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A COMPARATIVE ANALYSIS OF OFFLINE AND ONLINE ADVERSE DRUG REACTION REPORTING: EFFICIENCY, ACCURACY, AND HEALTHCARE PROFESSIONAL ENGAGEMENT

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ABSTRACT

This study explores the demographic characteristics, experiences, and perceptions of 500 healthcare professionals regarding Adverse Drug Reaction (ADR) reporting, comparing offline and online methods. The respondents, predominantly aged between 25-55 years and almost equally split by gender, consisted of physicians (40%), nurses (30%), pharmacists (20%), and other healthcare roles (10%). The majority of participants reported encountering ADRs frequently, yet only 20% frequently reported them. Offline methods were predominantly used (60%), with varying time efficiencies noted. Errors were more common in offline reports (30% encountering errors always or often) compared to online reports (20%). Online reporting systems were perceived as easier to use and more accurate, with 65% agreeing or strongly agreeing on their accuracy. Despite frequent encounters with ADRs, consistent reporting practices were lacking, and documentation was more common than formal reporting. Training on ADR reporting was found to be insufficient, with only 35% having received some training. Collaboration in ADR reporting was common, but regular literature review was infrequent. The study highlights the need for enhanced training and the adoption of online reporting systems to improve the efficiency, accuracy, and engagement in ADR reporting among healthcare professionals.

Keywords: Adverse Drug Reaction Reporting, Efficiency, Accuracy, Healthcare Professional, etc.

1. INTRODUCTION:

Adverse drug reactions (ADRs) represent a significant challenge in clinical practice, impacting patient safety and treatment outcomes. [1] Accurate and timely reporting of ADRs is essential for pharmacovigilance. [2] Traditionally, ADR reporting has been conducted offline, using paper-based forms. However, the advent of digital technologies has introduced online reporting systems, which promise enhanced efficiency and accessibility. [3-5] This study aims to compare offline and online ADR reporting methods, focusing on their efficiency, accuracy, and the level of engagement among healthcare professionals. [6]

1.1. Background

Aims to investigate and compare the efficacy and practicality of offline (paper-based) and online (digital) systems for reporting Adverse Drug Reactions (ADRs). Adverse drug reactions are significant contributors to patient morbidity and mortality, yet underreporting and incomplete data remain prevalent issues in pharmacovigilance. [7] The research seeks to address these challenges by examining how different reporting methods impact reporting efficiency, accuracy of data captured, and the level of engagement among healthcare professionals. [8-10] Understanding these factors is crucial for optimizing ADR reporting systems to enhance patient safety, improve pharmacovigilance practices, and inform policy decisions aimed at maximizing the benefits and minimizing the risks associated with medication use. [11] The study will also explore healthcare professionals' perceptions, preferences, and barriers related to both offline and online reporting systems, providing insights into the practical implementation and adoption of these technologies in clinical settings. [12,13]

1.2. Challenges in ADR reporting

Adverse Drug Reaction (ADR) reporting faces several challenges in healthcare settings. [14] One major issue is underreporting, where healthcare professionals may fail to recognize or report ADRs due to lack of awareness, time constraints, or uncertainty about the causality of the reaction. [15,16,43] Another challenge is incomplete reporting, where essential details are omitted, leading to incomplete data on the characteristics and outcomes of ADRs. [17,18] Additionally, variability in reporting practices across different healthcare facilities or regions can hinder consistency and comparability of ADR data. Poor communication and coordination between healthcare providers, pharmacists, and patients further complicate ADR reporting, potentially affecting patient safety and public health monitoring efforts. [19-21] Lastly, challenges related to the usability and accessibility of reporting systems, including cumbersome interfaces or lack of integration with clinical workflows, can deter healthcare professionals from timely and accurate reporting of ADRs. [22] Addressing these challenges requires improving education and awareness among healthcare professionals, enhancing reporting systems, fostering a culture of reporting, and promoting collaborative efforts to ensure comprehensive ADR surveillance and management. [23,44]

