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Perceptions and barriers of adverse drug reaction reporting within inpatient state psychiatric facilities

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Abstract

Introduction: Adverse drug reactions (ADRs) are a leading cause of morbidity and mortality for hospitalized patients. Health care organizations track ADRs to reduce patient mortality, reduce hospital readmissions, decrease costs, and improve patient care. Differing definitions of ADRs cause confusion among providers, leading to hesitation with ADR reporting. The objective of this study was to understand health care professionals' perspectives of ADR reporting within inpatient state psychiatric facilities.

Methods: A survey was sent to 143 health care professionals throughout 25 inpatient state psychiatric facilities within 1 state. The survey assessed the definition of an ADR, confidence in reporting, barriers to reporting, the role of reporting, who should report and review ADRs, and strategies for process improvement.

Results: The survey had a 75.5% response rate with 108 respondents. Most respondents could identify the definition of an ADR, were moderately confident in reporting ADRs, and understood the importance of ADR reporting. Barriers to ADR reporting included the reaction not being serious, a lack of information about the ADR, or not enough clarity on how to report an ADR. Fear of retaliation was an additional barrier to ADR reporting. Training and direction on ADR reporting, education on real versus perceived consequences, a designated point person to aid in reporting, and better access to reporting technology were suggested improvements for ADR reporting.

Discussion: From this survey, it is evident that respondents believe improved education and training, improved communication regarding reporting consequences, and consensus on the definition of an ADR would encourage reporting.

Keywords: adverse drug reactions, reporting barriers, fear of retaliation

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Introduction

The Centers for Disease Control and Prevention[1] estimate that adverse drug reactions (ADRs) cause 1.3 million emergency department admissions each year with 350 000

patients being hospitalized after evaluation in the emergency department. ADRs cost the US health care system 30.1 billion dollars annually.[2] One in 7 patients experience an ADR, and ADRs can increase a hospital stay from an average of 8 to 20 days[3] and are a leading cause of morbidity and mortality for hospitalized patients.[4]

Despite the American Society of Health-System Pharmacists' (ASHP)[5] recently published guidelines defining ADRs as unavoidable, literature suggests otherwise. In a study by Pirmohamed et al,[6] as many as 9% of ADRs are reported to be definitely avoidable, resulting from prescribing not aligned with current medical guidelines, and 63% are considered possibly avoidable if health care professionals had exceeded limited obligatory efforts to explore and reconcile all factors contributing to a potential ADR. ADRs also lead to prescribing cascades, in which medications are prescribed to treat an ADR rather than changing the medication thought to be responsible for the reaction.[7]

ADR reporting can reduce patient mortality and severe outcomes, reduce hospital readmissions, decrease overall costs, and improve patient care.[8,9] In the United States, the FDA[10] encourages ADR reporting through the FDA Adverse Event Reporting System. The Institute for Safe Medication Practices[11] provides reports of serious ADRs reported through the FDA to identify areas in which patient safety can be improved. Serious or severe ADRs are defined as events that cause death, hospitalization, birth defects, or disability.[10,11] However, severe ADRs are reported as little as 10% of the time.[12,13] If health care professionals are not reporting ADRs, it can be difficult to identify trends to help prevent future ADRs.

There are many definitions of an ADR, and often, there is confusion between an ADR and a side effect. Two commonly used definitions of an ADR are from the World Health Organization stating that an ADR is "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man"[14(p5)] and from the original guidance from ASHP that defines an ADR as an "unexpected, unintended, undesired, or excessive response to a drug."[15(p417)] ASHP states that the term "side effect" is not included in the definition of an ADR and, rather, a side effect is an "expected, well-known reaction resulting in little or no change in patient management."[15(p418)] A clear understanding of the ADR definition will assist clinicians in identifying, treating, and reporting ADRs.[8,16,17]

The Joint Commission requires ADR reporting to help prevent future ADRs.[8,18] The Joint Commission identifies an organizational cause of ADRs as not developing an "effective safety culture,"[18(p1)] which includes strategies to prevent future harm. The Centers for Medicare and Medicaid Services developed a National Action Plan for Adverse Drug Event Prevention with oversight and incentives to encourage reporting and prevention of future ADRs.[19] Clinical trials identify adverse reactions of medications, but often, not all ADRs are known until medications are on the market, making ADR reporting crucial to improving patient care.[9,20]

Reasons for ADR underreporting include a lack of awareness and understanding on how to report an ADR.[8] Often, health care professionals do not feel appropriately trained in ADR reporting and prevention.[8] Elnour et al[8] provided a survey to 600 health care providers, and 51% responded that there are no strategies at their facility to prevent future ADRs. Although 73% of respondents agreed that ADRs are a cause of hospitalizations, 50% of respondents reported that there was no policy to report ADRs. Therefore, a lack of monitoring and reporting occurred due to gaps in knowledge and education surrounding ADRs.[8]

