



## ASSESSMENT OF THE COMMUNITY PHARMACISTS TOWARD MEDICATION SAFETY IN JORDAN

Muna Khashman\*, Alaa Yasin, Mutazbellah F. Alzu'bi and Samir Abdel Jaleel

Jordan.

\*Corresponding Author: Muna Khashman  
Jordan.

Article Received on 14/01/2022

Article Revised on 04/02/2022

Article Accepted on 24/02/2022

### ABSTRACT

This study was performed to evaluate the community pharmacists knowledge toward medication safety in Jordan. **Methods:** An online survey was conducted among community pharmacists in Jordan during January, 2022. Randomly 110 select pharmacists from pharmacy association. The questionnaire consisted of four parts. These parts were focused in sociodemographic characteristics, knowledge concerning pharmacovigilance (PV), attitudes regarding PV and ADR reporting in the workplace. The data which collected from the questionnaires were analyzed using the Statistical Package for Social Science version 21.0. Descriptive statistics such as frequencies, percentages, and means (SD) were used in the analysis. **Results:** The majority of respondents were men (62%) with a bachelor's degree (91%) and 5 to 7 years of work experience (32%). Most of the them understood the perception and purpose of PV. In addition, community pharmacists have a positive attitude toward reporting and only the minority of them reported that PV is the responsibility of pharmacists. Most of the them (80%) stated that there was no notification form at their workplace and the notifications were not widely perform. Half of respondents reported that not enough data provided by the patients is the major barrier of reporting ADR. **Conclusion:** The community pharmacist has a positive attitude towards medication safety. Jordanian government need to introduce more education programs toward medication safety and reporting side effects.

### 1. INTRODUCTION

Adverse reactions (ADRs) are a vital health problem.<sup>[1]</sup> ADR is define as any unintended and harmful drug reaction that occurs at doses used for treatment, diagnosis, or prophylaxis, other than failure of treatment.<sup>[2]</sup>

Various articles have reported that the majority of admitted patients to the hospitals are due to adverse drug reactions. These ADRs lead to increase motility and morbidity.<sup>[3,4,5,6,7]</sup>

An Iranian study found that about tenth of patients had at least one side effect<sup>[9]</sup> In Iranian study found that less than quarter of the patients had at least one ADRs.<sup>[10]</sup>

Another study that conducted in India said that side effects had a prevalence of 9.8%. Approximately that five percents of the cases were hospitalized and occurred during hospitalization.<sup>[11]</sup>

One study that conducted in Saudi Arabia found the half side effects were preventable.<sup>[12]</sup> The incidence of adverse drug reactions and other drug-related problems varies from country to country.

In Nepal, the incidence of adverse drug reactions were tenth of the respondents. Serious side effects were reported was mainly male.<sup>[13]</sup>

No medical center is specialized to side effects, which is why pharmacovigilance (PV) has become a very important aspect to guarantee the safe use of medicines in any medical center. The WHO definition of PV is "the science and practice of diagnosing, evaluating, understanding, and prophylactic ADRs or other potential drug-related problems"<sup>[14]</sup>

For early detection, ongoing monitoring and reporting of spinal side effects is recommended. ADR identification is the cornerstone of PV.

According to the World Health Organization, countries with the best notification rates should report at least 200 cases per 1,000,000 people per year. However, only 10% of serious side effects were notified.<sup>[16]</sup>

Jordan's reporting system is not working properly due to lack of awareness among health professionals about the role of exceptional events and PVs in improving health services, and lack of information on how, where, for what and who report adverse drug reactions.

Those barriers create a dangerous safety situation for the patient. We are not sure about the attendance of the pharmacists toward ADR reporting in Jordan.

Therefore, this study was conducted in Jordan to evaluate the community pharmacy knowledge toward medication safety in Jordan. From this study we can assess the obstacle that contribute to the interventions and help in creating o plans such as teaching and education

## 2. METHODS

A online survey was conducted among community pharmacists in Jordan during January 2022. Randomly 110 selected pharmacists from pharmacy association. The questionnaire consisted of four parts containing 20 questions. The first part focused in sociodemographic characteristics with six questions. The second part focused in Knowledge of the CPs concerning PV containing five questions. The third part focused in attitudes of the CPs regarding PV containing four questions. The fourth section focused in ADR reporting in the workplace containing six questions. The data which collect from the questionnaires was analyzed using the Statistical Package for Social Science version

21.0. Descriptive statistics such as frequencies, percentages, and means (SD) will use in the analysis.

The respondent pointed to the pharmacists worked in community and hospitals. The interviewee did not enter if he did not want to participate in the study.

