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Root cause analysis from the perspectives of patients in primary care units: cases study of typical adverse drug events†

Original article

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Abstract: **Objective:** To identify the root causes of typical adverse drug events through the lens of patient experiences proposing novel strategies to mitigate preventable harm.
Methods: A qualitative case study leveraging in-depth interviews with patients and families, anchored by Interactive Patient Participation Theory, to analyze 4 high-severity adverse drug events (ADE) cases.Cases were purposively sampled from 8 communities in China's National Adverse Event Monitor Center (2018–2023). Semi-structured interviews explored patient perspectives, with data analyzed via thematic coding and triangulation against clinical records.
Results: Five interconnected themes emerged: (1) erosion of trust, (2) communication breakdowns, (3) information asymmetry, (4) environmental inadequacies, and (5) technological alienation. Notably, 75% of participants had ≤high school education, and 50% used ≥7 medications daily, compounding ADE risks.
Conclusions: We considered elements mentioned by theory, exploring trust, communication, information, and support as the root causes. In addition, we added "adaptability to new technology" as an important and necessary component. It is important and necessary to analyze typical adverse drug events from the perspectives of patients.

Keywords: *adverse drug events • case study • medication safety • patients safety • primary care units • root cause analysis • qualitative study • theory*

1. Introduction

Adverse drug events (ADEs) refer to an adverse event that occurs in response to medication administration, which may have disadvantageous consequences for patients. By the end of 2022, the National Center for Adverse Drug Reaction Monitoring in China reported 597,000 cases of ADEs, over 60% of which arose from primary care units.[1] The primary care unit is the fundamental healthcare unit in China, taking responsibility for management of patients' illnesses and monitoring symptoms, and means particular importance to local

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residents. However, the scale at which ADEs began to surge demonstrated how susceptible the primary care setting was, exposing many loopholes in the community that need to be addressed immediately. This unfortunate situation is a common issue globally, and it has been reported that nearly half of the global medication-related disease burden comes from rural areas, towns, townships, and primary healthcare facilities.[2,3] ADEs have resulted in high rates of re-hospitalization, heavy economic burdens, shortened life expectancy, and even disability or death in more severe circumstances.[4] While prior studies predominantly focused on healthcare providers' perspectives, this study pioneers an exploration of patients' lived experiences, addressing a critical gap in understanding preventable ADEs.[5] The Organization for Economic Cooperation and Development (OECD) claimed that the worldwide medical expenditure incurred by patients improperly taking medications equaled $ 42 billion.[6] The total number of accumulated injuries could be underestimated, because the ADE-related injuries suffered by individuals in communities are not as obvious as those acquired in hospitals.[6] Approximately 50% of ADEs can be prevented efficiently if appropriate countermeasures are taken.[7] Therefore, it is particularly critical and urgent to determine the root causes of ADEs within the contexts of communities.

Patients play a central role in safeguarding their own medication safety. While prior research predominantly examines ADEs root causes through the lens of healthcare providers,[8,9] patient perspectives remain underexplored.[10] Those experiencing severe ADEs—often enduring prolonged primary care dependency—face multidimensional harm, yet their insights are frequently overlooked. This omission risks neglecting critical systemic drivers of preventable harm. The recurrent incidence of ADEs in primary care not only imposes substantial economic burdens but also perpetuates adverse health outcomes. Grounded in the Interactive Patient Participation in Patient Safety theory,[11] which positions patients as active agents in safety frameworks, this study underscores how latent psycho-social and structural factors shape ADE risks. Addressing these community-specific determinants is imperative for targeted intervention design.

2. Methods

2.1. Aims of study

The purpose of the study was looking forward to analyze root causes of typical adverse drug events in the community from the standpoints of patients, providing a novel viewpoint for medical staff to reduce and avoid the likelihood of adverse events.

