An Easy Pill to Swallow
A simple approach to improve medication safety

by Vincent Barba, M.D.

Even though much has been written and spoken about quality healthcare, most of us are pressed to define what it is and how to measure it. The Institute of Medicine (IOM)\(^1\) defines quality healthcare as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

In the clinical realm, quality healthcare is comprised of six dimensions:\(^2\)

- **Patient safety.** Freedom from injury due to medical care and protecting patients from harm.
- **Effectiveness.** Efficient care is evidence-based.
- **Patient-centered.** The patient is the most important member of the healthcare relationship. We must continually ask: Is care delivered in a patient-centered fashion? Does the system place the patient at the center of every equation in designing the delivery of care? What does the patient value as we evaluate processes and outcomes
of care? Involving patients and educating them about the dynamic nature of their own health issues is crucial to success.

- **Timeliness.** Care should be delivered in a timely manner. Much of our patients’ frustration with the healthcare system is related to treatment and testing delays.

- **Equitability.** Healthcare should be consistent regardless of the patient’s ethnicity, gender or payer status.

- **Efficiency.** Is the care delivered in a way that avoids waste? Now more than ever we must eliminate waste from processes.

Patient safety is paramount in our quest for high quality and reliable healthcare. As caregivers, we struggle with an inconvenient truth: Humans make mistakes. No human performs perfectly 24 hours per day, seven days a week. Unfortunately, perfection is expected of physicians and nurses. Such unrealistic expectations lead us to use a system of training and punishment that operates under the myth of perfect medical performance. The goal is not attainable, yet we perpetuate this myth day after day. The myth also precludes us from properly examining the systems issues that fail to protect patients from human error.

A medical error 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...including problems in practice, products, procedures and systems.”

Even after more than 10 years of national effort, medical errors persist at alarming rates. A group of investigators reported there were approximately 37,600,000 annual admissions to 5,000 U.S. hospitals. Using the IHI Global Trigger Tool method, they estimated there were 49 adverse events per 100 admissions. That amounts to 18,424,000 adverse events annually in the United States.

That astonishing number alone should motivate us to action. However, productive improvements in this area have been slow.
In 2000, IOM attributed up to 98,000 deaths annually due to medical errors in the United States.\textsuperscript{5} Poor patient safety costs an estimated $17.1 billion dollars per year. Pressure ulcers are the most common adverse event. Medication-related adverse events are reported to occur more than 38,000 times annually and result in approximately 778,000 injuries.\textsuperscript{6}

In 2007, researchers reviewed literature to assess the incidence of preventable adverse drug events (ADE) in the ambulatory care arena. The incidence rate was reported to be 5.6 out of every 1,000 person months with an ADE preventability rate of 21%. The incidence of preventable ADE requiring hospitalization was noted to be 4.5 out of every 1,000 person months. Inadequate therapy monitoring was the main culprit of hospital admissions.\textsuperscript{5}

A cohort study of Medicare enrollees by a multispecialty group practice was published in 2003. It reported that the rate of preventable adverse drug events was 1.2 out of every 1,000 person months.\textsuperscript{6}

Patients are harmed every year because of poor medication safety practices. In order to improve this, many strategies have been deployed to avoid errors that lead to harm. All hospitals accredited by the Joint Commission must have a process for reconciling medication across the continuum of care for all patients. This safety goal has proven difficult to accomplish and the Joint Commission has revised it once already after suspending the measurement for a year.

**Three simple rules**

Many patients take more than one medication. The more medication a patient takes, the higher the risk of an adverse event. The three simple rules outlined in Table 1 are proposed to enhance
patient safety in the clinical practice setting when prescribing or evaluating a patient’s medications.

Table 1:

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<th>Three Simple Rules for Medication Safety</th>
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<td>1. Any medication prescribed must be clinically effective.</td>
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<td>2. Any medication administered must be safe for the patient to use.</td>
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<td>3. The therapeutic plan developed by the clinician with the patient must be followed.</td>
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If these rules were applied when treating every patient, every time, we could reduce the possibility of medication errors due to drug interactions and the use of the wrong treatment plan. Of course, this is predicated upon making the right diagnosis first. The three simple rules are the cornerstone of medication safety. These fundamental principles can be deployed using a communications-based approach that assures safety even after the patient leaves the clinician’s hands.

A step-by-step guide to medication safety

1. **Know your patient.** Medication safety begins by obtaining a complete medical history from the patient. This includes collecting information about allergies, how the patient has reacted to drugs and a complete list of medications the patient self-administers. When documenting patient history, the clinician must inquire about oral supplements and over-the-counter medications in addition to prescriptions. Patients may neglect to report medically significant nutritional and nutraceutical preparations they may be using. A complete history is an essential first step.
2. **Ask the right questions.** Evaluate each medication as it relates to the patient’s known medical history and follow the three simple rules by asking the following questions:

- Is this medication clinically effective for this problem we are attempting to treat?
- Is it safe for the patient to be taking this medication?
- Is the patient using this medication properly or at all?