## 3. RESULTS

### 1) Characteristics of the respondents -1

The majority of the respondents were woman 62%.

More than half of them were age group ranged between 30 and 39 years (52%, 52 of CPs).

Professional experience as a pharmacist in the Community mainly ranged between 5 and 7 years (32%, n = 32) and between 8 and 13 years (27%, n = 27). The minority of pharmacist have master degree 5% and the majority of them have bachelor degree 90%.

More than half of the pharmacists worked in community pharmacists (57%). The largest number of patients treated per day ranged from 30 to 60 patients (42%, n = 42). Furthermore, 40% of them worked more than 31 hours per weeks. Further results are shown in the table 1.

**Table one: characteristics of the respondents.**

1- Gender		
male	62	62
Female	38	38
2- Age		
20-29	21	21
30-39	52	52
40-49	20	20
50-59	5	5
More than 60	2	2
3-years of experience		
Less than 6 months		
6 months to 1 year	10	10
1 year to less than 4 years	20	20
5 years to less than 7 years	32	32
8 years to less than 13 years	27	27
More than 13 years	13	13
4-graduates level		
Bachelor	90	90
PharmD	5	5
Masters	5	5
5-number of patients seen/day		
Less than 20	4	4
30-60	81	81
61-100	10	10
More than 100	5	5
6-working of hours/week		
1-15hr	0	0
16-30hr	32	32

31-41hr	41	41
More than 41hr	27	27

## 2) Knowledge of the respondents toward PV

Regarding to the definition of pharmacovigilance, the majority of pharmacists (35%) showed that the PV was mainly concern of adverse drug reaction reporting and prophylactic of ADR. Approximately 52% of them showed that the purpose of PV is Increase patients safety in relation to the use of drugs. With regard to ADR, 31% of respondents reported that ADR is unresponsive to medicine patient and 25% showed that it complicated of the side effect of drugs.

About 52% of pharmacists believed that side effects were caused by over-the-counter drugs and 31% thought they could be caused by any herbal products. 62% of the them (n = 62) believed that side effects could be related to drug interactions. The minority of them (20%) reported that they don't know if the adverse reaction was according to drug-drug or drug –food reactions. Further results are shown in table 2.

**Table two: Knowledge of the community pharmacists concerning PV.**

STATE	Frequency	%
<b>1- pharmacovigilance (PV) is:</b>		
Concern to Adverse Drug Reaction writing	35	35
Relating to the safety of medications	10	10
Prophylactics of ADR	35	35
Understanding of risk factors connected to ADR	15	15
<b>2-The purpose of PV is/are to:</b>		
Increase patients safety in relation to the use of drugs	52	52
I don't know	48	48
<b>3-Adverse drug reaction (ADR) is:</b>		
unresponsive to medicine administered a pharmaceutical product	31	31
The complicated side effect of a drug	10	10
The adverse event of a medicine due to its use as marketing products	25	25
I don't know	9	9
<b>4-Do you think ADR is related to:</b>		
OTC drugs	25	25
Herbal drugs	52	52
Vaccines	31	31
All of the above	12	12
	5	5
<b>5- Do you think that an ADR due to:</b>		
drug-drug interactions	62	62
drug-food interactions	18	18
I don't know	20	20

## 3) Attitudes of the respondents toward PV

55% of pharmacists reported side effects throughout their pharmaceutical activities . Approximately 88% (n = 88) believed that doctors have major responsibility. Only the minority of respondents 7% reported that the family was responsible for this. Just over half of the pharmacists (58%) relied on the leaflet for ADR information, 53% of them depend on (n = 239) on the internet and 22% of pharmacists depend on the books.

In terms of response to reported side effects, approximately 58% indicated that trainings and conferences were needed to better identify side effects.

Around half of them (40%) face limited time / work and have difficulty assessing the availability of ADRs, and 31% did not know how to write these effects.

