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# Exploring the influencing factors of adverse drug reaction reporting among medical personnel: a COM-B model-based study

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**ABSTRACT**

**Background:** This study aims to identify the factors that influence medical workers' enthusiasm for reporting adverse drug reactions (ADRs). Understanding these factors is essential to implement targeted interventions that can improve and refine pharmacovigilance systems.

**Methods:** We adopted the Capability, Opportunity, Motivation, and Behavior model (COM-B) model as the theoretical framework and conducted qualitative research using in-depth interviews with clinicians, nurses, pharmacists, and administrators. 24 one-on-one interviews were conducted and audio-recorded. The interviews were transcribed verbatim, and subjected to thematic analysis to uncover the key factors affecting ADR reporting among medical staff.

**Results:** The participation included 24 healthcare workers from six different healthcare organisations. Analysis revealed that decreased motivation to report ADRs was due to inadequate judgment or inconsistent judgment criteria within the capability domain, poor awareness of ADRs and deficient communication skills within the psychological domain, unclear responsibilities within the motivation domain, and limited or no access to necessary resources within the opportunity domain. Facilitators of ADR reporting included sufficient cognitive and operational abilities, spontaneous and incentivized motivation, clear responsibilities and role expectations, and robust social support.

**Conclusion:** There is a critical need to develop comprehensive interventions that address the identified factors influencing ADR reporting. By improving the motivation of medical staff to report ADRs, the pharmacovigilance system can be significantly improved.

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## Background

The adverse drug reaction (ADR) reporting system is crucial for updating drug specifications and improving drug safety. It provides warnings about potential drug risks, informs medical workers and patients about specific contraindications and precautions, helps avoid unnecessary harm from drug use, and ensures patient safety (Zhao et al., 2021). This system supports the safety evaluation of new drug research and development, contributing to the creation of safer and more effective medications (H. Li, Deng, et al., 2022). Therefore, reporting ADRs is a vital component of drug safety management and a key measure in protecting public health rights and advancing pharmaceutical science and technology. China has established a comprehensive national ADR monitoring network, which includes national, provincial, and local organisations. This network is designed to facilitate early warning and the development of intervention measures (Li & Yin, 2019). The State Department of Drug Administration and Supervision plays a significant role by issuing annual ADR monitoring reports, disseminating drug safety information, and promoting the enforcement of pharmacovigilance regulations, improving the safety of drug use (Li et al., 2023). Despite these efforts, compared to World Health Organization (WHO) standards and practices in developed countries, China still has significant potential to improve both the ADR reporting rate and the quality of these reports. The impact of pharmacovigilance in China still needs to be consistent with the country's large population size (Zheng et al., 2018).

According to 2023 surveillance data from the State Drug Administration, 90.1% of ADRs were reported by healthcare organisations, with physicians accounting for 56.8%, pharmacists for 25.7%, and nurses for 12.5% of reports. These data indicate that healthcare workers within these organisations are the leading reporters of ADRs. Various expert analyses have highlighted that the factors influencing ADR reporting by medical workers are complex (Chen et al., 2021; Hou et al., 2016; Hu et al., 2022; Song et al., 2023; Tang et al., 2014; Wang et al., 2022). These factors include a lack of deep knowledge about ADRs and the need to report, inadequate institutional and policy environments, flaws in laws and regulations that incentivize reporting, cumbersome reporting processes, inconvenient reporting systems, and the heavy daily workloads and time pressures medical workers face. These issues can lead to the neglect or delay of reporting ADRs in practice. Despite these experts' insights, there is a gap in systematic research exploring the influence of these factors on the willingness to report ADRs from the perspective of front-line medical staff. The specific factors

influencing ADR reporting and their mechanisms of action remain unclear. Therefore, there is a pressing need to conduct field research with front-line medical personnel to understand and address these issues.

