

# Acute Care ISMP Medication Safety Alert | \*\*

Educating the Healthcare Community About Safe Medication Practices

# Education is "predictably disappointing" and should never be relied upon alone to improve safety



A recent editorial in the May 2020 issue of *BMJ Quality & Safety* provides a noteworthy description of why education <u>alone</u> is a weak, low-value improvement intervention.<sup>1</sup> The editorial examines the impact of a national education program in Australia aimed at reducing outpatient proton-pump inhibitor (PPI) prescriptions, which found no significant changes in discontinuation or dose reductions, the primary outcomes of the intervention. The authors acknowledge that educational initiatives alone are unlikely to make the inroads required to curb the prescribing

of PPIs. They offer several salient reasons why educational initiatives alone fail to produce results. They first reviewed numerous studies that have found negligible or no improvements when examining the impact of education on practitioners' behavior and clinical outcomes. Despite healthcare's over-reliance on this low-value intervention, the authors conclude that education is "predictably disappointing among improvement efforts," earning it a "necessary but insufficient" status among improvement interventions.<sup>1</sup>

ISMP agrees that education alone is a weak improvement strategy. Education has its place as a basic prerequisite—it provides healthcare practitioners with the required knowledge (what they know) needed to develop the skills (applying that knowledge) to do their job well. For example, education about new medications, devices, automation, processes, and known risks is fundamental to forming a well-qualified complement of practitioners to manage medication safety. But while knowledge and skills are a necessary first step, education ranks among the least effective interventions in ISMP's hierarchy of effectiveness of risk-reduction strategies (**Figure 1**), right below rules and policies, and far below more effective system-focused strategies such as forcing functions, barriers and fail-safes, and automation. ISMP has long noted that improvement strategies

System Reliability

**Human Reliability** 

with the greatest impact on patient safety and the ability to sustain improvement are those that make it hard for practitioners to do their cont'd on pg 2—Education >

Figure 1. ISMP's hierarchy of effectiveness of risk-reduction strategies. High-leverage strategies are most effective because they can eliminate the risk of errors and associated harm by 'designing out' hazards; however, they often require complex implementation plans. Mediumleverage strategies, which are easier to implement, reduce the likelihood of errors or minimize harm; however, they may need periodic updating and reinforcement. Low-leverage strategies, which aim to improve human performance, are easy and quick to implement; however, they are the least effective strategies for error prevention although frequently relied upon.



#### **Special Alert!**

# Prepare for vials of neuromuscular blocking agents without cap warnings

Due to the increase in demand for neuromuscular blocking agents for critically ill COVID-19 (coronavirus) patients on ventilators, a drug shortage has occurred with certain products, including vecuronium and rocuronium (www.ismp.org/ ext/486; www.ismp.org/ext/487). To assure continued availability of these two critically important drugs, the US Food and Drug Administration (FDA) has no objection to the request for the abbreviated new drug application (ANDA) holder, Gland Pharma Limited, to temporarily manufacture (June until July/August 2020) these drugs without the vial cap (seal) incorporating the usual statement, "Warning: Paralyzing Agent," required by USP and FDA (Figure 1). Supply constraints prevent Gland from obtaining the products with the usual warning statements on the vial cap in time to address the shortage.

This temporary situation has obvious safety implications since the absence of the warning may make the vials look more like other medications in similar size vials and cap colors. Neuromuscular





**Figure 1.** Images of currently approved cap (left) and temporary cap (right) for vecuronium bromide injection 10 mg vial and 20 mg vial.

blocking agents are high-alert medications because of their well-documented history of causing catastrophic injuries or death when used in error. Staff awareness about the absence of the usual warning statement is critically important, as will be safe handling, as noted below.

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job wrong, and easy for them to do it right. Education never achieves this goal and is a weak improvement strategy when used alone for the following reasons.

#### (Education relies heavily on human memory and vigilance

When a risk or error is linked to a knowledge deficit, education may be required to provide practitioners with the requisite knowledge they need to do their job. However, application of that new knowledge is heavily dependent on human memory and vigilance. Education does not guarantee that the new information has been learned, will be correctly applied in the right circumstances, and will lead to the desired skills. Additionally, knowledge and skills may erode over time, especially if they are not needed or not reinforced through routine activities.

There are several human factors explanations regarding why individuals may forget new information or fail to apply new knowledge correctly.

