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Exploring willingness to use adverse drug reaction reporting systems: a multicentre qualitative study in China based on the technology acceptance model and task-technology fit integration approach

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ABSTRACT

Background Adverse drug reaction (ADR) reporting systems are critical for monitoring and managing drug safety. However, various factors influence the willingness to use these systems. This study aimed to investigate the willingness to use ADR reporting systems through an integrated model of the Technology Acceptance Model (TAM) and Task-Technology Fit (TTF) theory, conducting a multicentre qualitative study from the user's perspective.

Methods This study used qualitative research methods, including in-depth interviews with clinicians, nurses, pharmacists and administrators who reported ADRs through the National Adverse Drug Reaction Monitoring System (NADRMS) and the China Hospital Pharmacovigilance System (CHPS). The interviews were audio-recorded, transcribed verbatim and analysed using QDA Miner software for data management and thematic analysis.

Results Eighteen healthcare workers from five healthcare organisations participated in the study. They found the ease of use and usefulness of the current NADRMS and CHPS to be acceptable. The essential technical requirements identified included accuracy, standardisation, timeliness and confidentiality. However, challenges such as inaccurate information capture, unstable interfacing with medical record systems, low reporting efficiency and lack of data sharing were highlighted. Overall, front-line healthcare workers exhibited a generally negative attitude towards using NADRMS and CHPS, driven more by necessity than preference. Factors influencing their willingness to use these systems included ease of use, practicality, risk perception and social impact, with varying attitudes and requirements observed between user groups.

Conclusion This study provides practical recommendations that can be readily implemented to enhance the effectiveness and sustainability of ADR reporting systems. While front-line users in China acknowledged the systems' ease of use and usefulness, they also noted significant gaps in technological adaptation. They expressed the need for improvements in data openness and sharing, accessibility and system intelligence.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study adopts a qualitative research methodology, allowing for an in-depth exploration of front-line users' usage experiences and genuine perspectives.
⇒ It is grounded in the Technology Acceptance Model and Task-Technology Fit (TAM–TTF) integration model, enhancing the findings' robustness and theoretical foundation.
⇒ The hospitals sampled included various adverse drug reaction reporting systems currently in use across China, increasing the representativeness of the study results.
⇒ The study did not account for factors beyond the TAM–TTF integration model, such as macro-level policies and sociocultural contexts, which may influence the findings.
⇒ The study did not conduct a large-scale empirical investigation, which is planned for future research to build on these initial findings.

INTRODUCTION

Adverse drug reactions (ADRs) refer to any harmful, unintended reactions or effects of a drug that occur within its intended use and normal dose.[1] ADRs can pose significant health risks, reduce therapeutic efficacy and increase medical costs. Timely detection, proactive prevention and effective management of ADRs are essential to ensure patient safety and health.[2] Currently, China and most countries worldwide use a voluntary reporting system for ADRs. In this system, medical institutions, drug manufacturers and other entities voluntarily report adverse reaction incidents to the State Drug Administration

or local drug supervision authorities.[3] Among these entities, medical institutions are the primary contributors to voluntary reporting. Through active collection, summarisation and analysis of ADR data, voluntary reporting facilitates the timely identification and assessment of potential drug safety risks, safeguarding patient drug safety. Additionally, drug supervision authorities use the information reported voluntarily to improve drug safety management and oversight. The willingness and motivation of medical personnel to report ADRs play a central role in the effectiveness of this system.[4] However, current data indicate that ADR reporting in China needs to be improved, with reports often lacking quality and some ADRs are detected and warned about too late.[5]