The COM-B model is a behavioural science framework developed by psychologists at the University of London, UK. It serves as a psychological framework to understand and explain the occurrence and change of human behaviour, guiding the design of effective behavioural intervention strategies (Michie et al., 2011). The model posits that behaviour is influenced by the interaction of Capability, Opportunity, and Motivation (Keyworth et al., 2020). By examining these dimensions, the COM-B model helps pinpoint specific obstacles to behavioural change and tailor intervention strategies accordingly. In medical research, the COM-B model is utilised to investigate and influence various health behaviours, including patient self-management, clinical decision-making by healthcare professionals, and other health-related behaviours (Clark et al., 2022; Moullin et al., 2023; Xie et al., 2023). Similarly, the Task-Technology Fit (TTF) framework has been used to examine the barriers and facilitators of adverse drug reaction (ADR) reporting among community pharmacists [17]. Although the TTF framework emphasises factors related to the ADR reporting system, the COM-B model focuses on the behavioural and psychological dimensions of healthcare professionals. Both frameworks provide structured approaches to understanding the complex influences on behaviour, offering valuable theoretical support to policymakers seeking to promote health behaviour change and improve the quality of healthcare services. A recent study investigated the barriers and facilitators faced by healthcare professionals in Dutch hospitals when registering ADRs in electronic health records [18]. Through interviews with 16 healthcare professionals, the study identified barriers such as limited ADR knowledge, time constraints, and inadequate IT systems, while facilitators included improved knowledge, functional IT systems, and improved accountability. Based on the COM-B model, the study showed that addressing individual, social, and environmental factors could improve ADR registration and, consequently, patient safety. This study provides a useful reference for the present research. However, given the differences in social and cultural contexts, it is essential to explore factors influencing ADR reporting in China using the COM-B model. Information obtained from interviews with clinicians, nurses, pharmacists, and healthcare administrators can be instrumental in developing targeted interventions.

## Methods

### *Participants*

Purposive sampling, supplemented by representative sampling, was used to select study participants (Johnson et al., 2020; Palinkas et al., 2015). A total of

six medical institutions were selected for the study, including three that use the traditional reporting system, two that use the China Hospital Pharmacovigilance System (CHPS), and one that uses the electronic pharmacovigilance (EPV) system. CHPS is predominantly implemented in Chinese hospitals, focusing on clinical drug safety monitoring and integrating with internal hospital systems to facilitate ADR reporting and analysis by healthcare professionals. In contrast, EPV is a globally used electronic pharmacovigilance system with a higher degree of automation, which supports cross-border data sharing and is frequently used by pharmaceutical companies, healthcare institutions, and international regulatory agencies for ADR reporting and analysis. Although CHPS is widely adopted in China, EPV is less commonly employed [21]. Based on preliminary insights from the research team, managers in each healthcare organisation have a comprehensive understanding of ADR reporting, whereas clinicians, pharmacists, and nurses, as frontline practitioners, have different roles in clinical drug treatment decisions and patient management. These varying roles contribute to different perspectives on the ADR reporting process. Therefore, we selected a manager responsible for ADR reporting, a clinician, a pharmacist, and a nurse from each healthcare organisation, all of whom have experience with ADR reporting. This selection aims to capture a comprehensive understanding of the research topic from multiple perspectives. The inclusion criteria for the participants were the following: (1) participation in ADR reporting; (2) proficiency in language expression and communication skills; (3) willingness to participate in the interview, allow the session to be recorded, and sign the informed consent form. Exclusion criteria included (1) reservations about the research process and unwillingness to sign the informed consent form; (2) inability to adequately communicate on the topics discussed due to other factors.

## *Study design and methodology*

The research was conducted from October 2023 to February 2024. Using the COM-B model as the theoretical framework, this study employed the phenomenological method in qualitative research to conduct semi-structured, one-on-one interviews with participants. The interview guide was developed based on the COM-B model to align with the research objectives and themes. The development process involved group discussions, expert consultations, and pre-interviews. During group discussions, the research team collaboratively identified key factors related to the research topic, ensuring that all relevant aspects were addressed. Simultaneously, the team consulted experts in the field to gather feedback on the interview content, thereby enhancing its rigour and professionalism. In the pre-interview phase, preliminary interviews were conducted with at least one manager responsible for ADR reporting, one clinician, one pharmacist, and one nurse to assess the feasibility and

effectiveness of the interview guide. Adjustments were made based on feedback received. The final interview guide comprehensively reflects the various barriers and facilitators in ADR reporting, providing a solid foundation for subsequent research. The structured interview guide is shown in Box 1.

**Box 1. Semi-structured interview questions.**

1. **Cognition**
   'How familiar are you with adverse drug reaction reporting?'

2. **Motivation for Reporting**

   'Generally, under what circumstances do you report adverse drug reactions?'
   'What types of adverse drug reactions have you reported?'

3. **Opportunity Factors**
   (i) 'What factors may affect your willingness to report? Do you have any concerns about the reporting process?'
   (ii) 'Have you ever resisted reporting an adverse drug reaction that you deemed significant? If so, why?'
   (iii) 'Are there any incentives, punitive measures or task-related policies at your hospital? How do they impact your reporting behavior?'

## *Data collection*

The interviews were conducted quietly and independently audio-recorded using smartphones or other recording devices. Each interview lasted approximately 30–70 min. Before starting the interviews, the researcher provided an overview of the study objectives and collected basic demographic information from the participants, including sex, educational background, years of experience in adverse reaction reporting, and job title. The interview process was led by a team member trained in qualitative research methods. Although a preliminary interview outline was prepared, the participants' responses guided the flow and sequence of the discussion. The interviewers monitored the participants' understanding in real time to accurately capture their perspectives and perceptions. At the end of the interviews, personal identifiers were removed, and a research assistant transcribed the responses into text. During the implementation of the study, data saturation is considered achieved when researchers no longer encounter new themes or information during data collection.