These three simple questions get to the heart of quality care. In 2003, researchers reported that only 55% of patients receive appropriate care. By asking these three simple questions, each clinician can ensure their patients are being appropriately managed in each visit. In greater detail, let’s examine why this approach is effective.

**Is this medication clinically effective for this problem we are attempting to treat?**

The first question revolves around the clinical effectiveness of drug therapy. Is there evidence that this medicine treats the targeted condition and has desirable outcomes? The clinician should wonder, “Is this the best treatment for my patient? Will the mortality and morbidity be decreased by this treatment? Will other outcomes improve because of this drug?”

**Is it safe for the patient to be taking this medication?**

The second question delves into the inherent safety of the drug. It prompts the clinician to consider the following:

- What are the potential side effects and adverse reactions?
- Will this patient experience the known side effects or adverse reactions?
- How can we prevent these adverse events?
• Will this drug have an effect on the other medicine the patient takes?
• What will be the result of the medication interactions?
• Would possible adverse events be life threatening or require an emergency room visit?

Also considered in the second question is that the correct dosing is administered. The right drug in the wrong dose can be very harmful.

*Is the patient using this medication properly or at all?*

The third question is key to a proper therapeutic relationship. Have you connected with your patient in a way that ensures that they will follow the plan you have developed for them? Building trust into the clinician-patient relationship is the secret to success in providing safe and effective care.

Communication is at the core of rule three. Did you discuss drug therapy plans in detail and gauge the patient’s understanding of the implications for this therapy? Have you discussed the side effects and possibility of adverse events? Have you instructed the patient about what to do if adverse events develop?

Compliance usually depends on the tolerability of the drug or the cost. Discussing these matters up front may help alleviate the possibility of noncompliance. This also helps set expectations about the planned treatment so the patient can properly make important decisions about their care in an informed manner.

3. **Make information useful.** The next step toward medication safety is to edit the current list of medications in such a way that is useful to the next provider of care, ensuring that
no information is lost. For instance, it is useful to know that last year, Mrs. X was taking naproxen for her knee pain but stopped because she developed heartburn symptoms.

4. **Assess medication interactions.** It’s estimated that more than 27% of hospitalized patients develop a drug-drug interaction. The most common adverse effects are an increased risk of bleeding, hypotension and nephrotoxicity.⁸

All medications must be cross referenced in order to make an educated decision as to the risk and benefit ratio in continuing treatment as planned or changing the plan.

5. **Cross check the list.** Once the clinical encounter is over and a treatment plan has been developed, the clinician must reconcile the medication list to include any new or changed prescriptions. New medication must be cross checked with the existing list to examine it for drug-drug interactions and contraindications.⁹

6. **Information sharing.** A complete list of the medications the patient will take after the visit should be provided in written form with instructions to share the list with their pharmacist and other clinicians they may be visiting, including optometrists, dentists, chiropractors, physical medicine therapists and other clinical providers such as visiting nurses.

Patients should be encouraged to ask questions when speaking to clinicians and pharmacists. They should ask about side effects and drug interactions as well as compliance issues. Coach patients to ask questions such as: “What should I do if I miss a dose?” “How will this medication interact with my other pills?” “Are there any symptoms that should prompt me to stop this medication at once?”
Patient safety is a major public health threat and it’s responsible for thousands of deaths that cost billions of dollars annually. Medication errors account for over 700,000 injuries every year in the United States.

Following the three simple rules of medication safety by asking three simple questions for each medication a patient takes can improve the quality of care. This low-tech, back-to-basics solution to the complex problem of medication safety should have broad appeal to practicing clinicians. The major barrier to its implementation and use is the time clinicians have available to spend with patients.

Open communication between clinicians, patients and pharmacists is essential to the transformation of healthcare. It is the foundation of a safe enterprise that is able to reliably deliver the care our patients need consistently and effectively. Keeping in mind that only 55% of patients receive appropriate care, we must take every step necessary to deliver evidence-based care in a safe, timely and patient-centered manner that gives adequate consideration to cost and equitability. The application of just three simple rules should go a long way in improving medication safety.

About the author

Dr. Vincent Barba, M.D., is chief quality officer for the University Hospital and the New Jersey Medical School in Newark, NJ. He is a faculty member at the New Jersey Medical School and serves as an assistant professor in the medicine and preventive medicine faculties. Barba is a certified professional in patient safety and a fellow of the Society of Hospital Medicine and the American College of Physicians. He is a board certified internist who both teaches and practices hospital medicine and ambulatory care.
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