MCQs and open-ended questions	29%	Knowledge-Attitude-Practice Model
Qassim <i>et al.</i> (2014) ^[44]	2014	2013	223 (74.3%)	Self-administered	Yes/no, MCQs and open-ended questions	8 (3.6%)	Knowledge-Attitude-Practice Model
Mahmoud <i>et al.</i> (2014) ^[43]	2014	NM	104 (70.7%)	Self-administered	Yes/no, MCQs and Likert	13 (12.5%)	Knowledge-Attitude-Practice Model
Mulatu and Worku (2014) ^[41]	2014	May–November 2012	94 (88.3%)	Self-administered	Yes/no, MCQs and Likert scale	Total 101 (16.2%) no information about pharmacists	Knowledge-Attitude-Practice Model
Abdel-Latif & Abdel-Wahab (2014) ^[68]	2014	NM	78 (20.3%)	Self-administered	Yes/no and MCQs	NA	NA
Alshammari <i>et al.</i> (2015) ^[71]	2015	November–December 2012	332 (72%)	Self-administered	Likert and MCQs	NM	NA
Liu <i>et al.</i> (2015) ^[29]	2015	January 2008–December 2010	558 (92%)	Self-administered	Yes/no, MCQs, Likert scale and open-ended questions	NM	Knowledge-Attitude-Practice Model
Suyagh <i>et al.</i> (2015) ^[31]	2015	July–September 2012	208 (96.7%)	Self-administered	Yes/no, MCQs, Likert scale and open-ended questions	40 (19.5%)	Knowledge-Attitude-Practice Model
Williams <i>et al.</i> (2015) ^[38]	2015	2010	270 (45%)	Online	Likert scale	NM	Model
Almandil (2016) ^[69]	2016	April 2015–April 2016	331 (82.75%)	Self-administered	MCQs	11.2%	NA
Amin <i>et al.</i> (2016) ^[79]	2016	June–October 2014	203 (69.5%)	Self-administered	Likert scale	NM	NA

Table 2 (continued)

