

Virtual Mentor

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CLINICAL CASE

Labeling an Adverse Drug Event “Preventable”

Dan Blumenthal, MD, MBA

Dr. McKinley walks briskly into her office and consults her computer screen, then her watch. Way behind schedule, and it’s only 2 p.m., she thinks. A typical afternoon in her primary care clinic. She takes a swig of her coffee, peeks into the waiting room where six patients are sitting, and sweeps into exam room 2.

Mr. Chen is a 75-year-old man, recently emigrated from China, who speaks very little English. He has come with his adult son, who is proficient in English, for a follow-up on his high blood pressure. Mr. Chen’s son reports that his father has followed Dr. McKinley’s advice to eat less salt and exercise for 30 minutes a day. Because his in-office blood pressure is still elevated, Dr. McKinley decides to prescribe a low-dose beta-blocker. She carefully explains how to take the drug by halving each pill and asks Mr. Chen if he is taking any other medications, including complementary or alternative medicines. He hesitates, then says no. For a moment, Dr. McKinley wonders if her patient has told her the whole story and asks him again. He says no. She asks if he understands her instructions, and he says yes. Dr. McKinley leaves Mr. Chen and his son to tend to her next patient, who has been waiting for more than an hour with shaking chills and fever.

Mr. Chen goes home and begins taking his beta-blockers at twice the prescribed dose because he does not understand that he must halve the pills. As it turns out, he is also taking a Chinese herbal supplement that he does not believe Dr. McKinley would consider medicine. The double dose of beta-blockers, combined with the herbal supplements, causes acute hypotension, and Mr. Chen falls, breaking his hip.

Commentary

In *To Err is Human*, its 1999 landmark report on errors in health care, the Institute of Medicine (IOM) estimated that errors account for up to 98,000 deaths and 1 million preventable injuries in the United States each year [1]. The IOM report emphasized that lapses in patient safety are both common and costly and catalyzed efforts by many health care systems to identify and address errors and their underlying causes [2]. Nonetheless, recent evidence indicates that error rates have not declined appreciably in the decade since this report was published, and errors remain a significant cause of morbidity and mortality both in the United States and throughout the rest of the world [2].

While errors in ambulatory care environments have not been studied as extensively as those that occur in inpatient settings, approximately 1.2 billion outpatient

physician visits occur in the United States each year [3, 4]. Moreover, the available evidence indicates that preventable adverse drug events, including major medication errors like that in this case, are common in outpatient settings and lead to significant morbidity, mortality, and health care spending [3, 5-7]. Indeed, preventable adverse drug events occur far too frequently in our health care system. Mr. Chen's case affords an excellent opportunity not only to delve into the causes of and appropriate responses to adverse drug events in outpatient settings, but also to highlight a physician's ethical duties to prevent, report, and assist in addressing the root causes of errors in ambulatory care.

Terminology

An adverse event (AE) is an injury to a patient resulting from a medical intervention. AEs can be classified as preventable or unpreventable. A medical error, or preventable adverse event (pAE), is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" [8]. Errors can be further classified into errors of omission—which occur when a necessary action is not taken—or errors of commission, which result from an incorrect action [3]. Minor errors (or errors resulting in minor harm) are pAEs that lead to "prolonged treatment or [cause] discomfort"; major errors (or errors resulting in major harm) are those that cause serious disability or death [9].

An adverse drug event (ADE) is a patient injury due to a medication [5]. A medication error, or preventable adverse drug event (pADE), is "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" [10].

This definition does not provide objective criteria for determining the "preventability" of an adverse event. Because error classification can be subjective, some may question the morality of the labeling process. Consequently, they may be less willing to accept and admit that an adverse event was, in fact, preventable. Put another way, the fact that error classification is open to interpretation may lead a physician to feel more justified in denying that he or she has caused a preventable adverse event.

