Reducing Adverse Drug Events From Physician Error

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During the calendar year ending 2001, more than 3 billion prescriptions for medications were written in the United States at a cost of more than $132 billion dollars.[32-34] Estimates project this cost to rise to more than $400 billion by the year 2014. The passage of the prescription benefit bill during the Bush II administration greatly increased these costs. The growing use and reliance on prescription medications presents American society with major health, public safety, and public policy dilemmas. The helpfulness and efficacy of many prescribed medications is unarguable. When used appropriately for the conditions indicated, pharmaceuticals can contribute to the quality of life. On the other hand, medications are not without risk.

Estimates of the annual cost due to increased harm from medication related injuries ranges from a low of $72 billion to a high of $172 billion.[32] The fact that the increased harm and costs from medications may actually exceed the total annual cost of medications themselves begs for further study. Fatalities from adverse drug events in the United States are estimated to exceed 100,000 people on a yearly basis.[35] Annual non-fatal injuries from Adverse Drug Events (ADEs) are estimated to be about 650,000.[35,36] These statistics are alarming, but they only represent fatalities and harm to those patients in hospital settings. Data for ambulatory patients is sorely lacking due to an absence of an enforceable policy for systematically reporting ambulatory ADEs.

It is important for all healthcare providers to be knowledgeable regarding adverse drug events associated with prescription medications. Psychology, as a health care profession, is no exception. Knowledge of ADEs is particularly important for those psychologists seeking prescriptive authority. Knowledge on the types and incidence rates of ADEs also can shed light on whether medical school training is a necessary prerequisite to safely prescribe medications as argued by opponents of non-physician prescribers. Medical studies have long been concerned with patient safety related to the use of medications.[37, 38] The Harvard School of Public Health conducted one of the first studies to look at ADEs associated with prescription medications.[39] This Harvard benchmark study was a first attempt at trying to quantify the types and incident rates of medication errors in a large population of hospitalized patients. In a sample of more than 30,000 hospitalized patients, they concluded that medication errors were associated with serious outcomes that negatively affected patient safety. Overall, they found that

adverse events from medications comprised about 20% of total errors.

All prescription medications approved by the US Food and Drug Administration (FDA) are for specific purposes. Most medications are of little use outside their stated purpose, although many medications are used "off label" with little or no data to support their use.[40] Cardiovascular, gastrointestinal, endocrinological, antibacterial and hematological drugs are examples of medications that have little or no use for conditions other than purposes for which they are approved. These classes of medications comprise the greater share of fatalities and serious ADEs.[41-43]

The FDA delineates two types of drug related adverse events. Type A ADEs are harms resulting from prescription medication errors and other avoidable errors. Harms can range from a simple and minor rash to death. Type B ADEs are harms not related to errors but to the unique response of the patient to the drug, e.g., anaphylactic shock. "Undetected hypersensitivity or unknown inherited response to a medication" comprise this category of ADEs. The types of errors described in studies reporting on ADEs seem to change very little from year to year.[44, 45]

Prescribing of the wrong dose or the wrong medication, even when known allergies to a medication exist, is a major problem. Overdosing is another serious problem. When errors such as these occur time and again, chance occurrence is not a viable explanation.[46] In response to the escalating ADE problem, many hospitals have implemented ADE reduction programs such as using pharmacists to review physician medication orders.

A review of physician orders by pharmacists in order to provide medication counseling on all new prescriptions is now required by Medicare. This federal requirement has resulted in pharmacists being granted limited prescriptive authority in more than 40 states. Many of these prescription review programs have reduced ADEs associated with the types of errors presented in the cited studies.[47,48] There are many variables that can explain ADEs, e.g., physician distraction, workload, unfamiliarity with a specific medication. Specific training on ADE pitfalls in all pharmacological training is recommended for safe prescribing.