The voluntary reporting system for ADRs is a critical platform that drug regulatory authorities or related organisations maintain. This system's ease of use and effectiveness directly influence the quantity and quality of reported adverse reactions.[6] In developed countries like the USA, well-functioning systems include data collection, report generation, data management and analysis, feedback mechanisms and robust data sharing and confidentiality measures.[7] These systems ensure a positive user experience for front-line staff, improve drug safety monitoring and management and facilitate timely detection and treatment of adverse reactions.[8] In China, three central ADR reporting systems are used: the National Adverse Drug Reaction Monitoring System (NADRMS), the China Hospital Pharmacovigilance System (CHPS) and the Electronic Data Pharmacovigilance System (EPV).[9] However, the most widely used systems, NADRMS and CHPS, suffer from shortcomings such as complex reporting processes and limited functionalities.[5] EPV, although more advanced, is underutilised, with only about 0.03% of healthcare organisations employing it. These issues, compounded by low reporting rates, incomplete information, lack of supervision and information silos, undermine drug safety regulation and erode public confidence.

The integrated model TAM–TTF, which combines the Technology Acceptance Model (TAM) and the Task-Technology Fit (TTF) theory, elucidates the factors influencing individuals' acceptance or rejection of adopting specific information technologies and how these technologies align with user task requirements.[10] This theory is widely used to assess users' willingness to engage with technology.[10] The TAM, proposed by Davis in 1986, explains individuals' acceptance and usage behaviour of information technology by positing that adoption hinges on perceived ease of use and usefulness.[11] In contrast, TTF theory focuses on aligning technology with users' task needs, stating that users are more inclined to adopt technology when it effectively supports their tasks.[12] By integrating these theories, the TAM–TTF model highlights the importance of ease of use, usefulness and alignment with the user task requirements for technology adoption.[13] Despite its utility, there is a shortage of studies in China utilising the TAM–TTF theory to explore the willingness to use the ADR reporting system.

Given the increasing focus of the Chinese government on drug safety, there is growing attention to ADR systems. The policy support and training initiatives aim to improve system construction and promotion. Studies exploring ADR data analysis and system enhancements are underway to identify trends, risks and population-specific drug safety issues.[14] However, more research is needed to understand these systems' actual applications and effects, particularly from the standpoint of user experience. Using the TAM–TTF framework, this study aims to investigate medical staff's willingness, feelings and suggestions regarding ADR reporting systems, analyse factors affecting their willingness, compare existing systems and provide insights into system improvement.

METHODS

Study design and setting

This study explored the personal experiences, willingness and expectations of front-line staff in healthcare organisations who use the ADR reporting system. It used qualitative research methodology.[15]

Five sample hospitals from Henan Province in central China were selected. These included three healthcare organisations using NADRMS: the First Affiliated Hospital of Zhengzhou University, the Henan Provincial People's Hospital and the Second Affiliated Hospital of Zhengzhou University; and two organisations using CHPS: Henan Cancer Hospital and Zhengzhou Seventh People's Hospital. These hospitals, all large, tertiary-level, A-class general hospitals, are well represented by their extensive facilities, boasting approximately 20 000 beds in total and offering a wide range of services. Due to its low coverage, the EPV was under-represented in this study, with only one healthcare organisation in Henan province beginning to pilot this system in June 2023. Therefore, the medical institutions that use the EPV system were not included.

Participants

A purposive sampling method was used to select 4–5 key informants from each healthcare organisation. The informants included ADR managers, clinicians, hospital pharmacists and nursing staff. The inclusion criteria for the interview subjects were as follows: (1) a minimum of 3 years of full-time medical work experience at the sample hospitals; (2) possession of an intermediate or higher professional title; (3) familiarity with the operational processes of the ADR reporting system and (4) willingness to participate in the study. The selection process was designed to ensure diversity among interview subjects, including age, gender, years of work experience and job role. Eighteen front-line medical staff participated in the study, comprising five managers, six pharmacists, three doctors and four nurses. The demographic and professional details of all participants are presented in table 1.

Table 1 Overview of the demographic characteristics of participants

Demographic characteristics	Value
Number of participants	18
Sex, n	
Male	7
Female	11
Occupation	
Pharmacist	8
Nurse	5
Clinician	5
Age, years	
Mean (range)	38.79 (33–49)
Years of work	
Mean (range)	14.64 (4–32)
Number of ADR cases reported in 2023	
Median (range)	21.5 (2–82)

ADR, adverse drug reaction.