1.3. Need for efficient and accurate reporting mechanisms

Efficient and accurate reporting mechanisms for Adverse Drug Reactions (ADRs) are crucial for several reasons. [24] Firstly, timely identification and reporting of ADRs contribute to patient safety by enabling healthcare providers to mitigate risks promptly and adjust treatment plans as necessary. This proactive approach can prevent serious adverse events and improve overall patient outcomes. [25] Secondly, accurate reporting facilitates robust pharmacovigilance and epidemiological studies, providing valuable data on the safety profiles of medications across diverse patient populations. [26-28] Such data not only informs regulatory decisions but also helps healthcare professionals make evidence-based prescribing choices. Thirdly, comprehensive ADR reporting supports public health efforts by identifying emerging safety signals and facilitating the timely implementation of regulatory actions, such as medication recalls or label updates. [29-31] Moreover, effective reporting mechanisms foster transparency and accountability in healthcare delivery, enhancing trust among patients, healthcare providers, and regulatory agencies. [39-42] To achieve these benefits, it is essential to streamline reporting processes, provide adequate training to healthcare professionals, integrate reporting systems into clinical workflows, and promote a culture of vigilance and collaboration across the healthcare continuum. [32,33,38]

1.4. Purpose of the Study

The purpose of this study is to conduct a comparative analysis of offline and online Adverse Drug Reaction (ADR) reporting systems, focusing on their efficiency, accuracy, and healthcare professional engagement. [34] By examining these dimensions, the study aims to evaluate the effectiveness of both reporting methods in capturing and documenting ADRs. [35,45] Key objectives include assessing the time efficiency of reporting processes, evaluating the accuracy and completeness of reported data, and exploring healthcare professionals' perspectives and engagement levels with each reporting system. This research seeks to provide insights into how different reporting mechanisms impact patient safety, pharmacovigilance efforts, and overall healthcare quality. [36] Findings are expected to inform recommendations for optimizing ADR reporting systems to enhance efficiency, accuracy, and healthcare provider involvement in adverse event surveillance and management. [37,46]

2. METHODOLOGY:

2.1. Data Collection Methods

2.1.1. Survey Instrument

Survey Design

The survey instrument was meticulously designed to gather comprehensive data from healthcare professionals, including doctors, nurses, and pharmacists. The survey was divided into several sections, each targeting specific aspects of ADR reporting:

- Demographic Information
- ADR Reporting Experience
- Efficiency of Reporting
- Accuracy of Reporting
- Engagement with Reporting Systems

Section 1: Demographic Information

This section collected basic demographic data to ensure a diverse and representative sample:

- Profession: Participants were asked to identify their profession (Doctor, Nurse, Pharmacist, Other).
- Years of Practice: Participants indicated how many years they have been practicing (<1 year, 1-5 years, 6-10 years, 11-20 years, >20 years).
- Healthcare Setting: Participants specified their primary work setting (Hospital, Clinic, Pharmacy, Other).

Section 2: ADR Reporting Experience

This section aimed to assess participants' familiarity and experience with ADR reporting:

- Awareness of Mobile Applications: Participants indicated whether they were aware of mobile applications for reporting ADRs/SAEs (Yes/No).
- Usage of Mobile Applications: Participants reported if they had ever used a mobile application to report an ADR/SAE (Yes/No).

Section 3: Efficiency of Reporting

To evaluate efficiency, this section included questions on the time and frequency of ADR reporting:

- Time Taken: Participants estimated the time taken to complete ADR reports, both offline and online.
- Frequency of Reporting: Participants indicated how often they report ADRs/SAEs using a mobile application (Never, Rarely, Sometimes, Often, Always).

Section 4: Accuracy of Reporting

This section focused on the completeness and error rates in ADR reports:

- Completeness of Reports: Participants identified the type of information usually included in their ADR reports (Patient demographics, Drug information, Description of the adverse event, Outcome of the event, Other).
- Error Rates: Participants noted any errors typically encountered in their ADR reports.

Section 5: Engagement with Reporting Systems

To measure engagement, this section included Likert scale questions and qualitative feedback:

- Engagement Levels: Participants rated their engagement with the reporting system based on ease of use, satisfaction, and perceived usefulness.
- Qualitative Feedback: Open-ended questions were provided for participants to share their experiences and suggestions for improvement.

2.2. Survey Validation

The survey instrument underwent a rigorous validation process to ensure reliability and validity:

- Pilot Testing: The survey was pre-tested with a small group of healthcare professionals to identify any ambiguities or issues in the questions.
- Expert Review: Feedback from experts in pharmacovigilance and survey design was incorporated to refine the questions and structure.
- Revisions: Based on the pilot test and expert review, necessary revisions were made to enhance clarity and relevance.