92% of them affirmed that this responsibility corresponds to the Ministry of Health. Further results are shown in table below.

**Table three: Part three: Attitudes of the respondents toward PV.**

State	Freq.	%
<b>1-Have you ever come across an ADR?</b>		
Yes	52	52
No	30	30

Neutral/do not know/does not apply	10 8	10 8
2- Do you think ADR reporting should be a compulsory activity for you?		
Yes	63	63
No	20	20
Neutral/do not know/does not apply	10 7	10 7
3- Reporting ADR is responsibility of :		
Physician	83	83
Pharmacist	10	10
Patient	7	7
Family	0	0
None of the above	0	0
4- What are the sources of data that you sometimes use?		
Internet sites	<b>53</b>	53
Book	<b>22</b>	22
Medical journals	<b>10</b>	10
Companies	<b>3</b>	3
Drug information centers	<b>1</b>	1
The leaflets	<b>58</b>	58

#### 4) ADR notification in the workplace.

Approximately 15% responded positively, and approximately 31% responded negatively if they noticed any irregularity in their treatment. Only 5% of them (n = 5) reported ADE to the ministry of health.

Most of the them (95%) indicated that there was no registration form at their workplace.

Most of respondents (92%) answered no to the question whether their workplace give data on the reporting process.

The majority of them (n=80) reported that they have not good information regarding ADR reporting.

Regarding questions about reporting of side effects, % (n = 82) responded that the competent authorities did not widely publish reporting of side effects in Jordan, and 85% responded that there was a shortage information from the patients was a barrier to the notification system. Further results are shown below.

**Table four: - ADR reporting in the workplace.**

Statement	Frequency	%
1- Did you see any ADR cases in your pharmacy?		
Yes	45	45
No	50	50
Not true	5	5
2- whom you have written your intervention?		
Drug manufacture	25	25
Ministry of health	5	5
Other		
3- Is ADR reporting form available at your workplace?		
Yes	1	1
No	95	95
Not sure	4	4
4-Does your workplace give not good information regarding ADR reporting?		
Yes	80	80

*No	15	15
Not sure	5	5
5- do you need training ADR reporting?		
Yes	58	58
No	20	20
Not sure	22	22
6- Does your institution encourage you to write an ADR?		
Yes	5	5
No	92	92
Not sure	3	3

Part five: *Patient safety and response to errors and future in reporting.*

53% of the participants said they were trying to figure out what workflow problems led to their error. More than three quarter of respondents considered the role of information technology in support reporting and providing an online ADRs reporting program or website.

Half of them believed that an online application / site needs easy reach. Most pharmacists showed that reports of adverse reactions do not cause a nuisance at work. Additionally, the majority of them reported that reporting side effects protects the patients.

#### 4. DISCUSSION

This study was conducted to assess the pharmacists knowledge toward ADR reporting and PV. The majority of them were young, worked in not government pharmacy, with 5 to 7 years of experience in a public pharmacy, and with a pharmacy degree.

The broad knowledge reflects practical problems. In short, the results showed a positive attitude towards PV. However, the practical role of the them needs to be developed and strengthened.

In general, pharmacists in Jordan are considered health consultants and are easy to evaluate without payment. Most patients choose to receive consultations treatment due to side effects from them.

Therefore, it is necessary to include the pharmacists in the side effects reporting systems. The profiles of the CPs e.g. age, employment status, experience, degree, indicated that they have an adequate level of education and practice. Thus, it is supposed that they might have acceptable knowledge suitable for this study.

For example, PC profiles. Age, employment status, experience, academic degree indicate that they have a sufficient level of education and practice. Therefore, it is assumed that they may have enough suitable knowledge for this study.

This study also showed that most respondents are familiar with the PV concept and its purpose.

The response rate was similar to that of the Lebanon study.<sup>[19]</sup> Numerous studies have shown that pharmacists are recognized as the healthcare professionals with the most complete knowledge of the pharmacological aspects of medications and, therefore, play a fundamental role in the identification and prevention and control of adverse drug actions.<sup>[20,21,22,23]</sup> Continuous education program are need to increase their knowledge.