Medication Errors in Ambulatory Care

ADEs and pADEs are quite common in ambulatory care settings. According to a recent review of the literature on outpatient ADEs, the median incidence is 15 out of every 1000 person-months (the number of people in a study cohort multiplied by the number of months they were observed). Roughly 20 percent of ADEs are considered preventable and can therefore be classified as errors. Importantly, the majority of outpatient pADEs will lead to, or necessitate, hospital admission [3].

Mr. Chen's case draws attention to a diverse array of risk factors for, and causes of, errors in ambulatory care. These contributing factors can be broadly grouped into six categories: (1) patient-related causes, (2) physician-related causes, (3) medication-

related causes, (4) causes related to the health care delivery organization, (5) causes related to the health care system, and (6) causes related to health care professionals other than the patient's physician. Mr. Chen's case highlights at least three patient-related risk factors for a pADE: (1) Mr. Chen's use of an *undisclosed* complementary or alternative medicine (CAM), which increases his risk of suffering a drug-drug interaction; (2) his limited English proficiency (LEP), which heightens the risk of communication mishaps; and (3) Mr. Chen's age, which elevates his risk of suffering both preventable and unpreventable ADEs [11, 12].

Let's look at the physician-related risk causes of the error that Mr. Chen suffers. First, Dr. McKinley fails to adequately question Mr. Chen about his use of CAM. The ethical principles of nonmaleficence and beneficence dictate that Dr. McKinley must be sure that she has all information that she deems necessary and obtainable before making recommendations to her patients. While Mr. Chen's hesitation in answering Dr. McKinley's question about his use of CAM does give Dr. McKinley pause, she responds by repeating her initial question. Not surprisingly, she gets the same answer. Had she used a different approach to assess CAM use—by clarifying that CAM includes all herbal supplements, teas, foods that he believes have medicinal properties, and pills that are not prescribed for him by a physician or purchased in a pharmacy—Mr. Chen might have given her more information.

Second, while she asks Mr. Chen if he understands her directions about how to take his new medication, she does not *assess* his understanding by asking him to repeat her instructions back to her. Third, Dr. McKinley allows Mr. Chen's son to interpret for him, despite evidence (of which Dr. McKinley might not be aware) indicating that professional interpreters commit fewer interpretation errors than do ad-hoc interpreters, including those who are fluent in both English and the patient's preferred language [13, 14].

Dr. McKinley must give Mr. Chen her full and undivided attention during his visit. She must also fully consider, and do everything in her power to mitigate, potential harms that could result from her interventions. Yet Dr. McKinley must also balance her ethical obligations to Mr. Chen with similar ethical obligations to her other patients—one of whom is acutely ill. Striking this balance can be particularly difficult when concurrently caring for an acutely ill and a well-appearing patient. As healers, we, like Dr. McKinley, may feel as though a sick patient needs us more than a seemingly healthy one. We may even consciously or unconsciously reallocate our time between them accordingly. But, it is at these times that we must be most aware of the tendency to gravitate towards the ill and make doubly sure that in doing so we do not simultaneously violate our ethical obligations to the healthy.

Furthermore, the ethical principle of respect for autonomy dictates that Mr. Chen should make his own decisions about his care—including whether or not to continue drinking herbal tea while taking a beta-blocker, or to take twice the prescribed dose—as long as he is deemed competent to do so. Dr. McKinley's responsibility is to ensure that he is fully informed about, and understands, how to use a medication

appropriately and that he is aware of the potential benefits and risks associated with taking this medication. While we might assume that Dr. McKinley discussed these benefits and risks with Mr. Chen, the case does not clarify that this conversation took place. If she did not present the benefits and risks of beta-blocker therapy to Mr. Chen she would have violated his right to autonomous and fully informed decision making. Furthermore, by allowing Mr. Chen to leave her office without understanding how to mitigate the potential risks of this new medication, she would also potentially be undermining her own ethical obligation to do no harm.

