

important to disclose risk information, overwarning without appropriate context is not helpful. Prescribers ignore vague, difficult-to-interpret warnings, even for risks that have been deemed serious.<sup>3</sup> In addition, dizzying lists of all known and theoretical ADEs, regardless of severity, frequency, or causality may discourage prescribers and patients from using a valuable drug. As proof, risk communications have been shown to reduce prescribing of drugs, often with poor health outcomes.<sup>4,5</sup>

The FDA guidance document on the presentation of information in the “Adverse Reactions” section of the drug label offers a framework for selecting, characterizing and organizing adverse event information.<sup>6</sup> The document suggests that ADEs that occur at the same rate as placebo, should generally not be included. Vague terms such as “common,” “rare,” “infrequent,” or “frequent” should be avoided unless linked to specific frequencies. An example of a specified frequency for “common” ADEs would be those that occurred in at least 10% of treated patients and at a rate at least twice that of placebo. Furthermore, ADEs should be reported in a hierarchical manner, with those that occurred with higher frequency first, followed by those that caused therapy discontinuation and those that occurred with lower frequency but were serious (eg, fatal, life threatening, or caused or prolonged hospitalization). In all cases, only those ADEs for which there is plausible causality should be included.

Since these guidances are not legally binding, it is not known to what extent drug labels follow these recommendations. A consistent approach to the selection and risk characterization of ADEs in the drug label is needed, particularly with the documented proliferation of ADEs that now reside in the drug label. At the minimum, drug labels should present ADE information in a standardized format using common terminology and definitions so that health care providers can systematically process and manage the deluge of clinical data. The recommendations set forth by FDA guidance documents provide an excellent starting point.

As with all quality health care improvement initiatives, a validation process for drug labels linked to outcomes—including health care provider comprehension, perception of drug benefits, and risks and usability—as a decision-making tool are needed. The information within the drug label must receive regular, rigorous evaluation for currency and clinical relevance to health care providers of varying background, training, and experiences. While studies exist evaluating modes of effective risk-benefit communications to patients, little has been published regarding communication of drug information to health care providers.<sup>7-9</sup> Responsible oversight on the development and revision of drug labels is necessary to ensure the effective delivery of unbiased, comprehensive, accurate, up-to-date, and user-friendly drug information.

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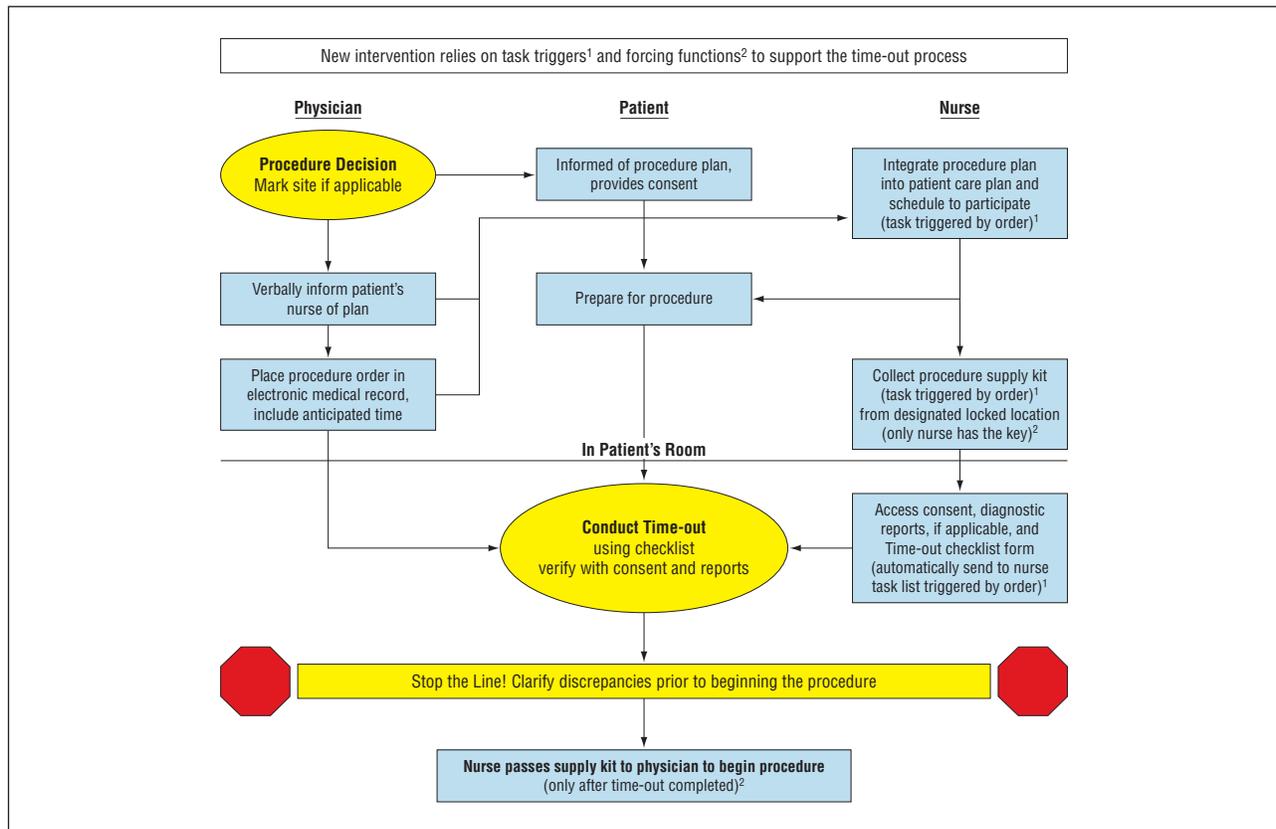
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### Process Changes to Increase Compliance With the Universal Protocol for Bedside Procedures

