Testing Patient Comprehension of Medication Labeling Is Important

To the Editor Diamantouros and colleagues’ addressed the need to improve written drug information for patients. They specifically assessed the content and reading level of drug information that patients commonly receive with their warfarin prescriptions. We applaud the authors’ efforts to further understand the complex nature of communicating balanced information to patients who receive high-risk medications with a narrow therapeutic index. Budnitz et al reported that nearly 100,000 older Americans are hospitalized for adverse drug reactions every year and that most of these emergencies relate to 4 common medications, including warfarin.

We recently conducted consumer research to evaluate patient-friendly prototypes for 3 prescription drugs, one of which included warfarin sodium (Coumadin; Bristol-Myers Squibb Company). Our study solicited consumers’ preferences about formatting of information, their motivation to read drug information, and their ability to navigate and understand the information. Consumers preferred a single page of simplified written drug information and correctly answered more questions about a medicine when information was presented in a patient-friendly format that incorporated simple, clear statements in lay terminology.

A main goal of providing patients with written information is to help them understand how to safely and effectively take their medicines. Creating and testing patient drug information can help achieve this goal. Patient information must be simple, friendly, and easy to navigate. Leaflets should include simple, clear statements in lay terminology that are easy to follow. Consideration should also be given to the target population for the drug (eg, age, sex, medical conditions), ordering of information, and prominence of information. Notably, in our study, simple and familiar icons helped consumers find important information.

Other studies also demonstrated that simple list formatting improves patients’ understanding, recall, and speed of accessing information in comparison with paragraph format. Furthermore, health literacy experts advocate for patient information that meets the “fire drill test” or the ability to read and understand information if a fire drill goes off in the building. The principle is that patients must be able to find information and take the appropriate actions (eg, stop drug therapy, call your physician).

In closing, involving consumers in the development of simple and clear drug information is pivotal to making sure that the right information gets to the right patient at the right time.

In the words of Martin Fischer, a German-born physician and author, “Knowledge is a process of piling up facts; wisdom lies in their simplification.”

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Cardiac Arrests During Endoscopy With Anesthesia Assistance

We would like to compliment Cooper et al on their recent study; however, the issues of using propofol during endoscopy go beyond their findings. Propofol, when used for deep sedation in gastrointestinal (GI) endoscopy, can lead to airway obstruction and apnea. Airway-associated complications are responsible for approximately 30% of all perioperative deaths during deep sedation provided in remote locations. With improvements in diagnostic and therapeutic techniques, anesthesia requirements at remote locations have increased. The reported incidence of cardiac arrests during general anesthesia is approximately 5.5 per 10,000 patients. Similarly, values for spinal and regional anesthesia are 1.3 to 1.8 and approximately 1.5 per 10,000 patients, respectively. Inevitably, sedation provided at remote anesthesia locations is also subject to complications, including cardiorespiratory arrests.

The Hospital of the University of Pennsylvania has seen a 300% increase in GI endoscopy procedures performed with anesthesiologist-provided sedation over the last 4 years. With this in mind, after institutional review board approval, critical incidents in patients undergoing GI endoscopy with anesthesia assistance from September 8, 2008, to March 26, 2012, were reviewed, with an objective of learning the possible events leading up to such incidents. A total of 8102 (78%, esophagogastroduodenoscopy with ultrasonography; 8.2%, endoscopic retrograde cholangiopancreatography; 2.2%, sigmoidoscopy; 1.2%, esophagogastroduodenoscopy with tumor ablation; and 10.4%, miscellaneous) endoscopic procedures were performed. The case records of patients who had cardiac arrests were studied in detail. There were 2 brief cardiac arrests with immediate resto-
ration of ventilation and circulation under the supervising anesthesiologist’s direction (Table). Both patients were transferred to the emergency department for monitoring with uneventful discharge.

Despite significant advancements in airway management, airway difficulties resulting in inadequate ventilation and oxygenation remain the most common cause of cardiac arrest in patients undergoing outpatient GI endoscopy under propofol administration. Our study estimates a cardiac arrest incidence of approximately 2.47 per 10,000 procedures. Often, cardiac arrests in adults are attributed to primary cardiac causes. However, in GI endoscopy, difficulty in titrating sedation with propofol leads to respiratory complications, which lead to cardiac events. Furthermore, capnography is not reliable in detecting apnea, especially during upper GI endoscopy, because of carbon dioxide used for insufflation.

Our incidence of cardiac arrests is higher than previously reported (0.7 per 10,000 procedures) for monitored anesthesia care and adds to the findings of Cooper et al. The possible reasons for an increased incidence of cardiorespiratory arrest over past reports could be the increasing use of propofol (which has a narrow therapeutic window), complexity of procedures, and increasing comorbidity.

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In Reply We thank Goudra and Singh for their interest in our study of complications following anesthesia assistance for colonoscopy. Their findings of a 3-fold increase in the use of anesthesia-assisted endoscopic procedures are certainly consistent with our results in Medicare beneficiaries as well as in privately insured individuals. Although our study could not directly measure patient severity of illness and instead included a validated claims database comorbidity index, other studies suggested that much of the increase has been in patients at low risk for adverse events with conscious sedation.

The specific complications that we selected could be attributed in part to the depth of sedation and thus did not include measures such as polypectomy-related perforations and hemorrhage and, as reported by Goudra and Singh, cardiac arrest. With the ability to access to medical records, they were able to directly attribute 2 cases of cardiac arrest to the use deep sedation. Although the absolute number of serious complications is low, their findings reinforce the need to carefully balance the benefits of propofol, in terms of a potentially better patient tolerance and postprocedure recovery, with the harms, in terms of costs of care and a potentially greater complication risk.

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