Data collection

We began by reviewing existing literature and considering China's socioeconomic conditions and government policies to gain a preliminary understanding of the relevant research bases. This initial review helped to inform the development of an interview outline, which was initially formulated through group discussions. Subsequently, this outline was refined into a modified interview guide based on insights gained from preinterviews. The detailed interview guide included general questions and follow-up queries tailored to elicit comprehensive insights, as outlined in box 1.

The formal interview phase lasted approximately 1 month, from January 2024 to February 2024. We employed semistructured interviews to conduct in-depth, one-on-one sessions with the participants. Before formal interviews, preliminary discussions were held with interviewees to communicate the basic content and objectives of the interviews. With the help of the Henan Drug Evaluation Centre, we determined the location and time of each session. The interviews were conducted in a quiet and comfortable setting, typically in the sample hospital office, after obtaining written informed consent from each interviewee.

All interviews were facilitated by two researchers, XDX and XY. XDX was primarily responsible for asking questions and engaging with participants, while XY focused on taking detailed notes and contributing additional questions as needed. If an interview did not sufficiently cover a topic or if new questions emerged that necessitated further exploration, additional participants were recruited until data saturation was achieved. Data saturation was when no new information was obtained in subsequent interviews.

Box 1 Interview guide

1. How much do you know about reporting adverse drug reactions?
2. Do you think the current system is user-friendly? Please elaborate.
3. What factors might affect your willingness to report?
4. Do you have any concerns about reporting adverse reactions?
5. Do you have any suggestions for improving the current adverse drug reaction reporting system?

Data analysis

Thematic analysis, a qualitative research methodology, was used to identify, analyse and report patterns within the data.[16] This method involves several key steps: familiarising oneself with the data, initial coding, searching for themes, reviewing themes, defining and naming themes, and finally, reporting these themes. By systematically analysing the data, researchers can extract meaningful insights and provide reliable descriptions and explanations of the findings. Thematic analysis can be conducted using either deductive or inductive approaches. In this study, we applied an inductive thematic analysis, guided by the TAM–TTF integration model, to explore the underlying themes.

The data analysis process is shown in table 2. The audio recordings of the interviews were transcribed verbatim by researchers XDX and XY within 24 hours of each session. Following transcription, both researchers independently performed open coding using the QDA Miner Lite software (free version) to generate initial codes after familiarising themselves with the material. They then reviewed these codes to establish logical relationships between them and to identify overarching themes. During the data processing phase, the transcriptionists noted key features and significant points from the transcriptions for subsequent discussion. After the initial coding, the study team, under the guidance of industry experts (ZY) and methodologists, held group meetings to organise the coding. Using the TAM–TTF model as a framework, the team compared and analysed all discrepancies in the data analysis process to achieve consensus on the coding. Two examples of the analysis process are presented in table 3. This study adhered to the Consolidated Criteria for Reporting Qualitative Studies checklist.[17]

Trustworthiness

In alignment with the practices outlined in previously published studies by our research team, several measures were implemented in this study to ensure its credibility:[18] (a) All study members had extensive experience in conducting qualitative research, which underpinned the integrity of the study process. (b) The study team included experts in qualitative research methodologies to effectively address any methodological challenges encountered during the study. (c) Following data analysis,