The Institute of Medicine (IOM) of the National Academies of Sciences performed a comprehensive investigation of medical errors and published this landmark study as To Err Is Human (2000).[34] One of the major findings of that study was that annual fatalities from medication errors surpassed deaths from

motor vehicle accidents (43,458), breast cancer (42,297), and AIDS (16,516). Many of the findings and conclusions of this study, however, have been challenged.[49,50] Generally, these studies dispute both the incident rate and seriousness of ADEs cited in the IOM study. Acknowledging that some of the findings on ADEs may be overstated, the IOM study sheds much light on the risks associated with current prescribing practices.

Classes Of Medicines Most Related To Injury And Harm To Patients

Opiate and cardiac medications contribute the greater share of all ADEs and fatalities.[51,52] Available data suggests that the risks of ADEs associated with psychotropic medications may be far less than those of drugs used for other disorders but nonetheless potentially dangereous.[53,54] Although the data cited in many studies is more than 10 years old, the more recent studies generally are consistent with the earlier studies.

In the year ending 2000, more than 16,000 deaths from gastrointestinal complications were attributed to non-steroidal anti-inflammatory drugs.[43] In addition, several thousand more deaths involving cardiovascular complications also were attributed to this same class of medication, which is used to treat common inflammation.[48] Increasingly, we see psychotropics being used for conditions for which they are not approved and with populations never intended. Psychotropic drugs are often used by managed care organizations as a less costly substitute for psychotherapy. Weight loss, dermatological problems, student behavioral control, autism, inappropriate behavioral restraint, podiatry, pain management, and in dentistry, are examples of applications not indicated by research or, in many cases, by logic. Antidepressant medications are being prescribed for an ever- expanding catalog of newly created problems.[55,56] Uses of these medications, like many medications, go beyond those initially indicated and their use becomes more questionable.

Newer atypical antipsychotic medications, for example, are finding even greater use for non-psychotic conditions such as insomnia, and with children[57], who are populations generally excluded from drug trials. The incidence rates of injury and hepatotoxicity from psychotropic drugs are an area that physicians need to be concerned and remain alert about when prescribing these drugs. The standard of care requires baseline blood tests, which should be repeated to insure against liver and kidney damage. However, few primary care physicians follow these requirements. Greater risk to patients from psychotropic medications occurs when these types of medications are prescribed by medical

professionals who are not specifically trained in clinical psychopharmacology, and in the diagnosis and treatment of behavioral disorders.

An analysis of ADE studies, including fatalities, associated with psychotropic medications shows that psychotropic medications need strict monitoring when prescribed alongside other drugs.[58-60] These studies show that opiates, cardiovascular and non-steroidal anti-inflammatory drugs (NSAID) medications comprise the greatest share of serious ADEs. Clozaril, a drug used to treat schizophrenia in a population of treatment resistant patients, registers about 10-15 fatalities for every 10,000 patient years.[58] This is why behavioral healthcare requires that patients be seen for follow-up care while on psychotropic medications. Primary care physicians do not have the time or inclination to provide this care.

The intention here is not to scare, but to warn of the potential harms that can result from the inappropriate use of psychotropic medications. When ADEs do arise from the use of psychotropics, they can be attributed to prescribing the drug for the wrong populations, errors in the prescriptions[31] and to the inherent uniqueness in response of the patients receiving them. A few studies have provided some insight into the classes of drugs most associated with ADEs in hospitalized and outpatient settings.

Medical School Is Not The Most Effective Way To Reduce Prescribing Errors

Steel [61] argues that many ADEs are related to limited medical training in pharmacology and calls for physicians to be licensed to prescribe medications only in their specialty. Wiggins & Cummings[62] reported 1 million episodes of mental health care where psychologists with documented training in psychopharmacology managed both the combined use of psychotherapy and psychotropic medications without patients' complaints of how psychologists dealt with their medications. Several studies of the effectiveness of prescribing psychologists in the military show that they perform safely and with high standards.[63] These data suggest that the greatest danger to patients may not be a function of who prescribes but the content and quality of training one gets to learn how to prescribe.[64,48,39] Thus, the available data does not support the broad assertion that medical school education can fully prepare physicians to prescribe safely.