2.2. Research question

This study investigates patient perspectives on typical ADEs through a systematic analysis of cases sourced from primary care units. Using a mixed-methods approach, we purposively selected high-severity ADEs (e.g., medication errors leading to hospitalization) from community health records and conducted in-depth interviews with affected patients and families. Data were triangulated with clinical reports and analyzed via thematic coding guided by the theory, supplemented by root cause analysis (RCA)[12] to identify systemic, communication, and sociotechnical determinants of ADEs. This dual focus on lived experiences and structural factors aims to uncover context-specific prevention strategies for vulnerable populations.

2.3. Design

This study employed a case-based qualitative design, selecting 4 high-severity ADE cases from primary care units through the Safety Assessment Code (SAC) matrix.[13] Semi-structured interviews were conducted with affected patients or their family members (30–60 min per interview), focusing on their experiences, perceived causes, and safety responsibilities. Interview transcripts were coded thematically using NVivo 12.0,[14] guided by the Interactive Patient Participation framework,[11] to identify recurring patterns in trust deficits, communication barriers, and systemic vulnerabilities. RCA further mapped these themes to actionable intervention points.

2.4. Theoretical framework

RCA, a structured retrospective methodology, systematically identifies systemic contributors to adverse events in healthcare.[12] Aligned with Prof. Ye's[11] Interactive Patient Participation in Patient Safety theory—which emphasizes trust, communication, information, and support as pillars of patient engagement—we integrated "technology adaptability" as a fifth dimension, reflecting evidence on digital health disparities. Guided by this expanded framework, we applied RCA procedures (team formation, case identification, and causal analysis) to 4 high-severity ADE cases, prioritizing patient narratives to uncover context-specific drivers of medication errors. This dual theoretical and empirical approach aims to advance actionable strategies for patient-centered safety interventions.

2.5. Study setting and recruitment

A multidisciplinary RCA team (n = 10) was assembled, comprising a nursing department director (leader), 2 community nurse managers, 2 physicians, 2 pharmacists, and 3 RCA-trained nursing graduate students. Team leaders possessed extensive experience in clinical governance and patient safety initiatives, while frontline members conducted data collection, case identification, and participant interviews following standardized RCA protocols. Cases were retrospectively identified from January 2018 to December 2023 within the Guizhou Provincial Adverse Event Monitoring Database; covering 8 communities via purposive sampling of high-severity ADEs (SAC score = 3).

2.6. Inclusion and exclusion criteria

Inclusion criteria: (1) Age ≥18 years; (2) ≥3 months of continuous medication use (prescription/OTC); (3) history of ≥ 1 self-reported ADEs.

Exclusion criteria: (1) Vaccine-related reactions or allergies (attributable to physiological variability); (2) incomplete clinical documentation; (3) declined interview participation.

2.7. Data collection

A mixed-methods approach was adopted. Primary data included ADEs reports from 8 community-based National Adverse Drug Reaction Monitoring Centers (2018–2023), comprising patient case files, medical records, and nursing documentation. Demographic and clinical variables (e.g., medication history, education level, comorbidities) were systematically extracted into an Excel database (Microsoft Corp, Redmond, WA, USA) to contextualize qualitative findings. To mitigate recall bias, interviews were triangulated with adverse event reports from the National Adverse Drug Reaction Monitoring Center. Quantitative descriptors (e.g., medication counts, education levels) were extracted from Excel summaries to contextualize qualitative findings.

2.8. Participant interviews

Semi-structured interviews (30–60 min) were conducted with patients or their proxies (if cognitively impaired), prioritizing firsthand accounts of ADE experiences. Interviews focused on 3 domains: ADE circumstances and perceived causes; Patient roles in safety practices; Emotional and behavioral responses. Probes included: “Can you describe the events leading to the ADE?” “What factors do you believe contributed to this incident?” “How could patients better prevent such events in the future?” Face-to-face or telephone interviews were audio-recorded, transcribed verbatim, and anonymized to ensure confidentiality.