Al Rabayah et al[9] identify barriers, including how to fill out the ADR form, concerns on assessing the severity of an ADR, and a lack of clarity for the definition of an ADR versus a side effect of a medication. The survey shows that 64.4% of health care professionals strongly agree that ADR reporting is crucial to patient care improvements.[9] However, 37.5% of survey respondents say a lack of training and education serve as the main barriers to ADR reporting, and 81.7% were never trained in ADR reporting.[9]

Abu Esba et al[20] credit an increase in ADR reporting to more education and awareness surrounding the importance of reporting. This study finds that a third of the ADRs reported could have been avoidable, showing the importance of prevention efforts after an ADR is discovered.[20] A Norwegian study[21] identifies that, prior to an educational intervention, 93% of pharmacists in the intervention group and 91.5% of pharmacists in the control group had not reported an ADR to one of the national reporting centers. After an educational session, 51.4% of pharmacists in the intervention group had reported an ADR in the following 3 months and had a statistically significant improvement in their confidence and knowledge in ADR reporting.[21]

A survey[13] assessing hospitals and community pharmacies in Jordan identified that 69.7% of pharmacists were able to define an ADR, but only 8.2% had been trained on ADR reporting. In this study,[13] 91.2% of pharmacists had identified at least 1 ADR in the past year, but only 19.5% had reported an ADR in their career. The survey also demonstrates that 76% of pharmacists did not know how to report an ADR and 98.5% did not know when to report an ADR. Reasons for the lack of reporting include that there was not enough information from the patient, there was a lack of access to the reporting form, and there was a lack of awareness of national reporting.[13]

Demler and Chehovich[22] identify that most drug discontinuations at a state psychiatric facility were categorized as a change in therapy but were potentially in response to an ADR. Out of 1106 drug discontinuation reports, 569 discontinuations were due to a change in therapy, but only 5 ADRs were reported.[22] An ADR reporting process by which retribution is not a concern and prescribers have the ability to participate in reporting decisions might lead to increased ADR reporting.[22] Another study[23] at an inpatient psychiatric facility showed that 20.4% of ADRs at the facility were preventable.

Su et al[24] surveyed pharmacists and identified that 69.5% understood the definition of an ADR, but only 35% thought all potential ADRs should be reported. Although 78% understood how to report an ADR, only 14.6% of pharmacists had reported an ADR.[24] This study[24] identifies the major barriers to ADR reporting, including the hesitation to identify something as an ADR, a lack of participation in patient rounds, and time constraints.

The objective of this study is to understand health care professionals' perspectives of ADRs within inpatient state psychiatric facilities, barriers to ADR reporting, and methods to improve the ADR reporting process. This survey is unique in that it addresses ADRs in a psychiatric facility, a patient population for which there is limited literature surrounding ADRs. In the studies available in psychiatric facilities, they classify the types of ADRs caused by medications, but to our knowledge, this is the first study that focuses on health care professionals' perceptions of and barriers to ADR reporting in an inpatient state psychiatric facility.

Methods

A 10-question survey was distributed to health care professionals throughout 25 inpatient state psychiatric facilities within 1 state through the statewide pharmacy and therapeutics email list. The survey contained 9 multiple choice questions allowing free text comments and 1 free response question; it was developed by 2 pharmacists and 1 pharmacy manager and reviewed by 1 pharmacist and 1 medical director. The survey assessed the definition of an ADR, confidence in reporting, barriers to reporting, the role of reporting, who should report and review ADRs, and strategies to improve the process. Respondents were not required to answer every question, and 6 of the multiple-choice questions allowed respondents to select more than 1 response by stating *select all that apply*. Results of the free text responses were coded using the consensual qualitative research process[25] by 2 pharmacists and reviewed by 1 pharmacy manager.

Results

The survey was distributed to 143 health care professionals and received 108 responses (response rate of 75.5%). This study assessed different health care workers, including physicians, nurses, and pharmacists, with other respondents including 3 nurse practitioners, 2 pharmacy managers, and 1 nurse administrator (Table 1, question 1). The majority of respondents had been practicing in their field for greater