Table 2 Data analysis process

Step	Description	Output
1. Data familiarisation	Repeatedly read interview transcripts to become familiar with the data and note initial observations and ideas.	Researchers gain an initial understanding of the data and identify some potential initial codes.
2. Initial coding	Perform open coding using QDA Miner Lite software, marking data segments with specific initial codes.	A set of initial codes representing different concepts and ideas identified in the data.
3. Searching for themes	Group similar or related codes into broader themes, identifying recurring patterns in the data.	A set of preliminary themes, each comprising multiple related initial codes.
4. Reviewing themes	Evaluate and refine preliminary themes to ensure that they are logically consistent and accurately reflect the data content.	Revised themes, with inconsistencies or redundant themes eliminated.
5. Defining and naming themes	Provide clear definitions and names for each theme, ensuring that they have distinct boundaries and reflect the core issues in the data.	Finalised themes, each with a clear definition and name.
6. Reporting themes	Use the TAM–TTF integrated model as a framework to report and interpret the finalised themes, applying them to the study's findings.	Thematic explanations in the research report, showcasing key findings derived from the inductive approach.

TAM, Technology Acceptance Model; TTF, Task-Technology Fit.

the results were returned to each participant for verification, ensuring the rigour and consistency of the findings. (d) The study adhered strictly to established operational procedures for qualitative research. (e) There was no conflict of interest or power dynamics between the researchers and the participants, ensuring that personal attributes had minimal influence on the study outcomes.

Patient and public involvement

None.

RESULTS

Participant task requirements

Respondents emphasised that effective adverse reaction reporting was dependent on several key requirements: accurate information reporting, clear process descriptions, timely reporting, comprehensive data analysis and robust data-sharing capabilities, along with early warning functions. Specifically, these requirements include the following aspects.

Accuracy

The interviewees emphasised the importance of precision in the reporting process. They noted that the report must accurately capture critical details such as the generic name, manufacturer, specifications and production lot number of the drug involved in the adverse reaction. This level of detail is essential to facilitate effectively tracing the cause of the adverse reaction in later stages.

> So, our system allows us to track the lot number throughout the entire process. When we input the patient's information and select the drug name, the corresponding lot number is automatically displayed. This feature streamlines the process of tracing the specific batch involved in any adverse reactions. (P1)

Table 3 Examples of data analysis

Quotation	Initial code	Subtheme	Theme	Mapped TAM–TTF component
The system's connection is poor, and its compatibility with our workflow is lacking. The match between the system and our needs hasn't been well executed. (P1)	► Connection issues ► Lack of compatibility	► System-task misalignment	Fit	Task-Technology Fit
Actually, this system is indeed valuable. Even if I haven't personally observed the patient, I can still monitor their condition through the system. When reviewing the case, it helps identify potential adverse reactions more effectively. (P12)	► Enhanced monitoring ability ► Effective adverse reaction identification	► Improved clinical decision-making	Usefulness	Perceived usefulness

TAM, Technology Acceptance Model; TTF, Task-Technology Fit.

For instance, when entering patient details like name, gender, age, and diagnosis, the system captures all relevant drug information, including the State Drug Approval Number and the batch number. However, if an adverse reaction occurs, we still need to manually input the exact time of drug administration and confirm the lot number. (P2)

Ultimately, the system requires the user to input the lot number, and this is crucial because adverse reactions might be linked to a specific batch. For example, if there were previous critical incidents associated with a particular batch, accurately recording the lot number helps in identifying potential patterns or issues related to that batch. (P8

Normative

The participants highlighted the complexity of assessing adverse reactions, noting that multiple factors must be considered, including drug characteristics, individual differences, drug interactions, environmental factors, patient history and adherence to medication guidelines. They emphasised the need for clear descriptions of the processes involved in adverse reactions and standardisation of report writing. These measures are essential for accurately determining the logical relationships within adverse reaction reports.