2.9. Data analysis

Four high-severity ADEs were identified using the SAC matrix,13 a validated screening tool assessing safety risks, recurrence probability, and care quality impacts. Each case was independently scored by 2 raters on a 3-point scale: 1 (Low risk): Minimal severity, unlikely to recur; 2 (Moderate risk): Moderate harm, possible recurrence; 3 (High risk): Severe harm, high recurrence likelihood. Cases with unanimous SAC scores of 3—indicating maximal severity and preventability—were selected for in-depth analysis. Inter-rater reliability was confirmed via Cohen’s κ ($\kappa = 0.81$), ensuring methodological rigor.

2.10. Ethical approval

This study was approved by the Ethics Committee of Hospital of Medical University (NO: 2023837), and all interviewees provided informed consent. The study did not bring unnecessary risks to the participants and considered maximal protection of security and privacy. All the patients and interviewers (i.e. family members) in the study both agreed to write and publish the data, and they both signed the informed consent. In order to protect participants’ privacy, we had concealed name as an identifiable information, and we formally declared all the data only be used for academic research.

2.11. Data management and quality control

Interview recordings were transcribed verbatim within 12 h by 2 researchers, anonymized (coded as Patient 1–4, Nurse/Pharmacist A-J etc.), and analyzed using NVivo 12.0.[14] To ensure data validity, clinical records from the National Adverse Drug Reaction Monitoring Center were triangulated with interview narratives. Rigorous inclusion/exclusion criteria minimized selection bias, while dual independent scoring of cases via the SAC matrix and double-data-entry protocols enhanced objectivity. Statistical experts were consulted to resolve analytical discrepancies, ensuring methodological robustness.

3. Results

3.1. Characteristics of participants

Data were derived from 8 community-based National Adverse Event Detection Centers in Guiyang

Municipality. Four high-severity ADE cases (mean age: 76.75 ± 12.26 years; range: 61–89 years) were analyzed, with a male predominance (75%, n = 3). Educational attainment was limited: 50% (n = 2) completed primary education, 25% (n = 1) middle school, and 25% (n = 1) high school. Polypharmacy was prevalent, with 50% (n = 2) prescribed ≥ 7 medications daily, 25% (n = 1) 4–6 medications, and 25% (n = 1) ≤ 3 medications. Notably, 75% of participants (n = 3) had ≤ high school education, and 50% (n = 2) used ≥ 7 medications—demographic markers strongly associated with heightened ADE risks (OR = 3.2, 95% CI: 1.1–9.8).

3.2. Typical case descriptions

3.2.1 Case 1: Antibiotic-induced anaphylaxis

A 66-year-old male (Community A) with a history of hypertension (managed with amlodipine 5 mg/day) and no documented drug allergies self-prescribed oral amoxicillin (500 mg TID) from an unlicensed pharmacy in December 2019. Within 30 min of ingestion, he developed urticaria, angioedema (lip thickness: 15 mm), and bronchospasm (peak expiratory flow: 150 L/min). Emergency department records indicated hypotension (70/40 mmHg) and hypoxemia (SpO_2: 82%), necessitating epinephrine (0.3 mg IM), corticosteroids, and mechanical ventilation. Post-event allergy testing confirmed penicillin hypersensitivity (skin prick test: 10 mm wheal).

3.2.2. Case 2: Traditional remedy-induced necrotizing infection

A 78-year-old female (Community B) with a 15-year history of gout (allopurinol 300 mg/day; serum uric acid: 8.9 mg/dL) discontinued her medication due to perceived inefficacy and applied moxibustion ("firing wormwood") to her left calf in July 2020. Third-degree burns (10 cm × 8 cm) progressed to necrotizing fasciitis (C-reactive protein: 210 mg/L; wound culture: MRSA +), requiring surgical debridement and below-knee amputation. Post-operative evaluation revealed undiagnosed diabetes (HbA1c: 7.3%).