TABLE 1: Adverse drug reaction (ADR) survey questions and responses 1 through 5

Questions and Answer Choices	Percentage of Responses	No. of Responses
1. What is your current role?		
Psychiatrist	15.74	17
Medical specialist	5.56	6
Pharmacist	33.33	36
Nurse	35.19	38
Prefer not to answer	2.78	3
Other (please specify)	7.41	8
No. of respondents		108
2. How long have you been practicing in your field?		
0-5 y	6.48	7
6-10 y	13.89	15
11-15 y	12.96	14
15-20 y	13.89	15
21+ y	52.78	57
No. of respondents		108
3. What do you consider to be an ADR? (select all that apply)		
Overdose	29.63	32
Side effects	47.22	51
Withdrawal	19.44	21
Unexpected reaction	89.81	97
Unintended reaction	87.96	95
Excessive reaction	72.22	78
Other (please specify)	5.56	6
No. of respondents		108
4. How confident do you feel with the current process of reporting an ADR at your facility?		
Extremely confident	34.26	37
Moderately confident	50.00	54
Not at all confident	15.74	17
No. of respondents		108
5. What is a perceived barrier to ADR reporting in your facility? (select all that apply)		
Lack of time	21.36	22
Fear of retaliation	20.39	21
Lack of information about the ADR	33.01	34
The ADR was not serious/reaction is well known	45.63	47
Not clear how to report an ADR	33.01	34
Not your duty to report	5.83	6
Other (please specify)	29.13	30
No. of respondents		103

than 21 years, and only 6.48% of respondents had been practicing in their field for 5 years or less (Table 1, question 2).

When the respondents were asked what they consider to be an ADR, most of them identified with the earlier ASHP definition, including an unexpected, unintended, and excessive reaction, although some of the responses included answers that ASHP states is not an ADR, such as a side effect, overdose, and withdrawal (Table 1, question 3).[15] Other responses from this question included a synergistic reaction, harm caused by a drug, an allergic reaction, an unwanted effect, overdose, and any known or unknown side effect that has a negative impact on the patient and requires medical attention.

Regarding confidence with the current process of reporting an ADR at any of the facilities, 50% of respondents felt moderately confident in reporting an ADR, 34.26% of people felt extremely confident, and 15.74% were not at all confident (Table 1, question 4). For barriers to ADR reporting, 20.39% of respondents said they feared retaliation, speaking to the culture surrounding ADR reporting. Other responses included that the ADR was not serious or the reaction is well known. Of the respondents, 33% said they were not clear on how to report an ADR (Table 1, question 5). For the free text responses, 9 professionals said there are no perceived barriers to ADR reporting, 5 professionals said a barrier is a lack of education about the definition of an ADR, and 2 professionals said a barrier is miscommunication about the ADR. Additional responses included defensiveness of prescribers, prescribers not reporting, a lack of accountability, delays in reporting, the ADR reporting process being too complex and tedious, and a lack of clarity on how ADRs are decided.

When asked about the role of ADR reporting, 0 respondents selected that ADR reporting has no role (Table 2, question 6). Most respondents (83.33%) agreed that ADR reporting can decrease risks to our patient population, can improve our medication use process, and is part of pharmaceutical care (Table 2, question 6). In other responses, 2 respondents said ADR reporting is a necessary educational tool, 4 people said it can improve patient care and safety, and 1 person said it can increase public awareness and knowledge about medications. A few respondents believed the purpose of ADR reporting is to satisfy governing bodies rather than improving patient care. These responses included that ADR reporting is to satisfy the Joint Commission, ADR reporting indicates the institution's compliance with medication monitoring, and ADRs are an administrative requirement for statistics with no impact on patient care.

For whom should report and review ADRs, the primary responses included prescribers, pharmacists, and nurses, and other responses included the patients themselves (Table 2, questions 7 and 8). For suggested strategies to improve the ADR reporting process, 84.71% of respondents listed training and direction on what and how to report as their suggestion for improvement, 60% of respondents wanted better access to reporting technology, and 61.18% of respondents felt that strategies to improve the ADR reporting process included training on perceived versus real consequences of ADR reporting and a designated point person to assist with ADR reporting (Table 2, question 9). Other responses included interprofessional care team meetings and a need for an easier and more streamlined method to report.

For the free response question asking respondents for any additional comments they would like to address regarding ADR reporting, 19 out of 108 health care professionals responded (Table 2, question 10). These responses demonstrate that understanding a shared definition of an ADR, more training and education, and a streamlined and transparent process of reporting and following up on ADRs can encourage ADR reporting.

Discussion

Because 47.22% of respondents believe a side effect is an ADR (Table 1, question 3), this speaks to the need for increased education and a shared definition of an ADR. In comparison with a study[26] focused on community pharmacists rather than an inpatient facility, a lack of time is identified as a barrier to ADR reporting, which 21.36% of our respondents identified as a barrier as well (Table 1, question 5). The study[26] focusing on community pharmacists also identifies that ADR reporting can be limited by the belief that the reaction was not severe enough to report, which 45.63% of our respondents had answered in this survey (Table 1, question 5).