Reference (publication year)	Year	Survey period	No. of respondents pharmacists (response rate %)*	Survey delivery	Scale	% Reporters of ADEs*	Theory used
Bule <i>et al.</i> (2016) ^[23]	2016	March–June 2014	10 (NM)	Self-administered	Yes/no and Likert scale	2.6%	NA
Dorji <i>et al.</i> (2016) ^[50]	2016	November 2014–January 2015	434 (65%)	Self-administered	MCQs	NM	NA
MM <i>et al.</i> (2016) ^[46]	2016	November 2015	76 (87.4%)	Mail	Likert scale	Pharmacists 17 (70.8)	Knowledge-Attitude-Practice Model
Shamim <i>et al.</i> (2016) ^[42]	2016	June 2013–August 2014	106 (29.7%)	Self-administered	Likert scale	NM	Knowledge-Attitude-Practice Model
Umar <i>et al.</i> (2016) ^[27]	2016	NM	249 (91.5%)	Self-administered	Yes/no	NM	NA
Yu <i>et al.</i> (2016) ^[51]	2016	September–November 2014	1001 (76.1%)	Self-administered	Likert scale	294 (29.4%)	Knowledge-Attitude-Practice Model
Alsaleh <i>et al.</i> (2017) ^[45]	2017	February–April 2015	485 (83.2%)	Self-administered	Yes/no, MCQs and open-ended questions	35 (21.7%)	Knowledge-Attitude-Practice Model
Al-Worafi <i>et al.</i> (2017) ^[59]	2017	NM	179 (41.8%)	Self-administered	Yes/no, MCQs and open-ended questions	0%	NA
Cheema <i>et al.</i> (2017) ^[37]	2017	April–September 2012	138 (60%)	Post and e-mail	Yes/no and MCQs	44.90%	NA
Said & Hussain (2017) ^[72]	2017	NM	91 (60.7%)	E-mail	Yes/no, MCQs and open-ended questions	community 14% hospital 12.1%	NA
Ali <i>et al.</i> (2018) ^[101]	2018	NM	41 (30.3%)	Self-administered	Yes/no, MCQs and open-ended questions	17.78%	NA
Bahnassi, A. & Al Harbi (2018) ^[54]	2018	December 2013–July 2014	656 (77%)	Self-administered	Yes/no, MCQs, Likert scale and open-ended questions	10.80%	Knowledge-Attitude-Practice Model
Hajj <i>et al.</i> (2018) ^[36]	2018	March to July 2016	1857 (92.8%)	Self-administered	MCQs	NM	NA
Hallit <i>et al.</i> (2018) ^[30]	2018	March–July 2016	187 (93.5%)	Self-administered	Yes/no and MCQs	NM	Knowledge-Attitude-Practice Model
Laven <i>et al.</i> (2018) ^[52]	2018	November 2017	127 (64.5%)	Self-administered	Yes/no, MCQs and Likert scale	60 (47.2%)	Knowledge-Attitude-Practice Model
Lemay <i>et al.</i> (2018) ^[86]	2018	January–May 2016	167 (34.4%)	Self-administered	Yes/no, MCQs and open-ended questions	21.7%	Knowledge-Attitude-Practice Model
Li <i>et al.</i> (2018) ^[64]	2018	January–February 2017	232	Online	Yes/no, MCQs and Likert scale	35.3% (82)	NA
Moinuddin <i>et al.</i> (2018) ^[55]	2018	September–November 2016	32 (88.6%)	Self-administered	Yes/no, MCQs and Likert scale	NM	Knowledge-Attitude-Practice Model
Nisa <i>et al.</i> (2018) ^[34]	2018	January–June 2017	34 (95.5%)	Self-administered	Yes/no, MCQs and Likert scale	11.70%	Knowledge-Attitude-Practice Model
Seid <i>et al.</i> (2018) ^[73]	2018	March–May 2017	25 (NM)	Self-administered	Yes/no, MCQs and Likert scale	NM	Knowledge-Attitude-Practice Model
Shanko & Abdela (2018) ^[28]	2018	February–March 2015	21 (91.4%)	Self-administered	Yes/no and MCQs	52.4%	NA
	2019		1870 (78.9%)		Likert scale		NA

Table 2 (continued)

Reference (publication year)	Year	Survey period	No. of respondents pharmacists (response rate %)*	Survey delivery	Scale	% Reporters of ADEs*	Theory used
Aldryhim <i>et al.</i> (2019) ^[24]		December 2016–February 2017		Web and paper-based survey		10.2% (community pharmacists) and 26.8% (hospital pharmacists)	
Al Rabayah <i>et al.</i> (2019) ^[47]	2019	May 2014–December 2015	30 (82%)	Self-administered	Yes/no, MCQs Likert scale and open-ended questions	NM	Knowledge-Attitude-Practice Model
Kopciuch <i>et al.</i> (2019) ^[56]	2019	January 2016–January 2018	522 (58%)	Self-administered	Yes/no and MCQs	198 (38%)	Knowledge-Attitude-Practice Model
MCQs, multiple choice questions; NA, not available; NM, not mentioned; TPB, theory of planned behavior; VAS, visual analogue scale.							
*Percentages are for pharmacists only.							

source for adverse drug reaction reports at the lowest cost. Spontaneous reporting systems are essential for early detection of signals that can lead to precautionary measures such as drug warnings, modifications in the information found in the leaflets and in some cases results in withdrawal of drugs from the market.^[81] However, the capacity of these voluntary systems is reduced because of under-reporting. This review specifically focused on the barriers and facilitators of ADE reporting by pharmacists. The results of this review indicated that deficiency in understanding of basic concepts related to pharmacovigilance and ADE reporting process were the main barriers to reporting by pharmacists. To enhance reporting of ADEs, most pharmacists suggested providing continuing education or special training courses related to pharmacovigilance and reporting process.