In the context of adverse reaction reporting, it is crucial to adhere to standardized writing practices. If the report is not written in a standardized manner, it can create significant challenges for healthcare providers, particularly for doctors and nurses, as I often have to step in to complete the entire process. This can be quite troublesome. (P13)

Our process requires detailed and standardized documentation. Beyond the patient's basic information, the report should thoroughly document all events leading up to and following the adverse reaction. This level of detail is essential for clarity when reviewing the process retrospectively, allowing for a clear and immediate understanding of the sequence of events. (P8)

Oh, it's important to note that if the report does not meet the formatting requirements, it cannot be submitted. (P1)

Many workers, when reporting adverse reactions, have descriptions of the process that are not standardized. We have repeatedly informed them about this issue and emphasized that they must provide clear and accurate descriptions. (P4

Promptness

Participants stressed that healthcare professionals must detect adverse reactions as early as possible during consultation. After detection, serious adverse reactions should be reported immediately to the healthcare provider or drug regulatory agency. Delayed reporting can hinder timely intervention and treatment, exacerbating the harm and risk of adverse reactions.

If we identify that a patient is experiencing an adverse reaction, we must report it immediately to ensure prompt intervention. (P12)

There are some adverse events that we can detect in a timely manner, allowing us to provide immediate feedback based on clinical observations. (P18

Confidentiality

Participants recognised the need for transparency in reporting adverse reactions and protecting patient privacy. They emphasised that while it is essential to maintain openness, healthcare organisations and drug regulators must also safeguard the confidentiality of patient information and the reports themselves. This balance is crucial to ensure both effective monitoring and patient trust.

Data security remains a constant concern, particularly for leadership, who are highly sensitive to issues surrounding the protection of information. This topic is always at the forefront of discussions due to its critical importance. (P10)

The primary focus is on safeguarding patient privacy and ensuring that sensitive personal information is protected. Concerns about privacy are often the driving force behind these security measures. (P12)

A significant reason our hospital has not yet implemented the new system is due to concerns about potential information breaches. The system requires all medical records and related data ports to be accessible, which raises fears about the exposure of patient information. Given the large volume of sensitive data involved, maintaining the confidentiality of patient records is paramount. P2)

Data sharing

The participants highlighted the importance of reporting and analysing adverse reactions to detect and identify ADRs promptly. They firmly expected that the reporting process would facilitate data sharing, allowing the results to serve an effective early warning function. This shared data enhance overall drug safety and pre-emptive risk management.

For example, when we encounter adverse events and the data is promptly shared, it allows us to respond quickly. This not only enhances our caution in future treatments but also enables us to notify patients about potential risks associated with certain medications. (P17)

Early warning is the first thing, Secondly, we can use this information to remind patients and guide them in the safe use of medications. Thirdly, it enables us to monitor post-market drug safety and provide critical feedback to manufacturers. (P15)

The data provides a warning effect for clinical drug use, particularly concerning serious adverse reactions, such as granulocyte deficiency with infection during anti-tumor chemotherapy. Additionally, quarterly notifications about adverse reactions can influence clinical decision-making regarding drug selection. (P12)

Statistical analysis of adverse reactions is essential. If a particular reaction is notably severe or widespread, it may necessitate the suspension or withdrawal of the drug from circulation. This proactive approach allows us to advise patients in advance about potential adverse reactions and encourages them to seek timely medical attention if necessary. (P7

Tool functionality

Inaccurate capture of information

Interviewees reported challenges with the accuracy of the information automatically captured by the system. Specifically, they noted inaccuracies in detail, such as generic names, manufacturer specifications and the production lot number of medicines.

The system automatically captures certain information, such as dosage and administration method when a doctor prescribes medication. However, it often fails to translate this information into the specific format required by the system, such as converting milligrams into Chinese characters or accurately documenting intravenous injections. This necessitates manual corrections at a later stage. (P13)

Sometimes, I think this information is inaccurate. (P8)

After recording the drug information, we often need to manually correct issues, particularly when the system fails to capture the correct batch number. This inaccuracy is partly due to the limitations of our internal system. (P9

System integration challenges

The participants noted a significant issue with the current system: its lack of integration with the medical records systems of healthcare organisations. This disconnect makes it challenging to accurately describe and trace the processes involved in adverse reactions.