## *Data analysis*

Thematic analysis was applied for the data analysis process. Four research team members independently reviewed the initial interview data, including two with extensive experience in qualitative methods. Through this review, the research team designed an initial coding framework based on comparison and consensus (Coghill et al., 2022). The process began with a

comprehensive analysis of the relevant literature to identify potential themes and concepts. Subsequently, two independent team members coded each interview transcript using the established framework to ensure objectivity and reliability. As new codes emerged or existing ones required clarification, the codebook and framework were collaboratively reviewed and refined. The codes were iteratively organised into themes until theme saturation was achieved, signifying that the framework could accommodate new data without further modifications. Once the codebook was finalised, two team members independently coded all transcripts. To ensure consistency, the team held regular meetings to discuss progress and resolve any discrepancies until a consensus was reached. This rigorous approach enhanced the transparency and reliability of the research while ensuring the completeness and accuracy of the analytical results.

### *Quality control*

To ensure the credibility of the study, several measures were implemented: (1) all researchers received systematic training in qualitative research methodologies, equipping them with the necessary skills for conducting interviews and analyzing data; (2) the textual transcriptions of the interviews were returned to the participants for verification to confirm the authenticity and completeness of the content; and (3) two members of the research team independently refined the themes and sub-themes using the same data set. These themes were discussed and further synthesised during team meetings to ensure a complete analysis and interpretation.

## Results

### *Demographics of participants*

A total of 24 medical staff from six medical institutions were selected to participate in this study, identified as P1 to P24. The basic information of the respondents is presented in Table 1.

### *Frame of factors influencing ADR reporting based on COM-B model*

Applying the COM-B model facilitated a comprehensive analysis and synthesis of the data, revealing key factors influencing medical staff's reporting of ADRs. These factors are organised into three main themes: capability, motivation, and opportunity. Capability factors include physical and mental aspects. Physical capabilities include operational ability and communication skills, essential for effectively using ADR reporting tools and discussing ADR incidents. Mental capabilities cover judgment and cognitive ability, which

**Table 1.** Basic information of respondents.

| Item | Mean [min, max] or n (%) |
|---|---|
| **Age** | 39.38 [24, 56] |
| **Year of Experience** | 15.2 [3, 32] |
| **Sex** | |
| Female | 17 (70.8%) |
| Male | 7 (29.2%) |
| **Job Title** | |
| Senior nurse in-charge | 4 (16.7%) |
| Associate chief senior nurse | 2 (8.3%) |
| Physician in-charge | 2 (8.3%) |
| Attending physician | 2 (8.3%) |
| Chief physician | 2 (8.3%) |
| Pharmacist in-charge | 5 (20.8%) |
| Associate chief pharmacist | 6 (25.0%) |
| Chief pharmacist | 1 (4.2%) |
| **Occupation** | |
| Nurse | 6 (25.0%) |
| Pharmacist | 12 (50.0%) |
| Physician | 6 (25.0%) |
| **Number of reported ADR cases in 2023** | 50.54 [2, 400] |

are crucial to accurately identifying and evaluating ADRs. Motivation factors are categorised into spontaneous motivation, which arises naturally from an individual's values and experiences, and reflective motivation, which includes motivations related to responsibility and tasks. Personal and professional ethics and the perceived importance of the task influence these motivations. Opportunity factors are divided into material opportunities, such as access to necessary resources and material rewards, and social opportunities, such as support from peers and the broader healthcare community. These factors provide the external conditions that facilitate or hinder ADR reporting. The interaction between capability, opportunity, and motivation factors is complex; capability and opportunity can influence motivation for reporting or may directly impact reporting behaviour. The relationships and interactions among these factors are visually represented in Figure 1, providing a schematic overview of the framework of influencing factors.