A meta-analytical study in India has shown that more than three quarters of Indian pharmacists are unfamiliar with the PV.<sup>[24]</sup> When it comes to PV, more than half of pharmacists suffer from low knowledge of adverse drug reactions.

Most of the pharmacists positively felt that a healthcare professional was responsible for reporting side effects.

Furthermore, almost a quarter of the them considered ADR notification as one of their tasks. The result is similar to the previous publish studies in India,<sup>[25]</sup> Korea<sup>[26]</sup> and other Saudi Arabia, Oman<sup>[19,27-31]</sup>

A study in India showed that reporting adverse reactions is the responsibility of the doctors.<sup>[32]</sup> However, there is a negative attitude among New Zealand pharmacists.<sup>[22]</sup>

Many pharmacy studies and reports on the intersectional distribution of medications are one of the main responsibilities.<sup>[33,34]</sup>

The positive result of this study may be related to partial information on the ADR reporting method. However, respondents stated that they faced many issues that made it difficult to be familiar with the reporting system, such as ignorance of ADR reporting procedures and judgments, the need for training on how to effectively identify ADRs, time constraints and pressure.

Similar problems have been mentioned above and numerous studies have shown a positive correlation between the level of knowledge and writing ADRs.<sup>[40-35]</sup> Another study which was conducted in Portugal showed

that increase education programs, increase their familiar with writing ADRS.<sup>[40]</sup>

The majority of pharmacist depend on the leaflet, internet and the books. We cannot depend on the internet because many websites haven't correct drug data.

In terms of ADR reporting methods, about half of pharmacists reported side effects to different authorities.

The results also showed that the notification system was not available. The majority of them reported that they have not enough training programs and reporting procedures.

A number of issues were raised during the notification process, including the lack of a government notification system and the lack of patient information.

In addition, some pharmacists have shown that workloads prevent accurate reporting, which is consistent with research findings in India.<sup>[32,41]</sup>

Furthermore, fear of legal repercussions has been one of the problems with the reporting system in Jordan's public pharmacies. Similar results were obtained in other studies.<sup>[32,41-43]</sup>

Considering the future of adverse reaction reporting in Jordan, just over half of the participants supported the idea of patient reporting. This result is similar to previous studies in India,<sup>[25]</sup> Great Britain,<sup>[44]</sup> and the Netherlands.<sup>[45]</sup>

As a result, the implementation of a "spontaneous reporting system" may be a key factor in the future. About a quarter of the five respondents supported the role of information technology in facilitating ADR reporting. The same result was obtained in a study in India.<sup>[46]</sup>

These study showed that more than a quarter in five pharmacists showed that reporting side effects increase safety.

A similar result was obtained in other studies.<sup>[32,41]</sup>

## 5. CONCLUSION

This observational study shows that pharmacists in the Jordan community have positive attitude and that the level of knowledge is acceptable. But there are many obstacles that should be overcome by continue educations programs. New technologies should be included to facilitate the reporting of side effects.

The Ministry of Health and pharmacy association should started to give these programs regarding PV and reporting systems. These will support the patients safety.