When an adverse reaction is reported, the system often records both drugs involved without distinguishing between them. For example, if a patient receives a particular medication and experiences a reaction, the entire set of orders is automatically pulled into the adverse reaction report. This lack of integration with the medical record system sometimes fails to accurately reflect the true sequence of events. (P10)

It's difficult to pinpoint the exact cause of an adverse reaction. Even when you open the case file and input the hospitalization number, the system doesn't effectively reflect the patient's condition on that specific day or the course of the disease. This disconnect makes it challenging to get a clear understanding of the situation. (P1)

High level of information security

The participants acknowledged that the current system incorporates extensive data security measures and possesses robust security features.

Well, in terms of confidentiality of our data, I believe the system is secure, as access is restricted to only those authorized to view the information. It's not accessible to everyone, ensuring a higher level of privacy. (P12)

My understanding is that data is uploaded directly through the intranet gateway with a single click, eliminating the need to export and upload it via an external network. This process significantly enhances security. (P13)

Data not shared

During the interviews, the participants expressed a strong desire for government authorities to facilitate open access to data and enhance the data-sharing capabilities of the current system.

Although we report potential adverse reactions, we often don't receive feedback on the outcomes. The data related to these adverse reactions is not consistently shared with us at the clinical level, nor is it disseminated from other hospitals or departments. (P18)

Like these data that we have is not easily accessible at the provincial level or beyond, particularly in our psychiatric specialty. Information sharing is not fully realized, making the data less readily available. (P16)

This limitation makes it difficult for healthcare professionals to go beyond basic reporting tasks. They often cannot access the data needed for further analysis or scientific research, which can be frustrating and hinder their ability to engage in more advanced work. (P11)

Inefficiencies in reporting

Participants criticised the first-generation system for its cumbersome and time-consuming reporting process. They emphasised that these inefficiencies significantly hindered the effectiveness and promptness of reporting adverse reactions, affecting overall response times and management.

Sometimes when you submit a medical order, it takes half a day for it to go through. You might have to wait 10 minutes after restarting the system for it to process. (P6)

The old system was plagued by delays and excessive complexity. It required too much fragmented information, which discouraged clinicians from reporting

adverse reactions. This inefficiency was a significant barrier to effective reporting. (P16)

People are complaining that this system (NADRMS) is very bad, noting that it's slow and cumbersome. Even when we report offsite, the process takes a considerable amount of time, making it far less convenient compared to other hospitals. (P2

Fit

The 'Fit' indicator evaluates the degree of alignment or adaptation between IT systems and the tasks they are designed to support. During the interviews, respondents expressed concerns about the current system's level of fit, indicating that it does not adequately meet the task requirements or support their workflow effectively.

The system's connection is poor, and its compatibility with our workflow is lacking. The match between the system and our needs hasn't been well executed. (P1)

Indeed, this system now, ah, is not functioning effectively. (P15)

Uh, this, if I had to judge, there's significant room for improvement. I hope to see enhancements in the future. P9)

Usefulness

Participants acknowledged the positive impact of the system on reporting adverse reactions. They noted that compared with traditional paper-based methods, the electronic system enhances efficiency and simplifies the reporting process, effectively reducing the complexity and workload associated with documenting adverse reactions.

Actually, this system is indeed valuable. For instance, even if I haven't personally observed the patient, I can still monitor their condition through the system. When reviewing the case, it helps identify potential adverse reactions more effectively. (P12)

This system (CHPS) does provide a lot of convenience to clinical care. (P16)

There are definite advantages to this system. By simply selecting the patient's name and department, their basic information is automatically populated. Additionally, the system retrieves medical orders, so you don't need to manually enter each one. You can search for specific orders, and a list of relevant medications will appear. (P3)

Ease to use

The participants reported that the system was relatively easy and convenient to learn and use. However, they also highlighted the need for regular training to ensure that clinical front-line staff are well acquainted with the system's operating procedures and understand the precautions necessary to report adverse reactions effectively.