Physicians need to go beyond medical schools' more limited training experiences in pharmacology by focusing greater attention on preventable ADEs. Given what we know about many of the causes of ADEs, specific training recommendations can easily be implemented to significantly reduce Type A ADEs. One positive recommendation would be to provide training in drug-drug interactions between drug classes. With more than 8,`000 medications now in general use, it is almost impossible to recall specific drug-drug interactions between single medications. Since most medications in a class behave similarly, this could reduce ADEs. For example, generally, non-steroidal medications (NSAIDS) can have serious drug-drug interactions with anti-hypertensives. Knowing this can alert physicians to this interaction and would require a more detailed look into specific drugs that are being considered in these classes. Conversely, a more thorough understanding of the patient would reduce errors resulting from polymorphisms and other significant pharmacodynamics.

We now have available very detailed, but easy to use, computerized pharmacology. These programs are easy to update and take very little time to master. In cases in which multiple medications are being used, performing a simultaneous drug-drug interaction search can take seconds. Pharmacology programs should train in their use and require students to acquire and use this technology. Yet, many physicians resist newer technology and still use written prescriptions which are difficult to read and cause many errors.

Many ADEs occur due to prescribers writing an incorrect dose of a medication. For example, medications, such as Levoxyl, a thyroid hormone substitute, must be prescribed in microgram doses. This drug is responsible for a significant number of ADEs with serious consequences simply because the prescriber writes the dose as milligrams. Reducing this type of ADE can be accomplished simply by providing training in dosing arithmetic similar to that required of nurses and physician assistants. Along this line, ADEs related to writing errors, which bad handwriting is the cause, can be significantly reduced by eliminating hand written prescriptions. Students who are trained from the beginning to order prescriptions in type will tend to use this method when they gain authority to prescribe.

Clearly, prescribing medications requires skills that must start with early training. As in many professions, there are those who may lack the skills needed to correctly and competently perform tasks.[65] Training that addresses ADEs is not prominent and included in the core subject matter of the majority of medical schools.[66] While this type of training may not guarantee the competence of any one prescriber, without specific training in ADEs, we may invite only more ADEs and their consequences.

Medical psychologists are in the unique position of being a positive factor in reducing ADEs while at the same time providing behavioral health services effectively and efficiently. General practitioners and other non-psychiatric physicians are neither mental health specialists nor psychopharmacologists. Commenting on a recent study on ADEs, Steel,[61] in his article, advocates that non-physicians and sophisticated computer systems need to be part of the prescribing process if ADEs are to effectively be controlled.

Concluding Statements

Collaboration between psychologists and physicians can result in more effective and safer treatment for behavioral health patients by reducing ADEs. Their knowledge of ADEs, pharmacological training, and the practice by psychologists to spend as much time with patients to develop working differential diagnoses, allow them to promote higher-quality behavioral healthcare, while being a conduit to physicians about their patients condition. With better treatment comes efficiency and a significant reduction in overall health care costs.[72-74] The Therapy in America Survey [71] reports that an estimated 59 million people received some form of mental health treatment in the two years reported on in the study. However, an estimated 24 million people received no treatment, even though they reported having symptoms severe enough to warrant a diagnosis and treatment.

Patients experiencing depression and seeing a general practitioner are often undiagnosed or misdiagnosed. McGynn[3] reports that only 53% of patients with depression receive an adequate standard of care; their symptoms go untreated or they are given medications for something they may not even need. Misdiagnosis, inappropriate medications, insufficient training in mental disorders, and poor pharmacology skills can all increase the likelihood of ADEs. Suicide rates among people who are not being seen by a mental health professional are several times greater than those patients receiving treatment.[75,76] Psychologists can fill a significant gap in behavioral healthcare by prescribing psychotropic medications, when appropriately indicated, and providing related psychological services.