3.2.3. Case 3: Diuretic overdose and electrolyte crisis

An 84-year-old male (Community C) with congestive heart failure (left ventricular ejection fraction [LVEF]: 35%) and chronic kidney disease (estimated glomerular filtration rate [eGFR]: 28 mL/min/1.73 m²) was prescribed furosemide 40 mg TID (3 times daily) for generalized edema in November 2022. Misinterpreting "TID" as 3 tablets per dose, he self-administered 120 mg TID for 12 weeks, resulting in hypokalemia (2.1 mmol/L), hyponatremia (125 mmol/L), and acute renal failure (serum creatinine: 4.2 mg/dL). Electrocardiogram (ECG) showed prolonged QTc interval (520 ms), necessitating intensive care unit admission for electrolyte correction and hemodialysis.

3.2.4. Case 4: Technology-assisted medication error

A 79-year-old widower (Community D) with atrial fibrillation (apixaban 5 mg BID) and mild cognitive impairment (Montreal Cognitive Assessment [MoCA] score: 18/30) received an electronic pillbox ("Ding-Ding") in March 2023. Confused by near-identical packaging of Da Shu Pin (dronedarone, antiarrhythmic) and Wei Shu Pin (famotidine, gastric ulcer treatment), he ingested 160 mg dronedarone daily instead of 20 mg famotidine for 5 days. Abdominal computed tomography (CT) revealed fecal impaction, with laboratory findings showing QTc prolongation (490 ms) and elevated liver enzymes (alanine aminotransferase [ALT]: 85 U/L). The pillbox's alarm system malfunctioned during the event.

3.3. Results of interviews

3.3.1. Theme 1: Erosion of trust in healthcare relationships

Patient 1: "I trusted my doctor, but after the medication caused harm, I'm unsure who to rely on now."

Patient 2: "Different doctors gave conflicting advice—it's confusing and makes me question their expertise."

Community Physician A: "Patients often compare our prescriptions to those from larger hospitals; not realizing community care prioritizes long-term safety over aggressive treatment."

Nurse B: "When patients self-adjust medications without informing us, it undermines trust and complicates care."

3.3.2. Theme 2: Communication gaps in care delivery

Patient 3: "The doctor said 'take it 3 times a day'—I thought that meant 3 pills each time!"

Family Member 4: "My father hesitates to ask questions, fearing he'll waste the doctor's time."

Pharmacist C: "We use simple symbols like sun/moon icons to explain dosing schedules, but literacy barriers persist."

Nurse Manager D: "With over 80 daily patients, time constraints limit our ability to explain details thoroughly."

3.3.3. Theme 3: Inequities in health information access

Patient 2: "We rely on TV ads for health advice—it's risky, but what else can we do?"

Patient 3: "Doctors use words I don't understand. I end up asking neighbors instead."

Physician E: "We've seen patients harmed by herbal remedies but struggle to counter deeply held beliefs."

Community Pharmacist F: "We host medication safety workshops, but low attendance shows we need better outreach strategies."

3.3.4. Theme 4: Systemic challenges in care environments

Patient 1: "Traveling to the clinic takes hours—it's exhausting just to refill prescriptions."

Patient 2: "The crowded waiting room feels chaotic. Doctors seem too rushed to listen."

Clinic Director G: "Our staff serves 10,000 residents with limited resources. We're exploring telehealth to reduce travel burdens."

Nurse H: "Infrastructure gaps, like delayed emergency equipment access, put everyone at risk."

3.3.5. Theme 5: Technology adaptation across generations

Patient 4 (Family Member): "The smart pillbox confused my father—he took a week's dose at once."

Patient 2: "I've lived without apps for 70 years. Why start now?"

Health Technologist I: "We designed voice-activated reminders, but many older patients find them intrusive rather than helpful."

Pharmacist J: "Hybrid systems (digital and paper) work best, yet policy often prioritizes full digitization."

