

Outpatient Drug Safety: The Final Frontier

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Admittedly, most P&T committees are concerned with the appropriate selection and use of pharmaceutical agents in the inpatient setting. However, with the diversity in our drug-delivery system, many of us are directly involved in creating formularies for largely ambulatory populations. Also, many P&T committee members are involved in drug use evaluations (DUEs), postmarketing studies, and cost-effectiveness analyses for products used in the outpatient setting.

Oftentimes, we do not consider the safety of the medication use process for ambulatory patients. We prefer to concentrate our efforts on the well-documented and broad-based problems of drug safety and on reducing adverse drug events (ADEs) for hospitalized patients. However, ADEs are very common in primary care, and many of them are preventable or at least ameliorable. I believe that monitoring and acting on specific drug-safety issues in the outpatient setting are crucial. In this regard, these steps are akin to the “final frontier” of drug safety.

What, then, is the scope of the ADE picture in ambulatory care? What are some of the predictors of ADEs and some possible strategies for improvement?

Ghandhi and associates¹ have provided an excellent overview of the ADEs that occur in the ambulatory setting. They found that nearly 25% of ambulatory patients have experienced ADEs. The researchers classified these ADEs according to their severity, rating them as “fatal or life-threatening,” “serious,” or “significant.” They also evaluated the preventability of these events, tagging them as “ameliorable,” “preventable,” or “not preventable.”

In a nutshell, many serious drug-related events that occur in the outpatient setting can be prevented or diminished. This fact should come as no surprise to active P&T committee members, who are often called upon to review ADE reports in both inpatient and ambulatory settings.

What I found surprising were the spe-

cific medication classes most frequently involved in ADE reports. These included selective serotonin reuptake inhibitors (SSRIs), beta blockers, angiotensin-converting-enzyme (ACE)-inhibitors, and nonsteroidal anti-inflammatory drugs (NSAIDs). Of course, all of these products are commonly prescribed in the ambulatory setting. I was also surprised that a detailed multivariate analysis showed that only the *number* of medications taken was significantly associated with ADEs; coexisting medical conditions, the age and sex of the patients, the type of medical practice, and even the type of prescription system were not predictive of a high or low number of ADEs; in fact, the mean number of ADEs per patient increased by 10% for each additional medication.

Why does this occur? Hammons and colleagues point out that although most outpatient care is less complex technologically than inpatient care, it is often more complex logistically. In other words:²

the infrastructure of ambulatory care frequently provides far less than optimal support for coordinating and managing that care. An episode of ambulatory care often requires communication and coordination among a number of clinicians, the patient, and family among several different sites. It frequently involves handoff and transitions over time. The complexity of negotiating the health care system is increased by insurer requirements that force clinicians and patients to use particular laboratories, imaging facilities, and consulting physicians with which they do not have working relationships. Again, the lack of reliable processes and systems for communication and coordination in outpatient care may be complicated by physician acceptance of inadequate support systems.

Are we doomed, then, in this final frontier, to simply accept an ADE rate of nearly 25%? A better understanding of the “system-ness” of outpatient ADEs is necessary. It appears that strategies to improve the processes of care for all patients in all

settings will be more effective than strategies that target only high-risk groups. This means that a system-based solution to ambulatory drug ADEs is critically important.

Additional strategies might mean improvements in doctor-patient communications, which could be achieved through interventions by pharmacists or nurses, better patient-education materials, e-mail follow-ups, and other system-based enhancements of ambulatory practice.

We might be able to make important advances simply by instituting the practice of asking patients whether they have any questions about their medications and by documenting their answers in the ambulatory medical record more precisely. Merely computerizing our prescription procedures or using a hand-held device to beam prescriptions to a pharmacy does not necessarily resolve the complexities inherent in this process. Indeed, Ghandhi and his team sadly indicated that the overall rate of ADEs did not differ significantly among clinics that used or did not use computerized prescription systems.¹

Dr. William Tierney is right³; he suggests that given the increasing number of powerful drugs available to care for an aging population, the problem of ADEs in the ambulatory setting will only become worse. We must begin to evaluate the systems involved in ambulatory drug dispensing and, through this evaluation, uncover appropriate system-based solutions.

P&T committees should expand their zones of influence and control by asking what goes on in the ambulatory setting in their own organizations.

Readers who are interested in research in this arena can visit the Agency for Healthcare Research and Quality's Web site,⁴ which recently featured the proceedings of a conference concerned with ambulatory patient safety.

As usual, I am interested in your views. You can reach me at my e-mail address, david.nash@jefferson.edu.

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