Few studies reported an association between demographic factors and practice setting characteristics and ADE reporting by pharmacists. Only workplace seems to be associated with ADE reporting. Hospital pharmacists were more likely to have better knowledge, favourable attitudes and reporting rate than pharmacist working in community settings.^[29,35,36,40,49] Most of the reports in the United States Food and Drug Administration Reporting System database reported by HCPs originated from hospital pharmacists.^[16,82] Hospital pharmacists are more directly involved in patient care, have access to medical records and see more patients with serious ADEs compared to pharmacists working in community settings. According to the WHO International Drug Monitoring Programme, community pharmacists make a small contribution to the national pharmacovigilance systems except for the Netherlands.^[16,83] Community pharmacists can have a unique contribution in pharmacovigilance by reporting ADEs associated with over-the-counter drugs (OTC) and are more likely to report adverse events associated with skin and eye as these manifestations are easily noticed by patient themselves.^[16,84]

In the light of the results of our review, inadequate knowledge of pharmacovigilance concepts, processes and functioning was present in more than 70% of studies and considered as a main barrier for reporting ADE. Fortunately, this obstacle can be modified by introducing more topics related to ADE reporting and drug safety within pharmacy curriculum, providing continuing education programmes and training as suggested by several studies included in this review. A recent literature review about pharmacovigilance education showed that pharmacovigilance interventions can range from short PowerPoint presentations and several training and interactive workshops.^[86] Intervention types included providing theoretical information about ADR reporting, identification of ADRs, medication safety modules, detection of ADRs and lectures on completing MedWatch forms.^[86] Other barriers that were frequently mentioned can also be linked to lack of knowledge, such as uncertainty that a specific drug is responsible to a particular drug reaction, and ADE is too trivial and well known to report. Yet, in reality, even, suspected ADE and all possible types of undesirable effects associated with a drug can be reported.

Lack of time, interest or reporting cards was reported as a negative factor in about half of the studies included in this review. Lack of time can be viewed as a reflection of work

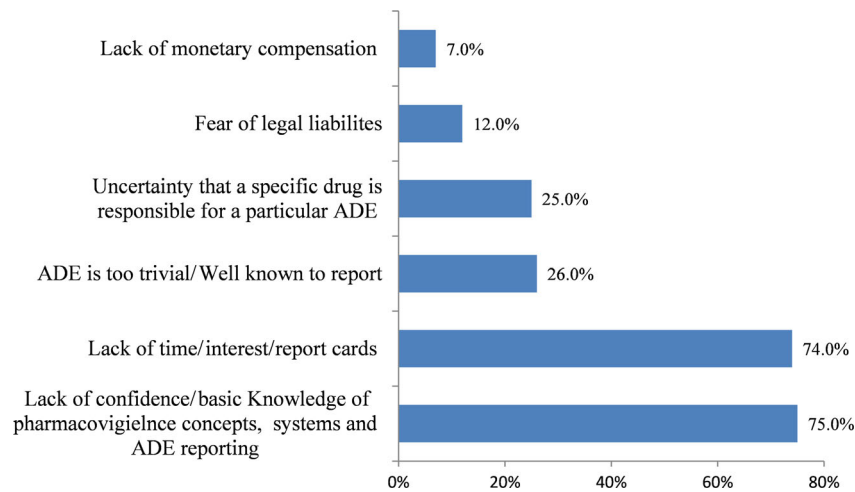


Figure 2 Top factors that negatively affect reporting of ADE by pharmacists. Other factors: uncertainty over who is responsible for reporting, disturbance of normal workflow, lack of complete medical history, fear of breaching patient confidentiality, deficient of professional environment.