**W**rong site, wrong procedure, and wrong patient events can be devastating to patients. Between 1300 and 2700 such events are estimated to occur annually in the United States.<sup>1</sup> These are also called “never events” because processes can be implemented to prevent them.<sup>2</sup> In 2004, The Joint Commission (TJC) created the Universal Protocol (UP) as a mandatory safety standard in an attempt to eliminate wrong procedures through a preprocedure verification process, procedure site marking, and a “time-out” (correct site, procedure, and patient).<sup>3</sup> Up to 70% of wrong site procedures may be prevented if the time-out process is used.<sup>4,5</sup>

Although a number of publications have documented successful interventions for improving compliance with the UP in the operating room,<sup>6-8</sup> to our knowledge there are no data on compliance with this protocol for bedside procedures. In fact, wrong site/wrong patient events outside the operating room constitute a significant problem and result in substantial harm.<sup>2,4</sup> We developed an innovative reengineered process for bedside procedures with an aim to improve compliance with the UP.

**Methods.** This pre- and postintervention study focused on medical inpatient bedside procedures (lumbar puncture, paracentesis, and thoracentesis) at a large academic medical center from July 2008 to May 2010. The Northwestern University institutional review board determined this project exempt.



**Figure.** Verification process to ensure correct site, procedure, and patient, every time.

**Process.** As part of a quality improvement project, we redesigned our approach to bedside procedures incorporating TJC's UP. Using medical record review and billing data, an improvement team assessed staff compliance with the time-out process and identified the most frequently performed bedside procedures. The team also identified drivers of time-out noncompliance: a knowledge deficit of the UP and a primary communication gap because nurses were not notified when their patients underwent a bedside procedure. Time-outs relied completely on physician memory and vigilance, which is ineffective for successful process compliance.<sup>9</sup>

To address these issues, we implemented a physician-initiated process that incorporated task triggers, a forcing function, performance feedback, optimized use of the electronic medical record (EMR), and improved efficiency through supply design—elements that have been recognized in successful process change.<sup>9</sup> The new process begins with the physician's decision to perform the procedure (**Figure**) and placing a procedure order in the EMR (Powerchart; Cerner Corporation, Kansas City, Missouri), specifying the anticipated procedure time. The nurse, who receives electronic notification triggered by the order, can plan time to participate. The order triggers the delivery of a time-out documentation form to the nurse's electronic task list and also notifies the nurse to collect the appropriate procedural supply kit.