In comparing the results of this study with other previously reported ADR surveys, the need for education and policies on reporting was consistent, but the area where our survey identified an additional barrier was in the fear of retaliation and retribution. The Joint Commission[18] encourages a nonpunitive approach to ADR reporting and an environment that facilitates trust and accountability among health care professionals rather than blaming anyone for the ADR. With 20.39% of respondents answering that a barrier to ADR reporting is a fear of retribution and retaliation, there was discussion if the term *adverse drug reaction* contributed to this fear. While educating health care professionals on a shared definition of an ADR, an alternative term to an ADR may reduce the fear of retaliation. Some studies did assess for the fear of negative consequences when reporting an ADR, including a hospital study[27] and a study focused on nurse's attitudes at a hospital,[28] but the respondents did not

TABLE 2: Adverse drug reaction (ADR) survey questions and responses 6 through 10

Questions and Answer Choices	Percentage of Responses	No. of Responses
6. What do you see as the role of ADR reporting? (select all that apply)		
Decrease risks to our patient population	83.33	90
Can improve our medication use process	90.74	98
Part of pharmaceutical care	72.22	78
No role	0.00	0
Other (please specify)	9.26	10
No. of respondents		108
7. I believe ADRs should be reported by (select all that apply)		
Prescribers	95.37	103
Pharmacists	76.85	83
Nurses	87.04	94
Committee leaders	32.41	35
Patients	60.19	65
Other (please specify)	9.26	10
No. of respondents		108
8. I believe ADR reports should be reviewed by (select all that apply)		
Prescribers	96.30	104
Pharmacists	93.52	101
Nurses	79.63	86
Committee leaders	59.26	64
Treatment team	64.81	70
Other (please specify)	5.56	6
No. of respondents		108
9. Please list suggested strategies to improve the ADR reporting process in your facility (multiple choice question—select all that apply)		
Training and direction on what and how to report	84.71	72
Access to reporting technology	60.00	51
Training on perceived versus real consequences of ADR reporting	61.18	52
Designated point person to assist with ADR reporting once an ADR is identified	61.18	52
Other (please specify)	4.71	4
No. of respondents		85
10. Please list any additional comments you would like to address regarding ADR reporting (free response question)		
Need for easier and more streamlined method to report and track ADRs		6
ADR definition disagreement		6
Defensive prescribers/fear of retaliation		1
Guidance and supervision from those overseeing the process		4
Remove reporting quota		2
Transparent process		1
Need for patient involvement in the ADR process		1
Need for additional education/training		9
No. of respondents		19

identify the same fear of retaliation that is shown in this study. The study by Herdeiro et al[29] identifies that the likelihood of a provider reporting an ADR is related to the provider's attitude toward ADRs. This shows the importance of developing a program to reduce the belief that health care workers will receive negative consequences if an ADR is reported.

In addition, a gap in education and the need for ADR training is evident when 33% of respondents say they are not clear on how to report an ADR (Table 1, question 5). For the role of ADR reporting, because 0 respondents selected that ADR reporting has no role, this suggests that all respondents are aware of the importance of ADR reporting (Table 2, question 6).

Our study is unique in that other ADR surveys do not identify respondents' beliefs that ADR reporting is exclusively intended to satisfy governing bodies. Although this response was submitted as a free text comment, it was noted by three subjects, and therefore, we recommend that future studies should explore this as a potential subterfuge theory (Table 2, question 6). This concern also supports the need for a more transparent process and to be able to show that reporting ADRs can lead to future prevention strategies. From the results of the survey, implementing education and a more transparent process demonstrating that ADR reporting advances patient care can encourage health care professionals to report ADRs.

The results of this survey led to the development of a statewide pharmacy and therapeutics subcommittee focused on improving and streamlining the ADR reporting process. In an effort to improve ADR reporting, ADR policies from all 25 state inpatient psychiatric facilities have been gathered in an effort to develop a consistent process throughout all facilities. An additional survey was distributed to psychiatrists with the goal of exploring an alternative term for *adverse drug reactions*, which might reduce the fear of retribution and retaliation. Due to COVID-19, the ADR subcommittee efforts were temporarily paused, but education and training on ADR reporting and opportunities to reduce the fear of ADR reporting consequences continue as opportunities for the subcommittee to address ADRs and encourage reporting in the interim.

Limitations

The survey had 10 questions to limit the time it took to complete the survey and to encourage more responses, but more questions could allow further investigation into barriers and solutions for ADR reporting. This study was completed within inpatient state psychiatric facilities within 1 state and may not be as applicable to outside facilities or different states. The survey was reviewed by multiple health care professionals, but there is still the potential for bias due to the survey not being validated.

Conclusion

Survey respondents recognize that ADR reporting can decrease risk, improve the medication use process, and is a part of pharmaceutical care. However, survey respondents identified barriers and needs to improve the ADR reporting process to encourage reporting. Improved communication, education, and consensus on the definition of an ADR are needed to encourage health care professionals to report ADRs and reduce the fear of retribution and retaliation.

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