## REFERENCES

1. International Drug Monitoring: The Role of National Centres (WHO Technical Report Series No. 498). Geneva: World Health Organization, 1972.
2. Lee A, Thomas SHL. Adverse drug reactions In: Walker R and Edward C. Clinical pharmacy and Therapeutics. 3rd edition Churchill Livingstone, 2003; 33-46.
3. Pouyanne P, Haramburu F, Imbs JL, Begaud B. Admissions to hospital caused by adverse drug reactions: cross sectional incidence study. *Br Med J*, 2000; 320: 1036.
4. Wasserfallen J, Livio F, Buclin T, Tillet L, Yersin B, Biollaz J. Rate, type and cost of adverse drug reactions in emergency department admissions. *Eur J Inter Med*, 2001; 12: 442-7.
5. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalised patients. Excess length of stay, extra costs, and attributable mortality. *JAMA*, 1997; 277: 301-6.
6. Suh DC, Woodall BS, Shin SK, Hermes-De Santis ER. Clinical and economic impact of adverse drug reactions in hospitalised patients. *Ann Pharmacother*, 2000; 34: 1373-9.
7. Classen DC, Pestotnik SL, Evans RS et al. Adverse drug events in hospitalized patients. *JAMA*, 1997; 277(4): 301-6.
8. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*, 1998; 279: 1200-5.
9. Pourseyed S, Fattahi F, Pourpak Z, Gholami K, Shariatpanahi SS, Moin A, Kazemnejad A, Moin M. Adverse drug reactions in patients in an Iranian department of internal medicine. *Pharmacoepidemiol Drug Saf*, 2008; 19. (Epub ahead of print).
10. Gholami K, Shalviri G. Factors associated with preventability, predictability, and severity of adverse drug reactions. *Ann Pharmacother*, 1999; 33(2): 236-40.
11. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. *Br J ClinPharmacol*, 2008; 65(2): 210-6.
12. Al-Malaq HM, Al-Aqeel SA, Al-Sultan MS. Adverse drug reactions related hospitalization identified by discharge ICD-9 codes in a university hospital in Riyadh. *Saudi Med J*, 2008; (8): 1145-50.
13. Jha N, Bajracharya O, Namgyal T. Prevalence of adverse drug reactions with commonly prescribed drugs in different hospitals of Kathmandu valley. *Kathmandu Univ Med J (KUMJ)*, 2007; 5(4): 504-10.
14. Olsson S. The need for pharmacovigilance In: Gupta SK. Pharmacology and therapeutics in the new millennium. Narosa publishing house, New Delhi, 2001; 502-8.