4. Discussion

4.1. Patient-centric analysis: Bridging theory and practice

Our findings underscore the critical role of patient perspectives in understanding adverse drug events (ADEs), aligning with Ye's[11] Interactive Patient Participation in Patient Safety theory, which emphasizes trust, communication, information, and support as pillars of patient engagement. By incorporating "technology adaptability" as a fifth dimension, we extend this framework to address aging populations' unique challenges, as evidenced by Case 4, where a cognitive-impaired patient's struggle with an electronic pillbox led to medication errors. This theoretical expansion aligns with Haga's[15] observations on digital health disparities but uniquely positions adaptability as a mediator between structural barriers (e.g., rural healthcare access) and ADE risks. The integration of qualitative patient narratives (e.g., Case 3 misinterpretation of "tid") with RCA methodologies revealed that systemic factors—such as poor health literacy and fragmented care environments—interact dynamically with individual behaviors. For instance, Case 2 illustrated how cultural beliefs in traditional remedies over evidence-based treatments exacerbated risks, a phenomenon also observed in low-resource settings globally[2,3]

4.2. Trust erosion and communication failures: A systemic lens

Trust erosion, exemplified by Case 1 antibiotic-induced anaphylaxis, reflects broader systemic issues. Patients' reliance on multiple providers for conflicting advice mirrors fragmented care systems where coordination is lacking. Ye's[11] theory posits trust as foundational to patient participation, yet our data show that trust is easily destabilized by preventable ADEs, particularly when patients perceive negligence (e.g., Case 1 unlicensed pharmacy access). Communication barriers, highlighted by Case 3 dosing error, reveal a mismatch between clinical jargon and patient understanding. While Patient Report Outcome tools like symptom lists could mitigate such gaps,[16] their effectiveness depends on culturally sensitive adaptations—such as visual aids for low-literacy populations, as attempted but underutilized in our study (Pharmacist C's sun/moon symbols).

4.3. Information asymmetry and technological alienation

The "Medical Information Chain" hierarchy,[11] where patients occupy the lowest tier, was starkly evident in Case 2 reliance on folk remedies and non-official media. This aligns with global patterns where marginalized groups disproportionately face misinformation.[17] However, our inclusion of healthcare provider perspectives (e.g., Physician E's challenges in countering herbal remedy use) underscores that information gaps are bidirectional—providers often lack training in patient education strategies.[18] Technology alienation, exemplified by Case 4 pillbox confusion, highlights a paradox:[19] digital tools designed to enhance safety may inadvertently exclude aging populations. This resonates with studies in other aging societies (e.g., Japan's ADE patterns[2]), suggesting that "one-size-fits-all" technological solutions require localization.

4.4. Cross-cultural implications and generalizability

While rooted in Chinese primary care, our findings reflect universal challenges in aging, resource-limited settings. For example: Trust deficits, which are similar to OECD reports on rural healthcare,[6] distrust in community providers stems from perceived competency gaps. Environmental barriers, like overcrowded clinics, mirror struggles in Indian and Brazilian primary care systems.[20] Technology gaps via analogy to African studies,[21] cognitive decline and infrastructural limitations hinder tech adoption. Ye's theory, originally validated in urban Chinese hospitals,[11] gains broader relevance through our emphasis on adaptability. By contextualizing its pillars within diverse socioeconomic settings, this framework can guide tailored interventions—e.g., hybrid digital-paper systems for communities transitioning to technology.

4.5. Strengthening theoretical and practical synergy

Our mixed-methods approach—combining patient narratives, provider insights, and RCA—revealed interdependencies between Ye's theoretical pillars. For instance, environmental inadequacies (Theme 4) exacerbated communication failures (Theme 2), while information gaps (Theme 3) amplified distrust (Theme 1). This interconnectedness suggests that siloed interventions will yield limited success (e.g., improving technology without addressing literacy). Future studies should test this expanded framework in multicultural contexts, particularly in regions with similar aging demographics (e.g., Southern Europe, Southeast Asia).[22] Pilot programs co-designing interventions with patients—such as community-led medication safety workshops—could operationalize Ye's participatory principles while addressing local barriers.

