Pilot testing of checklists to discern adverse drug reactions and adverse drug events

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Abstract

Objectives: To estimate the prevalence of patient-reported adverse drug events (ADEs)/adverse drug reactions (ADRs) in the community pharmacy setting and determine the prevalence relative to pharmacist judgment.

Data sources: The 2009 version of the *Pharmacy Times* top 200 drugs was used to identify the prescription medications most commonly used within the ambulatory population during 2008. All ADEs/ADRs for each medication were obtained by combining the ADEs/ADRs listed in *Drug Facts and Comparisons*, Lexi-Comp, and Micromedex.

Methods: Checklists for each pharmacologic class within the top 200 medications (n = 51) were developed, with questions about the five most common ADEs/ADRs in each class. Ten community pharmacies administered the checklists. Patients requesting a prescription refill for a medication listed in the top 200 were asked to complete a class-specific checklist to determine ADEs/ADRs experienced in the previous 4 weeks. Upon completion, pharmacists engaged in routine counseling procedures, including a discussion of patient-reported ADEs/ADRs. Pharmacists indicated if they believed, based on their clinical judgment, whether the ADE/ADR reported was related to the medication.

Results: 2,057 checklists were completed, with a total of 10,285 potential ADEs/ADRs. Patients reported 2,185 ADEs/ADRs (21.24%), with 755 (7.3%) definitively confirmed by the pharmacist as being related to their medication.

Conclusion: Use of these checklists resulted in the identification of previously unrecognized ADEs/ADRs in the community setting. Routine use of these short, patient-completed checklists may assist pharmacists in earlier identification of ADEs/ADRs, which can have a positive impact on patient safety across settings.

Keywords: Adverse drug events, adverse drug reactions, pharmacy, pharmacists.

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In recent decades, the amount of medications consumed and the spending on prescription drugs has increased markedly, as more than 80% of adults older than 56 years take at least one prescription medication daily.[1,2] The concurrent rise in the number of prescriptions also has led to an increase in adverse drug events (ADEs) and adverse drug reactions (ADRs). An ADR is typically defined as "harm directly caused by a drug at normal doses,"[3] while an ADE is "harm caused by the use of a drug."[3] According to the Food and Drug Administration, although serious and fatal ADEs more than doubled from 1998 to 2005,[4] ADEs/ADRs overall may be underreported by as much as 94%.[5–7] The reported average annual prevalence of provider-reported ADEs/ADRs across community and hospital settings has been estimated at 0.5%.[8] The outcomes of ADEs/ADRs can be severe and costly. Patients presenting to the emergency department with an ADE/ADR have a higher risk of longer hospital stays, more outpatient visits, and nearly double the cost of care of those without ADEs/ADRs.[9] ADEs/ADRs result in at least 100,000 deaths yearly, and the costs associated with ADE/ADR-related morbidity and mortality are greater than $177 billion.[10–12]

Pharmacists are well prepared to address and resolve medication-related problems that patients experience and can provide important information about ADEs/ADRs.[13] Previous research has demonstrated pharmacists' ability to reduce the incidence of ADEs in hospital and community settings but in hospital settings primarily.[14–24] The need to monitor patients in the ambulatory population for ADEs/ADRs is considerable. Given the demonstrated ability of pharmacists to prevent, address, and resolve ADEs/ADRs in the hospital setting,[14–24] pharmacists practicing in the community setting also are capable of performing the same tasks with regard to ADEs/ADRs. Counseling in the community setting has been found to reduce ADEs in cardiovascular patients[21] and with nonsteroidal anti-inflammatory drug use.[25] Because community pharmacists are highly accessible to patients, they are uniquely positioned in the health care system to address the issue of ongoing ADEs/ADRs in ambulatory patients and prevent serious outcomes.

The time constraints of modern practice may limit community pharmacists' opportunities to identify ADEs/ADRs, as pharmacists spent as much as 72% of their time in medication dispensing and managerial activities.[26] Tools such as TIMER (Tool to Improve Medications in the Elderly via Review) have been used during medication therapy management in the community setting to successfully aid pharmacists in identifying drug-related problems.[27] Other tools used in the community setting have been aimed at identifying inappropriate medications among older adult patients.[28] However, developing short pharmaceutical class–specific checklists based on common ADEs/ADRs that a patient might experience may allow busy community pharmacists to not only more efficiently identify whether an ADE/ADR is occurring and the causative agent but also assist other health care providers in optimizing medication therapy for patients. Routine administration of these medication-specific checklists could aid in earlier identification of ADEs/ADRs, especially in the ambulatory care setting, thereby improving patient safety and outcomes. These checklists also can assist in more accurate identification of the prevalence of ADEs/ADRs for specific medications.

At a Glance

Synopsis: Pharmacist administration of short, five-item checklists for the top 200 prescription medications in the community pharmacy setting resulted in the identification of adverse drug events (ADEs)/adverse drug reactions (ADRs). Patients reported 2,185 ADEs/ADRs, 755 of which were confirmed by pharmacists as being related to patients' medications. Short checklists can assist pharmacists in identifying and addressing ADEs/ADRs in the community setting, which may provide a better understanding of the incidence and prevalence of ADEs/ADRs.

Analysis: *Similar to previous research, this study found that adrenal corticosteroids, antidepressants, anticonvulsants, antihypertensives, and cardiovascular agents had high incidence rates of patient-reported ADEs/ADRs. A need exists for earlier identification of ADEs/ADRs in the ambulatory care setting, and community pharmacists are well positioned to assist in this important patient safety measure. Developing short checklists based on common ADEs/ADRs that patients might experience may allow busy community pharmacists to identify whether an ADE/ADR is occurring and determine the causative agent, as well as assist other health care providers in optimizing medication therapy for patients.*

Objectives

We sought to (1) estimate the prevalence of patient-reported ADEs/ADRs in the community pharmacy setting and (2) determine the incidence/prevalence of ADEs/ADRs relative to pharmacists' expert judgment.

Methods

Checklists for each pharmacological class were developed and contained questions regarding the five most common ADEs/ADRs in each class. Only the five most common ADEs/ADRs were used to keep the checklists brief and feasible for use in a busy community pharmacy. As described previously in greater detail, the five most common ADEs/ADRs within the class were iden-