- Distractions or lack of attention during the educational process may mean that the new knowledge was never encoded properly in the memory, so it was never really "learned." <sup>2,3</sup>
- Everyone learns differently and at a different pace; they differ in their natural, habitual, and preferred ways of absorbing, processing, and retaining new information and skills. Thus, the methods and the duration of the educational experience may not be optimal for learning for all practitioners.
- New knowledge and skills fade over time, particularly if they have not been repeatedly applied, so individuals may simply forget what they have learned by the time it is needed.<sup>23</sup> Thus, rarely used knowledge or rarely performed activities require just-in-time education, rather than a once-and-done educational program.
- New information may conflict with old knowledge, resulting in competition and hampering the ability to learn.<sup>4</sup>
- The absence of appropriate retrieval cues may contribute to forgetting what has been learned.<sup>2,3</sup> Access to knowledge and our intention to act on that knowledge depends on appropriate memory cues that trigger retrieval of what we have learned—without them, we may fail to remember and apply the new knowledge in an appropriate situation.

#### **Education does not solve memory slips or lapses**

Education does little when used to address human error unless a knowledge deficit is uncovered. For example, a mental slip or lapse that leads to forgetting one step, such as verifying patient allergies¹ or a medication expiration date, of a complex medication use process is different from a mistake caused by a lack of knowledge. Human factors experts firmly agree that the unpredictable, transitory mental states that lead to human continued on page 3 — Education >

#### **ISMP** now accepting nominations for **CHEERS AWARDS**

In an ongoing effort to improve patient safety, ISMP takes great joy in recognizing others who share this same vision. Each year, ISMP celebrates individuals, organizations, and groups that have demonstrated exemplary commitment to the science and study of medication safety through innovative and creative projects, educational efforts, standards setting, or research. The winners will receive an ISMP CHEERS AWARD, which will be presented during an evening ceremony in early December—more to follow on the gala!

Nominations for this year's CHEERS AWARDS will be accepted through September 11, 2020. ISMP accepts external nominations, including self-nominations. The prestigious AWARDS spotlight efforts from all healthcare disciplines, and winners have included representatives from hospitals, health systems, long-term care, ambulatory care, community pharmacies, professional associations, federal and state agencies, as well as individual advocates. To submit a nomination, visit: <a href="https://www.ismp.org/node/1036">www.ismp.org/node/1036</a>.

Gland produces vecuronium bromide injection (lyophilized powder) 10 mg per vial and 20 mg per vial for its marketing partner, Fresenius Kabi. The cap with the required warning statement and the temporary cap without the warning statement are pictured in **Figure 1** (page 1). These products will have the same US container and carton labels as before, with a paralyzing agent warning statement on them; only the vial

caps will change. Vecuronium 10 mg vials

are expected to arrive for distribution in

mid-June; the date for distribution of the

20 mg vials has not been determined.

Gland Pharma also holds an ANDA for rocuronium bromide injection (50 mg per 5 mL, 100 mg per 10 mL) and provides this product to its marketing partners, Athenex Pharmaceutical Division and Almaject. Mylan Institutional LLC also has rocuronium injection that will be affected. The caps for these products will be temporarily manufactured without the usual statement, "Paralyzing Agent" (Figure 2). As with vecuronium, there is no change to the current US vial or carton labels. The date for distribution of the rocuronium products has not been determined.

Both FDA (<a href="www.ismp.org/ext/497">www.ismp.org/ext/497</a>) and Fresenius Kabi (<a href="www.ismp.org/ext/496">www.ismp.org/ext/496</a>) have also issued a letter about the absence of a warning on the caps.





**Figure 2.** Images of currently approved cap (left) and temporary cap (right) for rocuronium bromide injection, 50 mg per 5 mL and 100 mg per 10 mL.

These products are likely to be stocked in locations outside of intensive care units, including perioperative areas, emergency departments (EDs), and ambulatory surgery centers. So, it is important for hospitals and health systems to communicate the changes and prepare clinical staff wherever these products are stocked and/or used. Depending on the organization, these products may be found in crash carts; automated dispensing cabinets (ADCs); anesthesia carts, kits, and trays; and in other storage locations.

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errors, such as forgetfulness, preoccupation, and distractibility, will not be lessened by education.<sup>5</sup> Nor would education lead to improvement if a physician prescribed an overdose by transposing the dosing numbers or inadvertently selecting a look-alike product from a drop-down menu. Simply educating practitioners about the importance of checking allergies and expiration dates, or about avoiding overdoses or selection of the wrong drug in drop-down menus, will achieve little or no reduction in errors.

Instead, these types of human errors require system-level interventions to 'design out' hazards through automation and forcing functions that prevent transposed numbers from leading to serious overdoses, drug name search requirements that avoid look-alike product names in drop-down menus, or just-in-time cues and prompts to check patient allergies or expiration dates. Education is only appropriate when a knowledge deficit leads to a human error. Even then, education should be bundled with other more effective risk-reduction strategies and not relied upon solely as an improvement strategy.