Mr. Chen's medications—both new and old—contribute to this error as well. Beta-blockers and other “cardiovascular drugs”—including antihypertensives, antiarrhythmics, and digoxin—are implicated in ADEs more often than any other class of medications [6]. Other medication classes commonly associated with ADEs include diuretics, contraceptives, central nervous system medications (including antidepressants, antipsychotics, and antiepileptic medications), analgesics (including opioids and nonopioids), anti-infectives, hypoglycemics, and anticoagulants [3, 5, 6]. Of course, even if Mr. Chen had told Dr. McKinley about his herbal supplement, she might not have known about its effects on blood pressure and potential interactions with a beta-blocker.

Features of Dr. McKinley's organization most likely also contributed to this error. Dr. McKinley's workday is consistently hectic. While she may think that she has learned to cope with being overworked and running behind with patients, her tight schedule forces her to rush. Indeed, knowing that her next patient has been waiting “for over an hour with shaking chills and fever,” Dr. McKinley may well have made a conscious decision not to question Mr. Chen at greater length about his medication regimen, educate him more completely, or request a professional interpreter for Mr. Chen's visit. A recent survey of primary care physicians supports the links between physicians' work burden and patient safety in ambulatory care. In this study, a majority of clinicians surveyed strongly agreed that a “heavy workload” increases rates of medication errors [12]. It is also quite plausible that Dr. McKinley did not request a professional interpreter because her institution does not provide easy access to them. If she believes that her clinic schedule, or any other organizational factor, prevents her from providing the standard of care to all of her patients, she has an ethical duty to advocate for institutional changes that enable her to meet these standards.

Solutions

In retrospect, at least three actions *could* have prevented this adverse event. First, Dr. McKinley should have devoted additional effort to investigating Mr. Chen's use of other medications, including CAM. Dr. McKinley rightly recognizes that Mr. Chen's hesitation when answering her question about medication use is a sign that he may be using medicines that she isn't aware of. However, she fails to recognize or address the possibility that he doesn't fully understand what she means by “medicine” and “alternative medicine.” Dr. McKinley should define these terms for Mr. Chen and provide him with specific examples of a range of complementary and

alternative substances and activities. If Dr. McKinley is specific with Mr. Chen about the exact pieces of information that she is looking for, she can be more confident about his answers.

Second, instead of asking Mr. Chen if he understands her instructions about how to use the beta-blocker, Dr. McKinley should ask Mr. Chen to tell her exactly how he plans to use it. The difference between these two methods of assessing understanding cannot be overestimated; while the former strategy forces the physician to trust the patient's assessment of his or her own understanding, the latter tactic allows the clinician to evaluate the patient's comprehension of instructions. Given that the elderly are at high risk for ADEs, that beta-blockers are commonly implicated in ADEs, and that up to 65 percent of pADEs—and the majority of pADEs requiring hospitalization—originate at the time that a drug is prescribed, Dr. McKinley should not allow Mr. Chen to leave her examining room without demonstrating that he understands how to take the beta-blocker as prescribed [3].

Third, if professional interpreters are easily accessible, Dr. McKinley should request one for Mr. Chen's visit. Many physicians in Dr. McKinley's position would allow Mr. Chen's son to interpret for him, not only because he speaks English and because Mr. Chen does not appear to object to having him do so, but also because requesting an interpreter disrupts work flow. Indeed, even if a professional interpreter were accessible, Dr. McKinley may perceive that the costs of requesting and waiting for an interpreter exceed the benefits of using one in this case. Nonetheless, the evidence indicates that professional interpreters improve patient safety, and Dr. McKinley should attempt to use one if at all possible [14]. More than 8 percent of the U.S. population speaks little or no English, and federal laws mandate that doctors provide patients with free access to professional interpreters [13]. Thus, if interpreter services are not readily accessible in Dr. McKinley's organization, she must work with her colleagues and organization's administrators to address this critical systems-level issue.

Here again, Dr. McKinley must weigh her ethical responsibilities to Mr. Chen, and his ethical right to autonomous decision-making, with similar ethical duties to her other patients. If requesting an interpreter would disrupt her work schedule so greatly that it compromised her ability to care for her other patients, then Dr. McKinley may be ethically justified in not doing so. However, if Mr. Chen did not feel comfortable using his son as an interpreter, or if Dr. McKinley questioned the ad-hoc interpreter's ability to facilitate clear communication with Mr. Chen, then she is ethically bound by the principles of beneficence and nonmaleficence to use a professional interpreter. Indeed, Dr. McKinley is morally responsible for actions that Mr. Chen takes based on her recommendations and guidance.

