

No quick fix for drug errors, but it can be done

By Joel B. Finkelstein

Five years after the Institute of Medicine released its last report on drug errors, a new report shows we still have a long way to go before the problem is corrected. What the Federal government is doing, and what you can do too.

Recently, the Institute of Medicine (IOM) released a follow-up to its 2001 report "To Err Is Human." This latest report has refocused attention on what still needs to be done to reduce the rate of drug errors and adverse events.

The new patient safety report, "Preventing Medication Errors" (part of the "Quality Chasm" series), calls on both the medical community and Federal agencies to speed up the process of adopting established methods for preventing errors when prescribing and administering prescription drugs. It also urges patients to become more involved in their own care and more proactive when it comes to informing their physicians about all the medications they are currently taking. See www.nap.edu/catalog/11623.html.

The IOM's Committee on Identifying and Preventing Medication Errors estimated that each year there are at least 1.5 million preventable drug-related injuries in US hospitals, long-term care facilities, and outpatient clinics.

Because that estimate was based on data collected only by those institutions and the Medicare program, the true scale of the problem is likely much larger, says panel co-chair, J. Lyle Bootman, PhD, ScD, executive director of the University of Arizona Center for Health Outcomes and Pharmacoeconomic Research in Tucson.

"The current process by which medications are prescribed, dispensed, administered, and monitored is characterized by many serious problems that threaten both the safety and positive outcomes we hope to achieve when we serve patients," Dr. Bootman said during a recent press briefing. "Each of the steps in the process needs improvement and further study."

What community practitioners can do

The IOM report lays out a number of recommendations for community physicians. Near the top of that list is switching to e-prescribing. Albert Wu, MD, a member of the IOM panel and a professor of health policy and management and internal medicine at Johns Hopkins University in Baltimore, says that when writing prescriptions, "It no longer makes sense for cancer specialists to be calculating drug dosages on the back of an envelope." Electronic record systems and related technology are crucial to ensuring that oncologists have the information they need on patients or drugs they are prescribing and at the point of service, Dr. Wu told *Community Oncology*.

There are several low-tech recommendations for physicians as well, such as simply gathering more and better information. "Patients need to speak up and physicians need to listen actively," says Dr. Wu. "There is too much of an opportunity for confusion about drugs. You need to make sure

that what you are prescribing is what the patient is actually taking, and in the correct dosage."

The IOM report advises that patients, or their family caregivers, should maintain an active list of all prescription and over-the-counter drugs and dietary supplements they are taking, the reasons for taking them, and any known drug allergies. "Every provider involved in the medication-use process for a patient should have access to this list," the report authors advise.

Attitudes will also have to change, says Dr. Wu. "Physicians need to adapt and figure out what they can do better. One of the conclusions of the earlier IOM report was that we cannot make patients safer simply by working harder. We need to work smarter too."

According to the IOM report, many adverse drug events are the result of a lack of knowledge about the effect of a medication in particular patients. The authors recommend that drug companies and researchers conduct more studies in special populations, such as children and seniors, so that physicians have enough information about what to expect when prescribing medicines, especially given widespread use of off-label prescribing.

One survey of cancer specialists found that 60% have prescribed drugs approved for a different disease, at a different dosage, or for a different schedule. Another study shows that one-third of cancer-related prescrip-

tions were off-label and more than half of cancer patients received off-label prescriptions.

Drug safety legislation

The Federal government needs to play a role in ensuring that physicians are provided with relevant data and safe drugs, the IOM report says. A few lawmakers have heeded that call with the recent introduction of drug safety legislation in Congress.

“The Enhancing Drug Safety and Innovation Act will raise the bar to ensure that drug safety is not an afterthought, but an integral part of the process from the very beginning,” said Sen. Mike Enzi (R-WY) in a statement to introduce the bipartisan measure which he is cosponsoring with Edward Kennedy (D-MA). “It requires drug makers to engage in better safety planning before a drug is approved for release to the public and will improve both the understanding of and response to risks that arise after a drug is on the market.”

Under the bill, the US Food and Drug Administration (FDA) would

approve drugs and biologics only when a risk evaluation and mitigation strategy is in place. The drug maker and FDA will review the strategy annually for at least the first 3 years. At a minimum, this strategy would have to include:

- FDA-approved professional labeling;
- regular reporting of adverse events;

- a surveillance plan to assess known serious risks and to identify unexpected serious risks;
- a timetable for periodic assessment of the strategy.

“Safe and effective use of medications requires that we all do our part, from the patient right up to the regulators and everyone in between,” says Dr. Wu.