## *Capacity factors*

### *Judgment*

Judgment ability significantly impacts the reporting of ADRs. Insufficient judgment ability can significantly diminish enthusiasm for reporting ADRs, manifesting in two primary ways. Causality judgment: Medical staff often struggle to assess the causality between a drug and an adverse reaction. This includes difficulties in distinguishing between what constitutes an adverse drug reaction and what might be an unrelated adverse event. This uncertainty can lead to underreporting, as staff may need to be more qualified to make accurate assessments. Consistency in reporting standards: There often needs to be

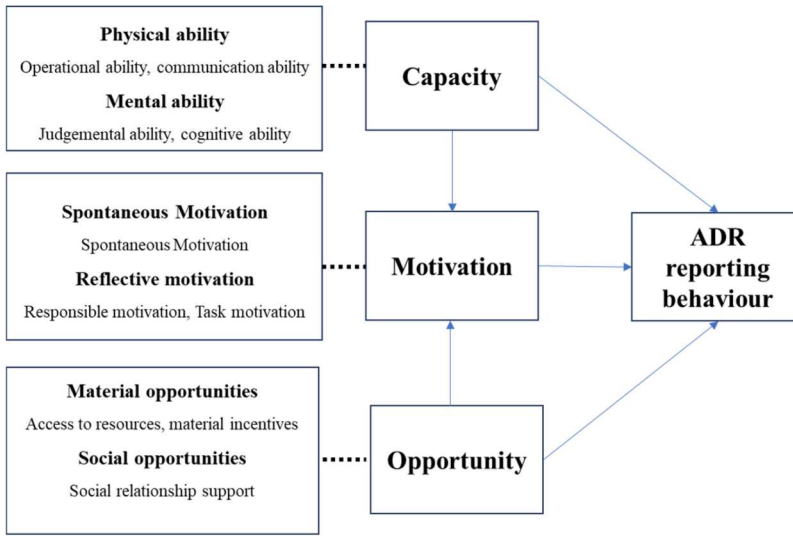


**Figure 1.** Framework of factors influencing adverse drug reaction reporting based on COM-B modelling.

more uniformity among medical staff regarding which types of ADRs should be reported. Some may believe that widespread adverse reactions, assumed to be well documented and understood, are not worth reporting. This inconsistency further impedes comprehensive ADR reporting.

Judgmental ability is closely related to healthcare workers' professionalism, training, and practical experience. It requires a deep understanding of pharmacology and patient care, where continuous professional development is essential. This study also highlights the beneficial role of pharmacists within healthcare teams. By integrating pharmacists trained explicitly in drug safety and interactions, healthcare facilities can improve the general capacity of their staff to recognise, assess, and report ADRs. Pharmacists significantly contribute to the identification, traceability, and reporting processes, improving the quality and accuracy of ADR reports. This collaboration strengthens the reporting system and ensures better patient safety outcomes.

> P10 (nurse) "When we are in clinical care, patients often are on multiple medications at the same time, and sometimes it is very difficult to determine which medication is causing or if it is a drug-induced reaction, and it is very difficult to determine causation, so it is often not reported as an ADR."

> P12 (pharmacist) "We really see very few ADRs in clinical care, and sometimes when they do occur, they may not prioritize drug factors, so ADRs are relatively under-reported."

> P8 (pharmacist) "Delayed adverse reactions caused by some medications are very hard to determine because they may not occur until some time after the

medication has been stopped, making it difficult to take the medication into account."

P9 (pharmacist) "Some adverse drug reactions are positively correlated with efficacy, and many antitumor drugs may have some correlation between their adverse reactions and clinical efficacy, and at such times these adverse reactions are not reported as a special event."

P11 (pharmacist) "We have a clinical pharmacist in our group who sometimes assists us in determining, recognizing and dealing with some of the adverse drug reactions, which I think greatly contributes to our ability to recognize them and can contribute to our active reporting of ADRs."

### *Cognitive capacity*

The influence of cognitive ability on ADR reporting is significant. It manifests in two contrasting ways. Enhanced reporting willingness: Medical workers with a solid understanding of ADRs recognise the importance and value of reporting. They understand that accurate and timely reporting can facilitate better treatment outcomes, prevent future incidents, and reduce medical disputes. This comprehensive knowledge fosters a proactive attitude towards ADR reporting, as these professionals view it to improve patient care and safety. Reduced enthusiasm for reporting: In contrast, medical workers who lack sufficient knowledge about ADRs often perceive the reporting process as a burden. They fear reporting may increase their workload and the risk of being involved in medical disputes. This fear stems from a misunderstanding of the implications of ADR reporting and a lack of awareness of the systemic benefits it offers, including enhancing drug safety and healthcare practices. This duality demonstrates the critical role education and training play in improving ADR reporting rates. By enhancing cognitive ability through targeted educational initiatives, healthcare institutions can change perceptions of ADR reporting from a potential liability to a vital aspect of clinical practice that improves overall healthcare quality.

P8 (pharmacist) "We report when we suspect that there is one, especially for some special patients, because ADR is an inherent property of the drug, and a patient with an ADR cannot be a problem with my treatment plan, it is an inherent problem with the drug, and I feel that in an environment of doctor-patient tension? reporting ADRs is a way to protect the medical staff."

P17 (pharmacist) "We pharmacists know that the reporting of ADRs can help identify some potential medication harm events, or late modification of drug inserts, and can greatly promote the rational use of medication, so we clinical pharmacists check and report any suspected ADRs we come across."