#### (Education does not easily change habits or at-risk behaviors

Education alone may do little to change unsafe complex behaviors that have become entrenched as habits. Many hold onto the belief that education cannot only get practitioners to engage in an action, but also change their unsafe behavior. However, there is widespread agreement that information and education alone will not translate into behavioral changes. The reasons that individuals develop unsafe habits and behaviors are often complicated and multi-factorial, such as attitudes, beliefs, motivation, ability, perceived threats, social norms, and cultural issues. For the most part, the role of habit is underappreciated, and education will not lead to better organizational performance because individuals will soon revert to their old ways of doing things.

Likewise, addressing at-risk behaviors, particularly rule-breaking or procedural deviations, is not as easy as merely re-educating practitioners. In most cases, practitioners already know and have been trained in the procedure or rule. Most at-risk behaviors are caused by system failures, leading practitioners to work around them. They are rarely associated with a lack of knowledge, but rather a lack of awareness of the risk associated with the task or not following the approved process. Reliance on re-education creates an illusion of managing the risk, with limited impact on improved behaviors and performance. In both cases—with unsafe habits and at-risk behaviors—redesign of the systems that are driving and rewarding those habits and behaviors is required, as well as coaching conversations that raise the perception of risk.

#### (Education does little to change system reliability

Education is provided in an attempt to improve human reliability, not system reliability. Reliability in humans, who are inherently fallible, is less attainable than reliability in systems, which can be designed to eliminate risk or errors, leading to transformational improvements. Education aimed at improving human reliability does little to redesign vulnerable systems. In hospitals, the misuse of insulin pens for more than one patient is a prime example of when education alone has not worked. In fact, education alone may set up practitioners to fail. Organizations that simply educate practitioners about how to achieve better outcomes within poorly designed systems are bound to be unsuccessful.

#### Education requires frequent repetition

Education that may be needed, even for everyday common situations and activities, is difficult to achieve because practitioner turnover necessitates periodic re-delivery of the same education. This problem is applicable to all organizations, as new practitioners who need that information are hired regularly. However, the problem is especially apparent in teaching hospitals, where students, interns, and residents frequently rotate in and out of specialty locations and units. Additionally, periodic re-delivery of the same education may be necessary to reinforce learning since its usefulness relies heavily on human memory and vigilance.

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We highly recommend that organizations review measures for safe handling of neuromuscular blocking agents outlined in our June 16, 2016 article, *Paralyzed by mistakes – Reassess the safety of neuromuscular blockers in your facility* (www.ismp.org/node/247), as well as our *Targeted Medication Safety Best Practices for Hospitals* (www.ismp.org/node/160; #7). If these products reach your facility, we suggest immediately affixing an auxiliary label noting, "Warning: Paralyzing Agent," to the vial caps. If not already in use, these labels can be purchased from your usual medical products supplier.

Please be prepared to have staff from the pharmacy or a medication safety officer visit various clinical locations in your facility or health system to work with practitioners in these locations to examine areas where these products might be stored, determine the likelihood of product confusion/mix-up, and act as necessary to store these products safely. Do not store vials in a way that only the caps are visible when looking down at them (Figure 3). Instead, be sure that vials are lying down so labels are visible in ADC drawers, anesthesia trays or drawers, or in other storage containers or shelving, particularly on low shelves in a refrigerator. Remind staff of the importance of barcode scanning prior to drug preparation and administration. Limit availability of neuromuscular blocking agents like vecuronium in ADCs to perioperative, labor and delivery, critical care, and ED settings; in these areas, store the drugs in a rapid sequence intubation (RSI) kit or locklidded ADC pockets/drawers. Take additional precautions, such as employing independent double checks, particularly when the ability to remove these drugs via override exists.



**Figure 3.** When vials are standing upright in storage, staff may select a vial based on cap color and may not notice if they have the wrong vial in hand (tranexamic acid, left, ropivacaine, right).

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#### Other influencing factors

Educating practitioners about desired behaviors may not be enough if there is external pressure to behave differently. For example, education about proper antibiotic prescribing does not make it any easier to dissuade patients who visit prescribers specifically for a prescription for antibiotics to treat a viral infection. Nor does education to avoid screening men over 75 years of age for prostate cancer equip practitioners with the materials or communication techniques necessary to reassure patients interested in such screening. Likewise, all the education in the world about preventing overutilization of diagnostic tests is not going to change the fact that a negative x-ray is first required by insurers before magnetic resonance imaging (MRI) can be ordered.