15. WHO. Safety of medicines: A guide to detecting and reporting adverse drug reactions. World Health Organization, Geneva, 2002.
16. Rawlins M. D. Clinical pharmacology. Adverse reactions to drugs. *British medical journal (Clinical research ed.)*, 1981; 282: 974-976
17. Hallit S, Hajj A, Shuhaiber P et al. Medication safety knowledge, attitude, and practice among hospital pharmacists in Lebanon. *Journal of Evaluation in Clinical Practice*, 2019; 25(2): 323-39. <https://doi.org/10.1111/jep.13082>
18. JSI Research & Training Institute, Inc. The KAP survey model, 2011. <https://www.spring-nutrition.org/publications/tool-summaries/kap-survey-model-knowledge-attitudes-and-practices>
19. Aline Hajj, Souheil Hallit, Elsy Ramia, Pascale Salameh & on behalf of the Order of Pharmacists Scientific Committee – Medication Safety Subcommittee Medication safety knowledge, attitudes and practices among community pharmacists in Lebanon, *Current Medical Research and Opinion*, 2017. DOI: 10.1080/03007995.2017.1361916.
20. Kalaiselvan V, Prasad T, Singh A. Current Status of Adverse Drug Reactions Monitoring Centres under Pharmacovigilance Programme of India. *Indian J Pharm Prac*, 2014; 7: 19-22.
21. Murdaugh LB. Competence Assessment Tools for Health-System Pharmacies. (4th ed), American Society of Health System Pharmacists, USA, 2007; 439-40.
22. Zolezzi M, Parsotam N. Adverse drug reaction reporting in New Zealand: implications for pharmacists. *Ther Clin Risk Manag*, 2005; 1(3): 181-8.
23. Parthasarathy G, Karin NH, Milap N. *Clinic Pharmacy Book: Essential Concepts and Skills*. Hyderabad: Universities Press, 2008; 43-53.
24. Bhagavathula AS, Elnour AA, Jamshed SQ. Health Professionals' Knowledge, Attitudes and Practices about Pharmacovigilance in India: A Systematic Review and Meta-Analysis, 2016; 11(3): e0152221.
25. Ravinandan AP, Achutha V, Vikram K Ramani, Santosh Uttangi, Sushil Kumar L. Study Of Knowledge, Attitude, And Practice Of Pharmacist Towards Adverse Drug Reaction Reporting In Davangere City. *Asian J Pharm Clin Res*, 2015; 8(3): 262-265.
26. Yu XM, Lee E, Koo BS, Jeong KH, Choi KH, Kang LK, et al. Predictive Factors of Spontaneous Reporting of Adverse Drug Reactions among Community Pharmacists. *PloS one*, 2016; 11(5): e0155517.
27. Qassim S, Metwaly Z, Shamsain M, Al Hariri Y. Reporting adverse drug reactions: Evaluation of knowledge, attitude and practice among community pharmacists in UAE. *IOSR J Pharm*, 2014; 4(4): 17-23.
28. Jose J, Jimmy B, Al-Ghailani AS, Al Majali MA. A cross sectional pilot study on assessing the knowledge, attitude and behavior of community pharmacists to adverse drug reaction related aspects in the Sultanate of Oman. *Saudi pharmaceutical journal: SPJ: the official publication of the Saudi Pharmaceutical Society*, 2014; 22(2): 163-9.
29. Khalili H, Mohebbi N, Hendoiee N, Keshtkar AA, Dashti-Khavidaki S. Improvement of knowledge, attitude and perception of healthcare workers about ADR, a pre- and post-clinical pharmacists' interventional study. *BMJ open*, 2012; 2: e000367.
30. Su C, Ji H, Su Y. Hospital pharmacists' knowledge and opinions regarding adverse drug reaction reporting in Northern China. *Pharmacoepidemiology and drug safety*, 2010; 19(3): 217-22.
31. Bawazir OA, Alsuwayt B, Alqahtani W, Al-Dhafiri A, Al-Shamrani M. Knowledge, attitude and practice of pediatricians and pharmacists in Riyadh City toward the use of sugar free medications. *The journal of contemporary dental practice*, 2014; 15(6): 755-60.
32. Ravinder K. Sah, Rakhmaji D. Chandane, Krishna, Sachin Manocha, Ajita Kapur. Knowledge, attitude and practice of pharmacovigilance among community pharmacists in Delhi, India. *International Journal of Basic & Clinical Pharmacology | March 2017 | Vol 6 | Issue 3*
33. Gavaza P, Brown CM, Lawson KA, Rascati KL, Wilson JP, Steinhardt M. Influence of attitudes on pharmacists' intention to report serious adverse drug events to the Food and Drug Administration. *British journal of clinical pharmacology*, 2011; 72(1): 143-52.
34. Sweis D, Wong IC. A survey on factors that could affect adverse drug reaction reporting according to hospital pharmacists in Great Britain. *Drug safety*, 2000; 23(2): 165-72.
35. Gavaza P, Brown CM, Lawson KA, Rascati KL, Steinhardt M, Wilson JP. Pharmacist reporting of serious adverse drug events to the Food and Drug Administration. *Journal of the American Pharmacists Association: JAPhA*, 2012; 52(5): e109-12.
36. Gavaza P, Brown CM, Lawson KA, Rascati KL, Wilson JP, Steinhardt M. Texas pharmacists' knowledge of reporting serious adverse drug events to the Food and Drug Administration. *Journal of the American Pharmacists Association: JAPhA*, 2011; 51(3): 397-403.
37. Irujo M, Beitia G, Bes-Rastrollo M, Figueiras A, Hernandez-Diaz S, Lasheras B. Factors that influence under-reporting of suspected adverse drug reactions among community pharmacists in a Spanish region. *Drug safety*, 2007; 30(11): 1073-82.
38. Ribeiro-Vaz I, Herdeiro MT, Polonia J, Figueiras A. Strategies to increase the sensitivity of pharmacovigilance in Portugal. *Revista de saude publica*, 2011; 45(1): 129-35.
39. Herdeiro MT, Polonia J, Gestal-Otero JJ, Figueiras A. Improving the reporting of adverse drug reactions: a cluster-randomized trial among

- pharmacists in Portugal. *Drug safety*, 2008; 31(4): 335-44.
40. Figueiras A, Herdeiro MT, Polonia J, Gestal-Otero JJ. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. *Jama*, 2006; 296(9): 1086-93.
  41. Salim M. The Current Perspective of Community Pharmacists towards Pharmacovigilance. *J Pharmacovigil*, 2015; 3: 180.
  42. Suyagh M, Farah D, Farha RA. Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Saudi Pharmaceutical Journal*, 2015; 23: 147-53.
  43. Grootheest AC, Mes K, Van den berg LT, et al. Attitudes of community pharmacists in the Netherlands towards adverse drug reaction reporting. *Int J Pharm Pract*, 2002; 10(4): 267-72.
  44. Blenkinsopp A, Wilkie P, Wang M, Routledge PA. Patient reporting of suspected adverse.