Risk-based strategy for outpatient pharmacy practice: Focus on opioids

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Abstract

Objectives: To highlight the limitations of community pharmacy practice and to propose a system change by implementing a risk-assessment method and management strategy for opioids in this arena.

Data sources: Selected by the author.

Summary: Numerous studies show that the U.S. health care system is subject to a high rate of drug misadventures involving primarily low therapeutic index drugs, especially opioids. Currently proposed approaches to managing opioids focus on access control, but without a broader consideration of patient-use problems that lead to morbidity and mortality. While pharmacists are well-trained health professionals, their primary focus has been on drug distribution rather than proper use. This article highlights the limitations in contemporary community pharmacy practice that likely contribute to the problem of opioid misuse and resultant morbidity.

Conclusion: A new model of practice is proposed whereby the most dangerous agents such as opioids are preidentified for a more formalized risk-based strategy focused upon optimal patient education and required follow-up.

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The data are now well known regarding a rising mortality due to prescription opioid misadventures.[1–4] Although the dangers of opioid overdose are real, it is unclear whether pharmacy has fulfilled its obligations to keep patients safe in terms of optimal use of these medications.

The purpose of this article is to highlight the limitations of community pharmacy practice and to propose a system change by implementing a risk-assessment method and management strategy for opioids in this arena.

Background: The opioid overdose epidemic

Approximately 80% of opioid overdoses occur in patients consulting multiple prescribers and/or receiving high doses of opioids. Lack of implementing patient risk-based education regarding proper use has resulted in substantial suboptimal use and overdoses.[3] Most overdose-related prescriptions are written by non–pain physicians rather than pain management teams, such that both prescribing and patient education may be suboptimal from the outset of the medication-use process.

To date, suggested approaches to this problem are principally focused upon patient screening, prescription monitoring, dose or prescription restrictions, provider education, and expansion of substance abuse treatment.[2,5–7] No publications have considered pharmacist involvement beyond restricting drug access or monitoring for "pill mills" (i.e., high-volume prescribing operations).[8] The few articles recommending actual patient education never mention pharmacy involvement, other than highlighting pharmacies as a distribution point for patient information forms.[9,10] Likewise, no current recommendations delineate in-depth follow-up by pharmacists for patients receiving these agents. Simply focusing on the agents themselves[11] rather than the patients and their proper medication use is not likely to address the overdose problem, and may instead lead to suboptimal use in terms of undertreatment, given the extra scrutiny of these agents.

To have a positive impact, patient care pharmacists will need to be able to (1) identify patients at greatest risk of harm from their medications and (2) deliver a greater intensity of service to those patients at risk. A focus on optimal use of opioids is proposed as an important opportunity for community pharmacy.

Key Points

Background:

- Opioids are involved in a large number of misadventures.
- Current approaches are focused upon access control.
- Pharmacist involvement is not considered beyond distribution.

Findings:

- Contemporary community pharmacy practice likely contributes to opioid misuse.
- A new risk-based practice model is proposed to optimize opioid use.

Step 1: Identifying patients at risk

The therapeutic index (TI) is an approach to highlighting the risk of individual drugs. It is calculated using clinical therapeutic/toxic dosing ratios.[12] A medication has a low TI when a change of 20% or less in dose produces serious undesirable pharmacodynamic effects, such as increased adverse events, decreased efficacy, and/or excessive pharmacologic effects.[12] The U.S. Food and Drug Administration (FDA) has defined narrow therapeutic ratio as less than a twofold difference in either the median lethal (LD_{50}) and median effective (ED_{50}) doses *or* in the minimum toxic and minimum effective blood concentrations.[13] The FDA approach also makes the point that such agents would warrant careful titration and patient monitoring. Data from outpatient safety studies show that a relatively small number of low TI agents, most of which have been marketed for 20 years, are resulting in markedly increasing morbidity and mortality.[14–16] Among the top 10 agents resulting in fatal outcomes that were voluntarily reported to FDA from 1998 to 2005 were several analgesics, including oxycodone (#1), fentanyl (#2), morphine (#4), and acetaminophen (#5).

A formal risk-based approach now being applied to opioids is the Risk Evaluation and Mitigation Strategy (REMS).[9,17] This strategy highlights long-acting opioids as a subset of these agents that deserve additional attention at the time of prescribing. The REMS approach encompasses manufacturer provision of prescriber education regarding optimal patient management as well as patient informational materials. Pharmacy involvement in REMS is limited to distribution of patient medication guides.[17] However, provision of such print materials has not had a substantial impact upon patient education, and targeting REMS to specific drug categories may lead to underprescribing or shifting prescriptions to agents without such requirements.[9]

Step 2: Optimizing pharmacist involvement

Counseling rules are a state board of pharmacy requirement for ambulatory, outpatient, and community pharmacies, but the substance of such counseling is unclear. While counseling is a well-recognized risk reduction strategy, current studies of outpatient pharmacist coun-