#### Conclusion

Selecting the best improvement strategy is not easy. Too often, an educational intervention is chosen without first determining if a plausible lack of knowledge is the main cause. Even then, solving the problem on the basis of education alone is seldom successful.<sup>1</sup> Beer et al. refer to healthcare's reliance on education as the "great training robbery," noting that systems spend large amounts of money and time on employee education without a good return on their investment.<sup>10</sup>

While education has been healthcare's single go-to response to a quality or safety problem in the past, it is time for a new, more effective approach. A single strategy, particularly one as weak as education, is not enough to change behaviors and prevent errors. Instead, numerous high-leverage risk-reduction strategies that improve system reliability (**Figure 1**, page 1) must be layered together, on top of education, to create a more robust safety system. This is important for organizations in their quest to attain highly reliable outcomes. A table of key safety strategies for improvement, including examples with high-alert medications, can be found for reference at: www.ismp.org/node/635.<sup>11</sup>

#### References

- 1) Soong C, Shojania KG. Education as a low-value improvement intervention: often necessary but rarely sufficient. *BMJ Qual Saf.* 2020;29(5):353-7.
- Klimesch W. The structure of long-term memory: a connectivity model of semantic processing. New York, NY: Psychology Press; 2013.
- 3) Weiten W. Psychology: themes and variations. 10th ed. Boston, MA: Cengage Learning; 2017.
- 4) Hatami S. Learning styles. ELT Journal. 2013;67(4):488-90.
- 5) Reason J. Human error. New York, NY: Cambridge University Press; 2003.
- VogusTJ, Hilligoss B. The underappreciated role of habit in highly reliable healthcare. BMJ Qual Saf. 2016;25(3):141-6.
- 7) Outcome Engenuity. Just culture training for healthcare managers. Eden Prairie, MN: Outcome Engenuity; 2018.
- 8) ISMP. A crack in our best armor: "wrong patient" insulin pen injections alarmingly frequent even with barcode scanning. ISMP Medication Safety Alert! 2014;19(21):1-5. www.ismp.org/node/555
- 9) Haskins J. 20 years of patient safety. Association of American Medical Colleges (AAMC) News. June 6, 2019. www.ismp.org/ext/493
- 10) Beer M, Finnström M, Schrader D. Why leadership training fails—and what to do about it. Harvard Business Review. 2016;50-7. www.ismp.org/ext/494
- 11) ISMP. Your high-alert medication list—relatively useless without associated risk-reduction strategies. ISMP Medication Safety Alert! 2013;18(7):1-5. <a href="https://www.ismp.org/node/635">www.ismp.org/node/635</a>

## ◆ Special Announcements

#### FREE FDA webinar—with ISMP

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a FREE webinar on June 30, FDA Drug Topics: Role of FDA and ISMP in Preventing Medication Errors. This webinar will describe the pre- and postmarket role of the Division of Medication Error Prevention and Analysis (DMEPA) in preventing and addressing medication errors. Speakers from FDA and ISMP will illustrate how DMEPA collaborates with ISMP and uses information shared from the ISMP National Medication Errors Reporting Program (MERP) to benefit overall drug safety. The role of pharmacists in identifying, preventing, and mitigating medication errors will also be explored. For details, visit: <a href="https://www.ismp.org/ext/30">www.ismp.org/ext/30</a>, and to register, visit: www.ismp.org/ext/31.

#### **FREE international ISMP webinar**

ISMP is presenting a FREE international webinar on June 23 (7:00 a.m. EDT), Medication Safety During the COVID-19 Pandemic: What Have We Learned in the **United States?** The program is intended for an international audience. During the pandemic, numerous medication safety compromises were made in the US. Independent double checks during medication preparation and administration were abandoned or abbreviated. Pharmacists were processing orders online from home, not the hospital. Unproven medications for prophylaxis and treatment of COVID-19 were used, sometimes sickening patients unnecessarily. Infusion pumps were kept outside of patients' rooms in critical care units to reduce nurse exposure and conserve personal protective equipment. Learn how and why these and many other changes were made, and where we will go from here. To register, visit: <a href="https://www.ismp.org/node/18044">www.ismp.org/node/18044</a>.

#### If you would like to subscribe to this newsletter, visit: www.ismp.org/node/10

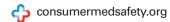


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# **Coming this Fall!**

ISMP has been awarded a contract from the US Food and Drug Administration to develop a new self-assessment tool that can help interdisciplinary perioperative teams in hospitals, ambulatory surgery centers, and other surgical sites pinpoint how currently designed systems, staff practices, and emerging challenges may impact perioperative medication safety.

# ISMP Medication Safety Self Assessment for Perioperative Settings



### Start building your perioperative assessment team to:

- Identify opportunities for improvement
- Create organization-specific, safety-focused initiatives
- Compare your results with demographically similar organizations



Expected release: **September 2020** 

Look for more information about this new assessment tool this summer!