The system provides templates that you can easily select and customize by inputting relevant details. This approach significantly simplifies the process, eliminating the need to manually enter information one by one. (P5)

The system is quite user-friendly. For instance, I spoke with the head nurse, and they mentioned that filling out forms is straightforward because the system provides templates. You simply choose the one that closely matches your needs and make minor adjustments. Overall, the operation is relatively simple. (P8)

You just tap to select the relevant option and modify the necessary details, such as start and stop times. This way, you avoid the tedious task of entering each detail individually. (P7)

Both CHPS and EPV allow you to complete tasks with just one click, which eliminates many unnecessary steps and streamlines the process. (P13)

Attitude

Reluctant under mandate

Many participants expressed a lack of willingness to use the system, highlighting the pressure they feel due to the mandatory policy requiring its use.

We're required to use the system because it's the only one available, and we've received training for it. While I've learned that EPV is a good system, we have no choice but to use it. (P14)

There are strict mandates, such as meeting an annual reporting threshold, which leaves little room for flexibility. (P3)

It's all part of the directive I've given them—it's a task that must be completed, and reporting is mandatory. (P4)

The system doesn't quite meet my expectations, but we have no alternative. The issue is that this lack of enthusiasm sometimes leads to missing valuable cases because it's not something I'm motivated to do voluntarily. P8)

Expectations

Participants outlined key areas for improvement in the system, focusing on three main aspects: (1) opening and sharing data, (2) enhancing system convenience and (3) improving system intelligence. Specifically, they strongly desire open data access to enable effective drug alert functions.

I'm wondering if in the future there's will be a way for pharmacists or administrators to access and open certain data ports. This raises the issue of data openness and accessibility. (P11)

I think the system could be more user-friendly if it were simplified and included better early warning features. For example, if there were alerts for drugs that are known to cause severe allergic reactions, a

pop-up warning would be helpful to increase awareness. (P12)

Well, I think at least for now the system should efficiently capture and analyze basic information. Ideally, it would also include an early warning feature to alert us to potential issues in advance. (P6)

The participants noted that the current system is still inconvenient and strongly desired enhancements that would improve its ease of use.

If the reporting process were more convenient, it would definitely encourage more people to submit reports. Convenience is the key factor here, in my opinion. (P5)

They probably just want the process to be faster and more streamlined, allowing for quicker reporting and easier tracking. This includes optimizing the process for filling out adverse reactions, which I believe could be improved. (P11)

In an era of advanced information technology, participants expressed a strong expectation for enhancing the system's intelligence to better meet their needs.

Well ah on a larger level, I think that that national system would be significantly improved if it could automatically recognize and process our PDFs, electronic files, or scans, allowing us to upload them directly. (P17)

It would be beneficial if the system could incorporate a feature that allows us to directly import scanned documents, Word files, or PDFs, automatically recognize the content, and submit it with a single click, eliminating the need to enter data manually. P18)

DISCUSSION

To the best of our knowledge, this qualitative study is the first in China to explore front-line users' willingness to engage with the ADR reporting system through the lens of the TAM–TTF integration model. Our findings indicate that while front-line users generally find the ADR reporting system satisfactory in terms of usability and utility, there is a significant gap in technological adaptability. Users often feel obligated to use the system due to work requirements and express a strong desire for future improvements.

The fundamental principles of adverse reaction reporting, including timeliness, accuracy, standardisation and safety, are widely recognised as essential.[1 19] Our study further emphasises these principles, revealing that the current technical requirements of the adverse reaction reporting system for front-line medical staff align with these key aspects. These requirements include accurately describing patient symptoms and medication use for subsequent assessment and management, integrating relevant information from medical record systems to ensure a comprehensive assessment of adverse reactions, prioritising patient privacy protection and facilitating data sharing. This alignment indicates the effectiveness of the system. However, our survey also highlights significant technical challenges in China's ADR reporting system, such as inaccurate information capture and inadequate interfacing with medical institution technology systems.[5 20]