Cost-efficient all-inclusive procedure kits for lumbar puncture, paracentesis, and thoracentesis were developed. Procedure kits are secured (only the charge nurse has the key), constituting a forcing function and requir-

ing physician-nurse communication. As reinforcement, each procedure kit contains a large red "stop sign" reminder to perform a time-out.

At the scheduled procedure time, the nurse accesses the time-out checklist in the EMR at the bedside. Together, the physician and nurse conduct the time-out, verifying the correct site, procedure, and patient. After the nurse documents the time-out, the supply kit is passed to the physician. Medicine nurses, residents, and hospitalists were trained on the new process during educational sessions, staff meetings, and monthly physician unit orientations. The process was tested and implemented on seven 30-bed medicine units from May to August 2009.

**Measurement.** Administrative data (*International Classification of Diseases, Ninth Revision* billing codes) were used to identify patients who underwent lumbar puncture, paracentesis, or thoracentesis on inpatient medicine units. Compliance with time-out was compared from baseline (July to April 2009 [10 months before]), to post-intervention (September to May 2010 [9 months]). A time-out was confirmed through documentation in the procedure note or a completed time-out form in the EMR. All records were independently reviewed by one author (H.B.). Another author (T.C.), blind to the study purpose, reviewed the same records to ensure reliability.

**Statistical Analysis.** Interrater agreement was calculated using the Cohen kappa coefficient. Pre- and post-compliance with the time-out process was evaluated using statistical process control and the  $\chi^2$  statistic. Multivariate logistic regression was used to control for time of pro-

cedure (day or evening), weekend or holiday, and nursing unit.

**Results.** There were 265 procedures (98 lumbar punctures, 115 paracenteses, and 52 thoracenteses) included in the study: 110 procedures before and 104 procedures after intervention. Interobserver agreement for medical record abstraction was high ( $\kappa=0.94$ ). Statistical process control revealed special cause variation at the time of the intervention (ie, significant improvement from sustained low compliance rates before the intervention to sustained high rates after; eFigure, <http://www.archinternmed.com>). Compliance with the time-out process significantly increased from 16% (18 of 110) at baseline to 94% (98 of 104) after intervention ( $\Delta P=78\%$ ; 95% confidence interval, 70%-86%). The multivariate analysis confirmed this result (odds ratio, 94.0; 95% confidence interval 33.9-260.3).

**Comment.** Our reengineered approach to TJC's UP for bedside procedures dramatically increased time-out compliance. To our knowledge, this is the first demonstration of such success for bedside procedures. Because UP compliance improves patient safety and reduces wrong site procedures in the operating room,<sup>5-7</sup> our intervention may also reduce wrong site bedside procedures up to 70%.<sup>4,5</sup> Periodic observation is needed to confirm that documentation reflects competent time-out performance.

As a pre- and postintervention study at a single institution we were unable to randomize or control for secular trends in compliance. However, there were no other known interventions during the study period, and given the large effect size of our intervention and use of a validated process to measure change pre- and postintervention (statistical process control), it is unlikely that the study design significantly biased our results. We were unable to measure adverse events from incorrect procedures because these events are extremely rare.<sup>4,5</sup> However, we expect this intervention will help reduce adverse events because of increased nurse awareness that a procedure is being performed and the use of time-outs to prevent wrong site or wrong patient procedures. In conclusion, a hospital-based intervention using a well-engineered process integrated with the EMR increases compliance with the UP for bedside procedures.

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## COMMENTS AND OPINIONS

### HEALTH CARE REFORM

#### Racial Disparities in End-of-Life Care

Mac and colleagues<sup>1</sup> reported racial disparities in the outcomes of communication about end-of-life treatment preferences and medical care in patients with advanced cancer. The authors speculate that racial bias on the part of health care providers could explain this finding. To explore this more fully, it would be useful to know racial or ethnic characteristics of the health care providers who conducted end-of-life care discussions in this prospective cohort investigation. For example, did clinicians of color participate in end-of-life conversations? If yes, was there evidence to suggest that clinician race or ethnicity might be a predictor of outcomes following an end-of-life discussion?