P6 (physician) "The patient would have felt that there was nothing wrong with the treatment because I reported an adverse reaction, would the patient have thought that there was something wrong with my treatment plan, and it would have been better not to report it more often than not."

P4 (nurse) "We are usually very busy with our clinical work, and ADR reporting is an extra job on top of our clinical work, which adds a lot of workloads but does not have much practical significance for patient management."

### *Operational capacity*

The ability to effectively operate the ADR reporting system is crucial and impacts ADR reporting in several significant ways. System usability: A user-friendly ADR reporting system that is easy to navigate and requires minimal operational skill can significantly enhance ADR reporting rates. Systems designed with a clear entry description and an intuitive interface facilitate quick and efficient reporting, encouraging medical personnel to engage with the system regularly. System complexity: In contrast, if the ADR reporting system is cumbersome, featuring a complex interface or an unclear process, it can deter medical personnel from its use. A complicated system can be a significant barrier, diminishing staff willingness to report as the process becomes a tedious part of their demanding workload. Staff proficiency: The proficiency of medical personnel in using the ADR reporting system also plays a critical role. Familiarity and skill in navigating the system can promote consistent and accurate reporting. Medical staff adept at using the system will likely report ADRs more frequently and with greater precision. Impact of system familiarity on reporting quality: If medical personnel are well-versed with the system, the quality of their reports may improve. This lack of understanding can lead to errors that require reports to be repeatedly revised and resubmitted, a frustrating process that can significantly reduce their motivation to report.

Overall, improving the operational capabilities of medical personnel and the usability of the ADR reporting system are key strategies to increase the efficiency and accuracy of ADR reporting. These improvements can improve health outcomes by ensuring that ADRs are reported promptly and accurately, facilitating timely interventions.

P20 (physician) "Our hospital is online with the CHPS system and has done an interface with the in-hospital system, it is very easy to operate. The system automatically synchronizes much of the required information, we just need to refine the details, it is very easy to report."

P22 (nurse) "We are just on-line with the new reporting system, people are not familiar with the operation of the system, many times they don't know how to use it, so they report less"

P23 (pharmacist) "Due to the lack of proficiency in the operation of the ADR reporting system, the reporting quality is often called back for re-filling, which can greatly affect the motivation to report."

P2 (pharmacist) "Every time you report an adverse reaction, you need to fill in information such as the batch number, expiration date, or approval number of

the drug, which is troublesome because so much of the original packaging can't be found, and the system can't automatically capture this information."

### *Communication skills*

This study shows that communication issues among medical workers significantly impact the reporting of ADRs. These challenges manifest themselves in several ways. Inconsistency in understanding: There is often a disparity in how doctors, nurses, and pharmacists understand ADRs. Each professional group may have different levels of training and awareness regarding identifying ADRs and the protocols for reporting them. This inconsistency can lead to varied interpretations and expectations among team members, complicating the reporting process. Lack of effective communication: Effective communication is crucial in ADR reporting. The absence of transparent and open communication channels can lead to misunderstandings or conflicts between reporting staff and other team members. These misunderstandings can arise from unclear responsibilities, differences in professional judgment, or the failure to share important information promptly. Impact on motivation: The combination of inconsistent understanding and poor communication not only complicates the reporting process but also significantly affects the motivation of medical personnel to report ADRs. When team members are not aligned and conflicts arise, it can create a discouraged environment that may discourage staff from participating in ADR reporting.

Addressing these communication issues requires training and systematic changes to ensure that all healthcare team members have a uniform understanding of ADRs and associated reporting procedures. Fostering a collaborative environment in which open and effective communication is prioritised can help mitigate misunderstandings and improve the overall motivation and frequency of ADR reporting.

P16 (pharmacist) "We (clinical pharmacists) sometimes find out during clinical visits that a patient may have a suspected adverse drug reaction and report it to the adverse drug reaction system, but the doctor will think that there is a problem with us questioning his medication regimen, and sometimes he thinks that it is the progression of the patient's disease course, and this inconsistency leads to a reluctance to report adverse reactions sometimes. "

P4 (nurse) "Sometimes we (nurses) feel that a patient is experiencing a condition that could be an adverse drug reaction and may report it, but the doctor may feel that the nursing staff is deliberately trying to get the doctor in trouble, which is very detrimental to the unity of our team, so sometimes we don't take the initiative to report it."

P24 (pharmacist) "Since adverse drug reactions are required to be recorded in the patient's case, which is good for traceability, our staff responsible for reporting adverse drug reactions sometimes force clinical reporters to improve the relevant records, and doctors believe that these tasks increase their workload

and the risk of patient medical disputes, and sometimes they choose to withdraw their reports."