Although the system technically allows for data sharing, various management policies and other factors hinder its effective implementation.[14] This discrepancy presents a substantial gap compared with systems in the USA and other developed countries. For example, the US FDA's FAERS is an open database containing many adverse event reports,[21] offering valuable information on drug safety for healthcare professionals, researchers and the public.[22] Our analysis indicates that front-line medical professionals in China rate the technical suitability of the ADR reporting system as very low. This sentiment aligns with findings from an Australian study, which identified inadequate IT systems as a critical factor affecting ADR reporting, time constraints, lack of financial incentives, and organisational support.[23]

Despite these challenges, our study shows that the current system has improved the efficiency of adverse reaction reporting compared with traditional paper-based methods.[2] Additionally, users of the second-generation system reported better efficiency than those using the first-generation system. In terms of perceived usefulness, the current system is generally satisfactory to users, consistent with findings from a survey of pharmacists in China. For example, pharmacists who use the CHPS system can complete reporting tasks more quickly and improve the quality and quantity of ADR monitoring reports.[24] Furthermore, the perceived ease of use of the current system is also positively rated.[25] Generally, medical staff, particularly those with higher education and better learning capabilities, find the system easy to operate. Some studies have also suggested that enhancing the functionality of the ADR reporting system, simplifying information categorisation and ensuring system stability through regular maintenance could further improve ease of use.[25]

Overall, the primary factor affecting medical staff's motivation to report ADRs is the degree of technological adaptation rather than the system's perceived usefulness and ease of use.

Regrettably, the study participants' responses indicated a prevailing sentiment of 'having to use' the ADR reporting system, which necessitates further investigation.[26 27] This sentiment is primarily influenced by two key factors: the task-oriented reporting frequency enforced by healthcare organisations and the system's inadequacies, both of which contribute to a negative attitude towards reporting.[28] Consequently, the quality of reported ADRs may be compromised, posing challenges in identifying clinically valuable ADR events and hindering the effective implementation of pharmacovigilance.[29]

Given these challenges with the ADR reporting system in China, participants highlighted three key expectations: opening and sharing data, improving system convenience and enhancing system intelligence.[29] These expectations align with the broader objectives of pharmacovigilance, which play a crucial role in safeguarding patient safety and ensuring rational use of drugs. By monitoring and assessing potential adverse reactions and other safety issues, pharmacovigilance helps identify potential drug safety risks promptly, assess the severity of adverse reactions and possible risk factors, promote rational drug use, enhance patient safety awareness and support regulatory and decision-making processes.[30] In this way, pharmacovigilance contributes significantly to public health and safety.

Data sharing, timely feedback and improved system convenience are practical needs from the patient's perspective. Previous studies on home-based patient perspectives suggest that adverse reactions often lead to interruptions in medication use, usually without consultation with healthcare professionals. Patients frequently lack the theoretical knowledge and operational skills necessary for reporting ADR and, therefore, expect a more user-friendly system that facilitates ADR reporting and feedback, not only for themselves but also to help their friends and family members.[31]

The strengths of this study are reflected in several key aspects: (1) the adoption of a qualitative research methodology allowed for an in-depth exploration of the usage experiences and genuine thoughts of front-line users; (2) the study was grounded in the TAM–TTF integration model, enhancing the robustness of the findings and (3) the inclusion of sample hospitals that use various reporting systems currently used throughout China increases the representativeness of the study's results.

However, the study also has some limitations. First, it did not consider factors beyond the TAM–TTF integration model, such as macro-level policies and the sociocultural context, which could influence the findings. Second, due to the constraints of the qualitative research methodology, the study did not involve a large-scale empirical investigation, which remains an area for future research.

Conclusion

Front-line users in China acknowledge the ADR reporting system's ease of use and usefulness but generally need to improve its technical adaptation. While they are forced to use the system to fulfil work requirements, they express a clear expectation for further improvements, particularly to enhance data openness and sharing, improve system accessibility and improve the system's level of intelligence.

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