In addition, Dr. McKinley could work with her organization to ensure that clinicians' busy schedules do not compromise patient safety, without, of course, compromising her ability to care for patients. If she anticipates devoting so much time to quality improvement and patient safety initiatives that she is unable to meet her ethical duty

to help all of her patients, she is morally responsible for finding an alternative, and equally effective, source of care for them.

While many primary care physicians would love to spend more time with each of their patients—and Mr. Chen’s case makes clear that spending additional time with patients can improve health care quality—financial, logistical, and demand-related realities prevent them from doing so. Physicians in ambulatory care practices must come up with thoughtful, systematic, and team-oriented approaches to ensuring patient safety in settings in which physicians’ time with their patients is limited. For example, computerized physician order-entry (CPOE) systems may reduce rates of ADEs, particularly those stemming from failure to identify drug allergies and drug-drug interactions and inappropriate dosing [4, 15]. Clinics can use nurses, pharmacists, and physician assistants to verify patients’ medication regimens, educate them about how to use a medication, and effectively evaluate patient understanding of these instructions. Some evidence also indicates that having pharmacists review clinicians’ prescriptions can reduce rates of ADEs [12]. These and other strategies for improving the quality of health care delivery in ambulatory care lie at the core of efforts to “reinvent primary care” around innovative delivery models like the patient-centered medical home [16, 17].

Responding to Errors in Ambulatory Care Settings

This case also raises at least two critical questions about the patient-physician relationship and the appropriate response to a preventable adverse event: what is the extent of Dr. McKinley’s duty to Mr. Chen, and how should she respond to this error? The ethical principle of nonmaleficence frames Dr. McKinley’s most basic obligation to Mr. Chen: to do no harm. The error caused Mr. Chen significant physical harm and mostly likely also precipitated emotional hardships, including depression, anxiety, or mistrust of his physician or the health care system. Thus, Dr. McKinley’s initial responsibility to Mr. Chen is to do everything in her power to remedy these harms and reestablish the integrity of their relationship. Dr. McKinley must be honest with Mr. Chen about what caused his fall and take responsibility for her role in this pADE [18]. Furthermore, the ethical principle of beneficence dictates that Dr. McKinley act to benefit future patients (including Mr. Chen)—to take appropriate steps to address the root causes of this error, a few of which were discussed above.

These obligations inform the actions Dr. McKinley should take. First, Dr. McKinley should express sympathy for Mr. Chen’s fall and broken hip. Second, she should disclose to Mr. Chen that his fall was probably caused by an interaction between his beta-blocker and his herbal supplement. She should also acknowledge and apologize for her failure to identify his use of herbal tea and his lack of understanding of how to use his beta-blocker. From an ethical perspective, disclosing and apologizing for a medical error is the most appropriate course of action [19]. Moreover, physician disclosure and apology has been shown to improve patient satisfaction, trust in physicians and the health care system, and the strength of the patient-physician relationship [18, 20]. Studies have shown that routine disclosure of medical errors

does not increase the risk of malpractice litigation and, in certain instances, may actually lower the likelihood that a patient will file a claim [20, 21].

Dr. McKinley should also report the error to her institution's patient safety committee or a patient safety organization (PSO). Error reporting helps to ensure the accuracy of institutional efforts to monitor error rates, facilitates efforts to address their root causes, and improves organizational learning from mistakes—all of which can help prevent future errors. Most hospitals and many clinics have implemented formal systems for reporting errors. Lastly, Dr. McKinley should work with her colleagues to identify any additional root causes of this error and to develop sustainable methods of mitigating the array of individual and systemic factors that precipitated it.

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Further Reading

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Dan Blumenthal, MD, MBA, is a first-year resident in internal medicine at Massachusetts General Hospital in Boston.

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