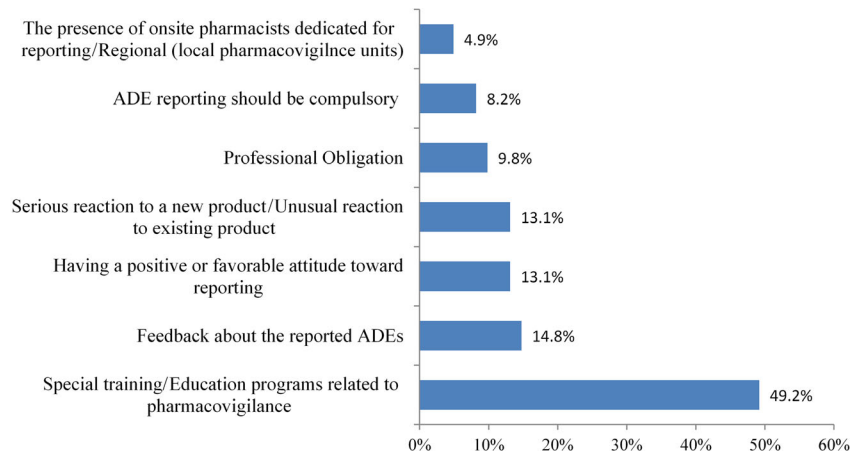


Figure 3 Top factors that positively influence reporting of ADE by pharmacists. Other reasons: encouragement from pharmacy department, participation in ward rounds, social influences, patient compliant or request to report, hospital written policy, providing a toll free number by the relevant authorities, and establishing incentive mechanisms.

overload, where the pharmacists have no time to report ADE, an indication that the pharmacists consider reporting as an additional burden and not as an essential part of their professional obligations. It is therefore intuitive that considering ADE reporting as a professional obligation was found to be a factor that positively influences reporting by pharmacists. Lack of reporting cards could be a reflection of lack of interest or lack of time to look for these cards. In order to overcome the barrier of the availability of reporting forms, spontaneous reporting systems such as MedWatch provide these forms online, in addition to the possibility of submission via mail, fax or phone.^[10]

Having a positive or favourable attitude was found as an important factor to predict reporting of ADE by pharmacists. Positive or favourable attitudes such as beliefs that reporting would improve patient safety, personally rewarding, and contribute to overall understanding about drug risk are important factors to consider when planning

interventions aim at improving reporting rate by pharmacists. Feedback from the pharmacovigilance centre containing information about the reported ADE was mentioned in about one fifth of studies included in this review as a positive factor, which could enhance reporting. In a study conducted in the Netherlands, receiving personalized feedback from pharmacovigilance centre was thought to be an important motivator to report an ADE in the future.^[85]

The main limitation of this review was the disparities in the methods, population of interest, data collection scales and techniques of the included studies. Variations in the way the questions were asked in the eligible studies might affect the results of this review, as some of them were close-ended and other questions were open-ended questions. Percentages were reported in most cases with no *p*-values, which make it difficult to draw definite conclusion about the comparisons between different working settings or HCPs. The factors that positively or negatively affect

reporting are not necessarily using the exact wording from the respective papers; slight changes were made to make them fit into the final list of factors. These changes are unlikely to alter the principal conclusion of this review.

Conclusion and implications

In this review, knowledge and attitudes of pharmacists towards pharmacovigilance were found to be related to ADE reporting. Among demographic and practice settings, only workplace seems to have an influence on reporting, where hospital pharmacists have better knowledge, favourable attitudes and reporting rate compared to community pharmacists. The role of pharmacists in ensuring safe use of drugs requires sufficient knowledge of pharmacovigilance concepts, process and functioning. Reporting of ADEs is an important element to ensure drug safety at the individual and population levels, and contribution of pharmacists is essential. To improve reporting of ADE by pharmacists, it is recommended to design tailored educational interventions based on the existed gaps in knowledge and attitudes that can be integrated within the pharmacy curriculum or within continuous education courses after graduation.

Declarations

Conflict of interest

The authors declare no actual or potential conflicts of interest.

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