P9 (pharmacist) "We previously suspected that the patient had an adverse drug reaction and were going to report it, but the patient's responsible caregiver thought that we doctors were not suspecting that there was an error in the nurse's dispensing or administration of the medication, which led to a conflict between the health care provider and the patient, so it was not reported later."

## *Motivational factors*

### *Spontaneous motivation*

Spontaneous motivation plays a crucial role in encouraging medical workers to report ADRs. Several perceptions and beliefs about the value and impact of ADR reporting fuel this intrinsic motivation. Professional responsibility: Many medical workers view ADR reporting as integral to their professional duties. They believe that monitoring and reporting ADRs are essential for patient care, timely adjustment of treatment plans, and crucial to ensuring drug safety. Contribution to patient safety: there is a strong belief among medical workers that reporting ADR directly contributes to patient safety. By documenting and reporting adverse reactions, they can help prevent similar incidents in the future, thereby safeguarding other patients from potential harm. Advancement of medical research: medical workers often recognise that the data collected from ADR reports provide valuable, first-hand information crucial for scientific research on drug safety. These data can lead to safer pharmaceutical practices and products and help medical researchers identify and explore new and meaningful research topics.

These spontaneous motives collectively foster a proactive approach to ADR reporting. When medical workers internalise these motivations, they are more likely to report diligently and accurately, driven by the knowledge that their efforts have a meaningful impact on patient care and the broader medical community.

P17 (pharmacist) "I am a clinical pharmacist in the Department of Oncology, the treatment process of oncology patients will occur more or less in adverse drug reactions, some even very serious adverse reactions. I through the report and collation of adverse reactions, I was able to provide the doctor with drug dosage adjustments or changes in the drug treatment plan recommendations, which greatly reflects the clinical value of our pharmacists."

P10 (nurse) "By reporting adverse reactions, it will give me an idea of the medicines in my medication regimen that have a high incidence of adverse reactions, and at a later stage I may not choose these medicines when I develop a medication regimen for my patients."

P11 (pharmacist) "Many details of the use of drugs after the market are actually not encountered during clinical trials, we may find some scientific research

ideas through the reporting and summarizing of drug unspiritual reactions, and form research topics to further explore the rational use of medication solutions for special populations."

### *Responsible motivation*

The impact of accountability motivation on the reporting of ADRs is twofold. On the one hand, clearly defined responsibilities for reporting ADRs can significantly enhance the motivation of medical personnel to engage in reporting activities. On the other hand, inappropriate accountability, such as punitive measures following the reporting of ADRs, can significantly diminish their motivation. This dichotomy highlights the need for well-balanced accountability mechanisms that encourage reporting without discouraging medical personnel through negative consequences.

P14 (pharmacist) " Once, after we reported a death case, multiple departments such as the drug manufacturer, hospital, and drug regulatory authorities repeatedly called the teacher who submitted the report, asking about the basis for the judgment and whether the death was ultimately related to the drug. This made us feel as if the adverse drug reaction we reported was being blamed for the patient's death, making the reporting teacher very uncomfortable. As a result, we became reluctant to submit similar reports afterward."

P20 (physician) "We have a safety officer in every department, his main responsibility is to carry out patient safety monitoring, and adverse drug reaction reporting is one of his most important responsibilities, so the general reporting motivation in the clinical departments is okay."

### *Task-based motivation*

The inclusion of ADR reporting in clinical department business assessment or as an essential component of individual performance evaluations can significantly promote the reporting of ADRs. However, when ADR reporting is driven primarily by task motivation, it often results in the reporting of mild, general ADRs that are already well-defined in drug instruction manuals. Consequently, there is a noticeable delay in reporting, accompanied by numerous instances of additional reporting completed merely to fulfil task requirements. Furthermore, due to the task-oriented assessment, there is minimal motivation to report new, serious ADRs. Identifying, following up, and continuously monitoring these serious ADRs require considerable time and resources, which are not adequately incentivized under current task-based evaluation systems.

P24 (pharmacist) "We do take the reporting of adverse drug reactions as an important part of the assessment for the clinical pharmacist's final assessment, without reporting enough of a certain number, he can't do the final assessment, so most of the adverse drug reactions in our hospitals are reported by clinical pharmacists."

P18 (physician) "We do report the number of ADRs as a mandatory task for the department's business assessment, and we must report a certain number each month, so sometimes we drive to the end of the month with a large number of ADRs to make up for it."

P6 (physician) "Since ADR reporting is a mandatory task for us and the matter takes a lot of time, we choose to report ADRs that are clearer in the drug inserts and easy to determine causality, and report fewer complex ones."