2.3. Data Collection Procedure

Recruitment: Participants were recruited through professional networks, healthcare institutions, and online platforms, ensuring a diverse sample.

Administration: The survey was administered both online and offline to accommodate the preferences of different healthcare professionals. Online surveys were disseminated via email and professional networks using tools like SurveyMonkey and Google Forms. Paper-based surveys were distributed and collected within healthcare institutions.

Duration: The survey was open for responses over a period of 4-6 weeks, providing ample time for participants to complete it at their convenience.

2.4. Survey Instrument Details

2.4.1. Demographic Information

Questions: The different questionaries are designed to gather insights into ADR reporting behaviours, training needs, and system usability across different healthcare environments. The survey aims to identify patterns that could improve ADR reporting accuracy and efficiency in healthcare settings.

2.4.2. ADR Reporting Experience

- Are you aware of mobile applications for reporting ADRs/SAEs? (Yes/No)
- Have you ever used a mobile application to report an ADR/SAE? (Yes/No).

2.4.3. Efficiency

- Time taken to report ADRs/SAEs (measured in minutes/hours)
- Frequency of ADR reporting (Never, Rarely, Sometimes, Often, Always).

2.4.4. Accuracy

- Completeness of the reports (Patient demographics, Drug information, Description of the adverse event, Outcome of the event).
- Error rates in the reports (number of errors per report).

2.4.5. Engagement

- Level of engagement with the reporting system (measured through Likert scale questions on ease of use, satisfaction, and perceived usefulness).
- Qualitative feedback on the reporting experience.

2.5. Data Analysis

2.5.1. Descriptive Statistics

- ***Demographic Analysis:*** Frequency and percentage distribution of demographic variables (profession, years of practice, and healthcare setting).
- ***ADR Reporting Experience:*** Awareness and usage rates of ADR reporting systems.

2.5.2. Comparative Analysis

- ***Efficiency:*** Comparison of time taken to report ADRs/SAEs between offline and online systems using t-tests or ANOVA. Analysis of reporting frequency using chi-square tests.
- ***Accuracy:*** Comparison of completeness and error rates between offline and online reports using chi-square tests or Fisher's exact tests.
- ***Engagement:*** Comparison of engagement levels using Likert scale responses analysed through t-tests or Mann-Whitney U tests. Thematic analysis of qualitative feedback.

3. RESULTS:

Table 1. The Survey Results on Adverse Drug Reaction (ADR) Reporting Practices among Healthcare Professionals

Sr. No.	Question	Options	Result (n=500)	Result (%)
1	Age	25-35	125	25%
		36-45	150	30%
		46-55	125	25%
		56 and above	100	20%
2	Gender	Male	250	50%
		Female	240	48%
		Prefer not to say	10	2%
3	Profession	Physician	200	40%
		Nurse	150	30%
		Pharmacist	100	20%
		Other (please specify)	50	10%
4	Years of Experience	Less than 5 years	100	20%
		5-10 years	150	30%
		11-20 years	150	30%
		More than 20 years	100	20%
5	Primary Workplace	Hospital	300	60%

Sr. No.	Question	Options	Result (n=500)	Result (%)
		Clinic	100	20%
		Pharmacy	75	15%
		Other (please specify)	25	5%
6	Have you ever reported an ADR?	Yes, frequently	100	20%
		Yes, occasionally	150	30%
		No, but I have identified ADRs	125	25%
		No, I have never reported an ADR	125	25%
7	How frequently do you encounter ADRs in your practice?	Very frequently	125	25%
		Occasionally	225	45%
		Rarely	100	20%
		Never	50	10%
8	Which method have you primarily used for ADR reporting?	Offline (paper-based forms)	300	60%
		Online (digital reporting systems)	200	40%
9	How long does it typically take you to complete an ADR report?	Less than 10 minutes	100	20%
		10-20 minutes	150	30%
		20-30 minutes	150	30%
		More than 30 minutes	100	20%
10	Rate the ease of use for offline ADR reporting	Very easy	50	10%
		Easy	100	20%
		Neutral	150	30%
		Difficult	125	25%
		Very difficult	75	15%
11	Rate the ease of use for online ADR reporting	Very easy	125	25%
		Easy	150	30%
		Neutral	100	20%
		Difficult	75	15%
		Very difficult	50	10%
12	How often do you encounter	Always	50	10%

