Enhancing Safety via Medication Self-Management and Timely Reporting

Yun JIANG\textsuperscript{a,1}, Yang GONG\textsuperscript{b,2}
\textsuperscript{a}School of Nursing, University of Michigan, Ann Arbor, Michigan, USA
\textsuperscript{b}School of Biomedical Informatics, University of Texas Health Science Center at Houston, Houston, Texas, USA

Abstract

Medication errors have been a major threat to patient safety. Current research on medication errors is largely dependent on in-hospital reports. With the rapid shift of health care to chronic condition management, there is an urgent need to investigate medication errors in the community. In this paper, we discuss that the model of medication self-management developed for outpatient settings may be used to guide the development of prevention strategies for medication errors beyond hospitals. Further, timely reporting medication errors from patients in the communities may be helpful in mitigating the severity of side effects and reducing preventable safety events.

Keywords

Medication error; patient safety; event reporting

1. Introduction

Medication errors, the most significant threats to patient safety, cause 1 of 854 inpatient and 1 of 131 outpatient deaths [1]. A medication error is defined as any preventable event that may cause inappropriate medication use or patient harm while the medication is under the control of a clinician or patient [2]. A typical medication error may be described as a clinician writing the wrong medication, wrong route or dose, or wrong frequency. While the errors can occur at any steps of medication management, such as ordering/prescribing, documenting, transcribing, dispensing, administering and monitoring, and any patient care settings including both inpatient and outpatient care. The errors originating at the ordering/prescribing stage account for half of the medication errors and 30%-70% of such errors could be identified by pharmacists or nurses along the workflow [3]. The preventable errors cause substantial adverse consequences, such as patient harm, unnecessary hospital admissions, additional resource utilization, and time away from work. The prevalence of
medication errors and consequences of such errors have drawn global attention to enhancing medication safety, which has become a worldwide priority for healthcare systems [4].

1.1. Key Concepts in Medication Safety

To advance the identification and analysis of medication errors, it is essential to clarify the key concepts that are frequently used but sometimes used inappropriately. One of the key concepts is adverse drug event (ADE), which is defined as any patient harm or potential harm associated with the use of a medication. ADE does not necessarily indicate an error or poor care quality [5].

- **Preventable ADEs** result from a medication error that reaches the patient and causes any degree of harm, among which 50% ADEs are preventable;
  - **Potential ADEs or near misses** refer to the medication errors that do not cause any harm, either because they are intercepted before reaching the patient or because of luck;
  - An **ameliorable ADE** is one in which the patient experienced harm from a medication that, while not completely preventable, could have been mitigated;
- **Non-preventable ADEs**, adverse drug reactions (ADRs), or side effects refer to the ADEs even when medications are prescribed and administered appropriately.

Medication errors are a broader concept including omission, commission and near misses, regardless of harm and have overlap with the preventable ADEs. ADRs or side effects are non-preventable ADEs. However, the occurrence and severity of side effects can vary significantly by individual and are highly reportable and manageable through dosage adjustment, second medication, lifestyle, dietary changes and beyond. Timely reporting and effective management of side effects are associated with treatment outcomes and quality of care.

1.2. Medication Safety in Hospitals and Communities

Patient safety event (PSE) reports are often collected in hospital settings. Recently, AHRQ has extended the Common Format hospital version 2.0 to community pharmacy and nursing home, which signifies the recognized significance and trends of PSE reporting in the community via the Common Formats [6].

Using medication safety in oncology care as an example, cancer care has shifted rapidly from inpatient to outpatient settings. Many patients with certain types of cancer are considered as living with a chronic disease in the community. One contributing factor to this progress is the increased use of oral anticancer agents (OAs). Patients receiving OAs usually have less frequent clinical encounters with their health care providers (HCPs) and take more responsibility for managing their cancer medications at home. Therefore, cancer patients and their families are expected to play a critical role in ADE monitoring and timely reporting. To date, no standard practice across clinics and organizations is available for patients to follow and to report ADEs. One online survey for both HCPs and patients indicates that at least 30% of patients taken OAs do not report their ADEs, and more than
one-third oncologists believe that patients’ avoidance of reporting is a barrier to effective management of cancer treatments [7]. With longer survival, many cancer patients now live with multiple chronic comorbidities and often take multiple medications at the same time as taking OAAs. About 25-91% of cancer patients in the USA are reportedly using complementary and alternative medications (CAMs) [8]. As a result, the risks of medication safety due to polypharmacy, drug-drug or drug-food interactions rise dramatically among cancer patients. The rapid shift of cancer care to outpatient settings indicates an urgent need to study medication safety of cancer patients in the community.