## *Opportunity factors*

### *Social relations support*

Social relationship support implies that the work involved in reporting ADRs is publicised and recognised by various stakeholders, including patients, other medical workers, the government administration, drug regulatory authorities, and social media. This type of support enables medical workers involved in reporting ADRs to appreciate the professional value of their efforts. Consequently, it promotes their motivation to report by affirming the importance of their contributions to patient safety and public health.

P21 (physician) "Our hospital's adverse drug reaction reporting work is particularly worthy of my pride, we previously reported risperidone-related adverse reactions were later adopted by the State Drug Administration for subsequent modification of the drug specification, received great affirmation and recognition of peers, but also prompted us to do a good job of this work, is a great motivation!"

P18 (physician) "As our hospital has been doing a good job in adverse drug reporting, then XX Hospital, which performs post-marketing surveillance of drugs, took our unit as a core participant to jointly carry out the relevant research, and we feel it is very meaningful and valuable for us to do this work."

P11 (pharmacist) "We had a previous case of a patient who might have suffered liver failure due to drug use, which we judged to be drug-induced, and it served as a good warning for the patient's follow up and community outreach and was reported by many media outlets."

### *Resource acquisition*

Access to resources significantly influences motivation to report ADRs. When medical workers cannot be informed of similar ADR occurrences across the province or country, share existing resources, or conduct ADR signal mining research based on available data, their ability to see the potential value of reporting is compromised. This lack of access to essential resources prevents medical practitioners from appreciating the broader implications of their reports and restricts their enthusiasm for reporting ADRs.

P23 (pharmacist) "We report so many adverse reactions each year, but we can't get a sense of the overall occurrences across the province or the country, the

current system doesn't support resource sharing, we can't see what other hospitals are reporting, and we don't feel like it's useful to report it."

P17 (pharmacist) "At present, we can't access resource data to carry out relevant statistical analysis or signal mining, and we feel that these data can't be well applied after reporting, unlike foreign databases that can support many signal mining studies."

### *Material incentives*

Such incentives may include material rewards for the ADR reporting process, recognition of ADR reporting as a bonus item for the promotion of medical personnel's titles, or a leadership focus on the importance of ADR reporting. These incentives can effectively increase the motivation to report ADRs. However, suppose the incentive mechanism is not clearly defined, such as distributing rewards to the clinical department rather than directly to the reporting individual. In that case, it may not reflect the value of the reporter's work. Additionally, if the reward amount is too low to be impactful or promised material incentives are not honoured, these factors can significantly diminish medical staff's enthusiasm to report. In such cases, poorly implemented incentives can become a constraining factor rather than a motivator.

P18 (physician) "Our hospital is to report adverse drug reactions has a certain performance subsidy, the money is not particularly large but affirms the value of my labor, really can promote us to report adverse reactions."

P20 (physician) "Our hospital is taking reporting of adverse drug reactions as an important indicator for departmental performance evaluation, so our motivation to report is quite high."

P21 (physician) "Our leaders pay special attention to reporting of adverse drug reactions, and when the work is done well, the leaders will give encouragement, and the value of the work can be recognized and encouraged by the leaders, which can really promote us to report positively on the mountain."

P6 (physician) "Our hospital says there are incentives for reporting adverse reactions, but they are never really honored (high emotion), so we were quite motivated at first, and then the motivation was very compromised."

P15 (nurse) "We say that there is an incentive for reporting adverse reactions, but this seems to be uniformly given to the department, and there is no special incentive for us reporters, which does not have much impact on the motivation to report, and sometimes it can be a negative impact because it is quite time consuming to report this."

## Discussion

This study applied the COM-B model to examine the factors influencing medical workers' motivation to report ADRs. Our findings revealed several

constraining factors: limited judgmental ability or inconsistent judgmental criteria within the capability domain, inadequate knowledge of ADRs and poor communication skills within cognitive capabilities, inappropriate retrospective responsibility within the motivational domain, and a lack of sufficient opportunities to access necessary resources within the opportunity domain. In contrast, the factors that facilitated ADR reporting included robust cognitive and operational capabilities, spontaneous, responsible, and task-oriented motivation, and strong social support and material incentives. Integrating clinical pharmacists into healthcare teams significantly improved the recognition and judgment of ADRs among professionals, enhancing ADR reporting. Although responsible motivation increased the number of ADR reports, it adversely affected the quality of those reports. Furthermore, a user-friendly operating system significantly improved medical workers' operational abilities and motivated ADR reporting, whereas a cumbersome system hindered their ability to report effectively.