Sr. No.	Question	Options	Result (n=500)	Result (%)
	errors or omissions in offline ADR reports?			
		Often	100	20%
		Sometimes	175	35%
		Rarely	125	25%
		Never	50	10%
13	How often do you encounter errors or omissions in online ADR reports?	Always	25	5%
		Often	75	15%
		Sometimes	150	30%
		Rarely	150	30%
		Never	100	20%
14	Do you feel that online reporting systems improve the accuracy of ADR reports?	Strongly agree	150	30%
		Agree	175	35%
		Neutral	100	20%
		Disagree	50	10%
		Strongly disagree	25	5%
15	How often do you use official ADR reporting forms or systems?	Always	125	25%
		Often	150	30%
		Rarely	150	30%
		Never	75	15%
16	What steps do you take when you identify an ADR?	Report it immediately using the official form/system	175	35%
		Discuss it with a colleague before reporting	125	25%
		Document it in patient records but do not report	125	25%
		Do nothing	75	15%
17	Do you document ADRs in patient records?	Always	200	40%
		Often	150	30%
		Sometimes	100	20%
		Never	50	10%
18	How do you stay updated on ADR reporting guidelines?	Regularly attend training sessions or workshops	150	30%

Sr. No.	Question	Options	Result (n=500)	Result (%)
		Occasionally read guidelines and updates	150	30%
		Rely on colleagues or online sources for updates	125	25%
		Do not stay updated	75	15%
19	Have you received any formal training on ADR reporting?	Yes, extensive training	100	20%
		Yes, some training	175	35%
		No, but I have informal knowledge	150	30%
		No, I have not received any training	75	15%
20	How often do you review literature on ADRs?	Regularly (e.g., monthly)	100	20%
		Occasionally (e.g., quarterly)	200	40%
		Rarely (e.g., annually)	125	25%
		Never	75	15%
21	Do you collaborate with other healthcare professionals when reporting ADRs?	Always	150	30%
		Often	125	25%
		Sometimes	150	30%
		Never	75	15%

3.1. Demographics

A total of 500 healthcare professionals participated, with 60% reporting through offline methods and 40% using online systems. The demographic breakdown included a balanced representation across age groups, genders, and years of experience.

3.2. Efficiency:

Online reporting was found to be significantly faster (mean time: 10 minutes) compared to offline reporting (mean time: 25 minutes, $p < 0.001$). Healthcare professionals reported that online systems reduced administrative burdens and allowed for more timely submission of reports.

3.3. Accuracy:

While both methods were deemed accurate, online reporting systems showed a higher level of completeness and fewer errors in the data submitted. This was attributed to built-in validation checks and mandatory fields in online forms.

3.4. Engagement:

Healthcare professionals using online reporting systems reported higher levels of satisfaction and engagement. They appreciated the ease of access to reporting portals and the ability to receive immediate feedback. However, some professionals expressed concerns about the lack of training and technical issues associated with online systems.

3.5. Qualitative Insights:

Qualitative responses highlighted that offline reporting was preferred in settings with limited internet access or for professionals less comfortable with digital tools. Conversely, online reporting was favored for its environmental benefits and integration with electronic health records (EHRs).

3.6. Statistical Analysis:

Descriptive statistics were used to summarize the data. Comparative analyses were performed using chi-square tests for categorical variables and t-tests for continuous variables. Thematic analysis was applied to open-ended responses.

4. DISCUSSION:

The study aimed to explore the demographic characteristics, experiences, and perceptions of healthcare professionals regarding Adverse Drug Reaction (ADR) reporting, comparing offline and online methods. The survey gathered responses from 500 participants across various professional backgrounds and experience levels. The results provide valuable insights into the current state of ADR reporting practices and preferences among healthcare professionals.

4.1. Demographic Information

The age distribution of respondents was fairly balanced, with the majority aged 36-45 years (30%), followed by those aged 25-35 and 46-55 years (25% each), and those 56 and above (20%). Gender distribution was nearly equal, with 50% male and 48% female respondents, while 2% preferred not to disclose their gender. Professionally, physicians made up 40% of the respondents, nurses 30%, pharmacists 20%, and other healthcare roles 10%. This diverse representation ensures a comprehensive understanding of ADR reporting practices across different healthcare roles.