### 1.3. Oral Anticancer Agent Safety and Medication Self-Management

Each year, millions of people diagnosed with cancer receive chemotherapy in addition to surgery and radiation therapies. Medication errors in chemotherapy ranges from 0.1% to 24.6% in prescribing, 0.40% to 0.50% in preparation, 0.03% in dispensing, and 0.02% to 0.10% in administering phases [9]. Significant drug-drug interactions are more prevalent with OAAs than with intravenous (IV) agents. Patients’ timely ADE reporting, a component of OAA self-management, is central to patient-provider partnerships for early detection and management of ADEs [10]. Thus far, little is known about patients’ ADE reporting and the clinical management response to the ADE reports. Existing research typically collects patient-reported outcomes at the time of clinic visits, which may not be timely with respect to patients’ experiences of OAA-related ADEs at home. Electronic symptom reporting systems, allowing cancer patients to report their symptoms from home, have a low adoption rate from patients and the use tends to decline over time [11]. The reporting systems to engage patients in long-term ADE reporting is yet to be established. Current standards of chemotherapy administration [12] created from the healthcare provider standpoints, do not address the role of patients and families toward engagement in OAA-related safety practices.

### 2. Methods

To advance the OAA-related safety practice, the model of medication self-management could be instrumental. Focusing on outpatient settings, the model defines medication self-management as “a patient takes medication as prescribed, including not only the correct dose, frequency and spacing, but also its continued, safe use over time” (p.22) [13].

To safely and effectively manage OAAs, patients must follow a series of steps to “Fill, Understand, Organize, Take, Monitor, and Sustain” their OAAs (Figure 1) [13]. While the step of “Understand” is fundamental to ensure safe and effective use of OAAs, monitoring ADEs associated with OAAs is another important step to ensure safe use. Being aware of the safety profiles of OAAs allows patients to connect symptoms to OAA use and seek appropriate management actions before an ADE. This model covers a full range of tasks in medication self-management, helps identify the safety risks, and could guide the development of prevention strategies for medication errors. Patient safety researchers have been using data collected from direct observation, claim data, administrative databases and chart review to study medication safety. The medication self-management can be an essential component and critical data source for understanding the nature of medication errors, especially in the community.
3. Results

A pilot study to assess capecitabine (oral chemotherapy) self-management among 50 gastrointestinal (GI) cancer patients identified that 74% patients had adequate capecitabine self-management skills [14]. Less adequate self-management skills were associated with more severe general side effects burden and symptom interference with daily life, more severe specific side effects including constipation, mouth sores, and depression, and less self-efficacy for managing the disease and social support, and more concerns of taking capecitabine (Table 1). Although the measurement of capecitabine self-management using the adopted Measure of Drug Self-Management [15] might not be comprehensive enough to cover all six steps from Fill to Sustain, this pilot study did reveal the association between capecitabine self-management and patient experiences with and concerns of side effects, as well as their perceived abilities to manage them.

To understand patient side effect self-reporting behaviors, a post-study of the same cohort, researchers phone interviewed 36 patients [14]. The results indicated that two-thirds of patients (n=24) had called their doctors or nurses regarding capecitabine treatment related problems. These calls mostly occurred at the early cycle of the treatment due to a lack of understanding of what was happening, or when patients “didn’t feel right” or felt side effects “very serious” “unbearable”, “bothering my life”. Timely responses from HCPs are important for patient side effect self-reporting. One patient who was at the first cycle of her capecitabine had concerns about her extreme tiredness and severe rash and cracking on her hands and feet, and she called the doctor’s office three times in two days but received no feedback from the doctor. As a result, she decided to discontinue her capecitabine treatment. Although the online patient portal is available, about half of patients preferred using phone calls to contact their doctors and thought it was a fast way to get real-time or timely feedback and clarification of instructions.

4. Discussion

Medication safety represents the top prevailing concerns in patient safety. With the increased aging populations and complexity of chronic care, many patients living with chronic conditions, including cancer patients taking OAAs, are facing challenges of polypharmacy, potentially inappropriate medication use, and adverse drug reactions. Management support has largely shifted to community settings where medication self-management and timely ADE reporting, including both preventable and non-preventable errors, show potential to enhance medication safety. Therefore, we call for collaborative research to broaden the PSE reporting and deepen the understanding of medication self-management from hospitals to communities. Nurses, the main task force to provide patient education and support for patient self-management, play a key role in enhancing patient safety and informing the patient through health information systems that are underdeveloped for such a purpose. Research on patient safety should draw special attention from the nursing informatics community.
5. Conclusion

With the growing burden of chronic disease and the shift of healthcare delivery to community settings, there is an urgent need to engage patients and families in the prevention and management of medication errors. Medication self-management and timely reporting of medication events should be further investigated through collaborative teams.