This study represents the first qualitative exploration in mainland China to specifically target front-line medical workers to investigate the factors influencing ADR reporting through face-to-face field research (Zhao et al., 2018). Previous analyses, primarily based on expert experience, identified multiple challenges impacting ADR reporting in China (Wang et al., 2022; Xue et al., 2023). These include medical staff's limited knowledge of ADRs, cumbersome reporting procedures, insufficient or inconvenient information systems, and the heavy workload facing healthcare professionals, which may divert their attention from documenting potential ADR events (Senhao et al., 2023). Additionally, the lack of an effective ADR reporting system within hospitals or health administrative departments, insufficient training, unclear legal responsibilities concerning ADR reporting, fear of legal disputes, and weak feedback mechanisms, which leave staff feeling their efforts are unresolved, all contribute to under-reporting (Jiao et al., 2024).

This study confirms these issues and reveals these factors' significant impact on the motivation to report ADRs. Uniquely, this research highlights the role of clinical pharmacists, finding that their integration into healthcare teams can significantly enhance ADR reporting across multiple levels (Huang et al., 2024; Yin et al., 2023). This information should influence the development of future reporting strategies. Additionally, this study offers a critical perspective on task-based motivation. Although it does increase the rate of ADR reporting, it also potentially compromises the quality of these reports. This suggests the need for comprehensive strategies that encourage reporting motivation among healthcare professionals beyond mere performance assessments (Easwar, 2020).

Communication skills are a critical component of the ADR reporting process, significantly influencing both the quality and consistency of reports in various healthcare roles [30, 31]. Knowledge gaps between

doctors, pharmacists, and nurses can reduce motivation to report ADRs, often resulting in miscommunication or a reluctance to participate in the reporting process. These disparities can impede the collaborative efforts necessary to ensure patient safety. To address this challenge, future training programmes should prioritise the development of strong communication skills within healthcare teams, fostering a culture of open dialogue and shared accountability in ADR reporting. By ensuring that all healthcare professionals, whether doctors, pharmacists, or nurses, have a comprehensive understanding of ADRs, the quality and frequency of reports can be significantly improved. Enhanced communication will also lead to more timely and accurate ADR reporting, ultimately contributing to better patient care [30, 32]. This integrated approach not only closes knowledge gaps but also empowers healthcare teams to collaborate more effectively, ensuring the highest standards of patient safety.

Improving the ADR reporting rate is crucial to ensure patient safety, optimise drug risk management, and enhance post-marketing drug regulation (Alomar et al., 2020). Based on the results of this study, the following strategies can be adopted to improve the ADR reporting rate: (1) enhance publicity and training: strengthen the publicity and promotion of adverse drug reporting. Improve regular training for medical staff, pharmacists, and other relevant personnel in ADR identification, recording, and reporting methods. Incorporate drug safety courses into medical schools and college curricula to foster a focus on ADR monitoring among future healthcare workers, improving their professionalism and sense of responsibility toward ADR reporting (R. Li, Curtis, et al., 2022); (2) implement advanced reporting systems: establish an informatization construction and automated reporting system for ADRs. Utilise advanced information technology to create a link between the electronic medical record system and the national ADR monitoring system. This integration would automatically extract relevant information, enabling convenient and efficient online reporting, simplifying the reporting process, and facilitating real-time ADR reporting (Joaquim et al., 2023); (3) improve incentives and implementation: develop a reward system that provides recognition or economic rewards to units or individuals who actively and accurately report ADRs. Ensure that these rewards are allocated to individuals to reflect the value of their efforts. Additionally, a scientific appraisal and evaluation system should be established, incorporating ADR reporting into the performance appraisal indices to promote medical institutions or individuals; and (4) strengthen data analysis and feedback: ADR supervisory departments should analyze reported ADRs promptly and provide feedback to reporters to improve their enthusiasm and continuity of reporting. Use reported data to improve drug use guidelines and prescribing behaviours, creating a virtuous cycle from monitoring to practice (Fossouo Tagne et al., 2023; Joaquim et al., 2023).

This study has several limitations. First, this study was confined to medical workers within medical institutions in Henan Province in China. The results primarily represent the situation in Henan. The exclusion of primary healthcare institutions may limit the general applicability of the findings. Second, given that the understanding of ADR reporting may vary between managers, clinicians, pharmacists, and nurses, the study did not conduct a differentiated analysis, which is another limitation of this research. Future research should expand the sample size of the questionnaire survey to explore and quantify the impact of each influencing factor more accurately.

## Conclusion

Only through a comprehensive and multidimensional improvement of the ADR monitoring system can we effectively increase the enthusiasm of medical personnel for ADR reporting. This approach is essential for developing a robust pharmacovigilance system, ultimately ensuring and improving public drug safety. Advancements in this area are crucial to safeguarding patient well-being, fostering a safer healthcare environment, and strengthening overall health infrastructure.

## Disclosure statement

No potential conflict of interest was reported by the author(s).

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