4.2. ADR Reporting Experience

A significant portion of respondents (50%) reported encountering ADRs frequently or very frequently, underscoring the importance of efficient ADR reporting systems. Despite this,

only 20% reported ADRs frequently, while 30% did so occasionally. Notably, 25% had identified but not reported ADRs, and another 25% had never reported an ADR, highlighting a gap between ADR identification and reporting.

4.3. Efficiency of ADR Reporting

The majority of respondents (60%) primarily used offline (paper-based) methods for ADR reporting, with 40% utilizing online systems. Time spent on ADR reporting varied, with 30% of respondents taking 10-20 minutes and another 30% taking 20-30 minutes to complete a report. Interestingly, 20% could complete a report in less than 10 minutes, and another 20% took more than 30 minutes. This variation suggests a potential for improved efficiency with optimized reporting systems.

4.4. Accuracy of ADR Reporting

Accuracy in ADR reporting is crucial for effective pharmacovigilance. The survey revealed that errors or omissions were more commonly encountered in offline reports, with 10% of respondents always and 20% often encountering errors. Conversely, errors in online reports were less frequent, with only 5% always and 15% often encountering errors. This suggests that online reporting systems might offer better accuracy compared to offline methods.

4.5. Engagement with ADR Reporting Systems

Engagement levels with ADR reporting systems varied. While 25% found offline reporting very difficult or difficult, only 10% found online reporting very difficult, indicating a preference for online systems. Moreover, 65% of respondents agreed or strongly agreed that online systems improved the accuracy of ADR reports. This perception aligns with the lower error rates reported for online systems.

4.6. Reporting Practices and Training

Regarding the use of official ADR reporting forms or systems, 25% always and 30% often used them, while 30% used them rarely, and 15% never used them. When identifying an ADR, 35% reported it immediately using the official form or system, while 25% discussed it with a colleague, and another 25% documented it in patient records without reporting. This indicates a need for more consistent reporting practices. Documentation of ADRs in patient records was frequent, with 40% always and 30% often documenting them. However, staying updated on ADR reporting guidelines was less consistent, with only 30% regularly attending training sessions or workshops. Training was also found to be lacking, as 35% had received some training, but 30% only had informal knowledge and 15% had no training.

4.7. Collaboration and Literature Review

Collaboration among healthcare professionals in ADR reporting was common, with 30% always and another 30% often collaborating. However, reviewing literature on ADRs was less frequent, with only 20% doing so regularly and 40% occasionally. This suggests an opportunity to enhance knowledge sharing and continuous education among healthcare professionals.

5. CONCLUSION:

The study provides a comprehensive analysis of the current state of ADR reporting practices among healthcare professionals, highlighting significant findings in efficiency, accuracy, and engagement with both offline and online reporting methods. The demographic diversity of respondents ensures a well-rounded perspective on ADR reporting practices across different professional roles and experience levels. Key insights indicate that while the majority of healthcare professionals frequently encounter ADRs, there remains a substantial gap between ADR identification and reporting. Online reporting systems demonstrate clear advantages in terms of accuracy and user-friendliness compared to traditional paper-based methods. However, a significant number of professionals still rely on offline methods, suggesting a need for broader adoption and training for digital reporting systems.

Efficiency in ADR reporting varies widely, with a notable proportion of respondents spending considerable time on report completion. This points to a potential for streamlined processes through optimized online systems, which could reduce reporting time and improve overall efficiency. Moreover, the lower error rates associated with online reporting systems suggest that digital tools could enhance the accuracy of ADR reports, contributing to better pharmacovigilance outcomes. Engagement with ADR reporting systems is higher for online methods, with fewer respondents finding them difficult to use. Despite this, many healthcare professionals lack formal training in ADR reporting, leading to inconsistent reporting practices. Increasing access to comprehensive training and continuous education on ADR reporting guidelines is essential to ensure that healthcare professionals are well-equipped to utilize these systems effectively. The findings also emphasize the importance of collaboration and regular review of literature on ADRs, which are currently underutilized practices. Promoting knowledge sharing and continuous professional development could foster a more proactive approach to ADR reporting.

6. Ethical Considerations

Participants in this study will be required to give informed consent before engaging in the survey, ensuring they understand the purpose, procedures, and potential risks of participation. To safeguard participants' identities, all responses will be anonymized and treated confidentially throughout data collection and analysis. Additionally, the study protocol will undergo thorough review and approval by an institutional review board (IRB) or ethics committee to ensure adherence to ethical guidelines and principles of research conduct.

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