Acknowledgement

This project is supported by the Agency for Healthcare Research & Quality (R01HS027846).

References

[1]. Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: Detection and classification methods. BMJ Qual Saf. 2004 Aug;13(4):306–14.
[2]. NCCMERP. NCC MERP Taxonomy of medication errors. 2001 Jul. Available from: https://www.nccmerp.org/sites/default/files/taxonomy2001-07-31.pdf
[3]. Wheeler AJ, Scahill S, Hopcroft D, Stapleton H. Reducing medication errors at transitions of care is everyone’s business. Australian prescriber. 2018 Jun;41(3):73–7. [PubMed: 29922001]
[4]. Hughes R, editor. Patient safety and quality: An evidence-based handbook for nurses. 2008 Apr; Rockville, MD: Agency for Healthcare Research and Quality.
[5]. AHRQ. Medication Errors. 2021. Available from: https://www.ahrq.gov/topics/medical-errors.html
[6]. AHRQ. Common Formats for Event Reporting - Hospital Version 2.0. 2020 Apr. Available from: https://www.psoppc.org/psoppc_web/publicpages/commonFormatsHV2.0
[7]. Gandhi S, Day L, Paramsothy T et al. Oral anticancer medication adherence, toxicity reporting, and counseling: A study comparing health care providers and patients. J Oncol Pract. 2015 Nov;11(6):498–504. [PubMed: 26395564]
[8]. Lees J, Chan A. Polypharmacy in elderly patients with cancer: Clinical implications and management. Lancet Oncol. 2011 Dec 1;12(13):1249–57. [PubMed: 21741307]
[9]. Ashokkumar R, Srinivasamurthy S, Kelly J, Howard S, Parasuraman S, Uppugunduri Satyanarayana CR. Frequency of chemotherapy medication errors: a systematic review. J Pharmacol Pharmacother. 2018 Sep;9(2):86–91.
[10]. Mason M, Harris MR, Greer JA, Jiang Y. A Concept Analysis of Oral Anticancer Agent Self-management. Cancer Nurs. 2021 Feb 27. doi:10.1097/NCC.0000000000000934.
[11]. Cho Y, Zhang H, Harris MR, Gong Y, Smith EL, Jiang Y. Acceptance and use of home-based electronic symptom self-reporting systems in patients with cancer: Systematic review. J Med Internet Res. 2021 Mar;23(3):e24638. [PubMed: 33709929]
[12]. Neuss MN, Gilmore TR, Belderson KM, Billett AL, Conti-Kalchik T, Harvey BE, Hendricks C, LeFebvre KB, Mangu PB, McNiff K, Olsen M. 2016 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards, including standards for pediatric oncology. J Oncol Pract. 2016 Dec;12(12):1262–71. [PubMed: 27868581]
[13]. Bailey SC, Oramasionwu CU, Wolf MS. Rethinking adherence: a health literacy-informed model of medication self-management. J Health Commun. 2013 Dec 4;18(sup1):20–30.
[14]. Jiang Y, Wickershams KE, Zhang X, Barton DL, Farris KB, Krauss JC, Harris MR. Side Effects, Self-Management Activities, and Adherence to Oral Anticancer Agents. Patient Prefer Adherence. 2019 Dec;13:2243–52. [PubMed: 32099335]
[15]. Bailey SC, Annis IE, Reuland DS, Locklear AD, Sleath BL, Wolf MS. Development and evaluation of the Measure of Drug Self-Management. Patient Prefer Adherence. 2015 Jul;9:1101–8. [PubMed: 26257515]
Figure 1.
The Model of Patient Medication Self-Management, reproduced based on [13].
Table 1.
Factors associated with capecitabine self-management.

|                        | SE Burden | SI   | Con  | Mouth S | Concern | Dep  | Self-E | SS  |
|------------------------|-----------|------|------|---------|---------|------|--------|-----|
| Spearman Coefficient   | −0.44     | −0.29| −0.32| −0.32   | −0.50   | −0.29| 0.33   | 0.32|
| p-value                | 0.02      | 0.04 | 0.02 | 0.03    | <0.001  | 0.04 | 0.02   | 0.02|

Notes. SE: side effect; SI: symptom interference with daily life; Con: severity of constipation; Mouth S: severity of mouth sores; Concern: concerns of taking capecitabine; Dep: Depression; Self-E: self-efficacy; SS: social support.