4.6. Consideration of patients' ability to adapt new technology

We have identified trust, information, support, and communication as root causes of typical ADEs under the guidance of theory. "Adaptability" should be added to these, perhaps Case 4 could illustrate that, because it is not easy for individuals who dwell in primary care setting to understand and manipulate intelligent adverse event reporting systems, as well as people who live in urban cities. In modern technological societies, rapidly emerging electronic appliances and digital equipment, such as automated tablet dispensers, smart medication kits, distant online phone calls, and others[15,23] are available to reduce the occurrence of ADEs. These may have high efficacy when used properly, but there are some specific situations we should consider with regard to them as well. With local community residents' ages rising, cognitive abilities declining, memories receding, attention spans decreasing, and hand–eye coordination abilities degenerating,[21] rural patients may be hindered from integrating into the popular technological revolution, and may develop negative attitudes toward accepting and adapting to new technologies. While rooted in Chinese communities, our themes resonate with global challenges in primary care. For instance, communication barriers and technology gaps mirror issues reported in OECD rural settings. Future studies should validate these findings in diverse cultural contexts, particularly in low-resource regions.

4.7. Limitations and future directions

While this study offers valuable qualitative insights into the root causes of ADEs through patient perspectives, its limitations must be acknowledged. The research design leans heavily on qualitative methodologies, generating rich narrative data from patient interviews while lacking complementary quantitative metrics to triangulate findings. The small quantitative sample size ($n = 4$), constrained by stringent SAC criteria and low ADE reporting rates in primary care settings, creates an imbalance where the depth of qualitative evidence outweighs its quantitative substantiation, potentially limiting statistical power and generalizability. Furthermore, the exclusive focus on Guizhou provinces restricts the applicability of findings to broader socioeconomic and cultural contexts within China. To address these limitations, future research should prioritize multi-center collaborations across diverse regions and healthcare systems while deliberately integrating mixed-methods approaches. This could involve pairing large-scale electronic health record (EHR) analyses with patient narratives to counterbalance the current qualitative dominance and strengthen causal inference through data triangulation. Such quantitative expansion would enable risk stratification for targeted interventions while preserving contextual depth. Additionally, multi-disciplinary efforts are needed to translate theoretical frameworks into practice, including co-designing low-literacy visual aids or voice-based apps with patients, standardizing RCA protocols for cross-regional training, and advocating for policies like mandatory technology adaptability assessments for older adults. By bridging the qualitative-quantitative divide and connecting Ye's expanded theoretical model with real-world

implementation, such initiatives could reduce preventable ADEs in aging populations worldwide, ensuring equitable safety improvements across cultural and technological divides.

5. Conclusions

This study pioneers a patient-centered investigation into the systemic drivers of ADEs within Chinese primary care communities. By expanding Ye's Theory through the novel integration of "technological adaptability" as a fifth determinant—particularly critical for aging populations navigating increasingly digitalized healthcare systems—we bridge a critical gap in medication safety frameworks. Our analysis reveals how deeply rooted sociotechnical barriers, including health literacy disparities and age-related technological exclusion, interact with structural vulnerabilities in community care. These insights directly inform pragmatic, culturally sensitive interventions such as visual medication guides for low-literacy patients and voice-activated reminder systems, demonstrating how theoretical advancements can translate into tangible safety improvements. By foregrounding patient narratives often absent from traditional safety analyses, this work not only enriches academic discourse but also provides a replicable model for global communities grappling with similar challenges in aging populations.

Data availability statement

Data not available due to ethical restrictions. Due to the nature of this research, participants of this study did not agree for their data to be shared publicly, so supporting data is not available.

Authors contribution

Gong was substantial contributions to the conception or design of the work, took charge of conceptualization and writing original draft; and interpretation of data for the work; Chen was drafting the work or reviewing it critically for important intellectual content, mainly focused on methodology and data collection; Zhou was final approval of the version to be published, took charge of reviewing and interviewing patients; and her main assignment was validation data, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethical approval

This study was approved by the Ethics Committee of Hospital of Medical University (NO: 2023837), and all interviewees provided informed consent.

Conflicts of interest

All contributing authors declare no conflicts of interest.

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