

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

ENFit enteral devices are on their way... Important safety considerations for hospitals



In our August 14, 2014 newsletter, we alerted health systems to upcoming changes in enteral feeding device connectors. An industry group, The Global Enteral Device Supplier Association (GEDSA), is coordinating this effort, and GEDSA member companies are introducing the new devices referred to as ENFit. The ENFit devices will not be compatible with a Luer connection or any other type of small bore medical connector, thus preventing misadministration of an enteral feeding or medication by the wrong route. Unlike current parenteral and oral syringes with male syringe tips that fit into female connectors, the new ENFit devices are just the opposite. They have a **female** tip on the syringe that will fit around a **male** connector on feeding tubes (**Figure 1**).

We previously urged health systems to plan for the enteral connector design changes, but that has been difficult because the actual devices have not been available. In general terms, during the first quarter of 2015, we were anticipating availability of enteral administration sets with a new female ENFit connector and a limited-use ENFit Transition Connector to facilitate compatibility between the new ENFit system and the existing port. The ENFit connector system also requires the use of a new enteral-specific syringe that can be used for medication administration, flushing, and feeding. Distribution of the



Figure 1. New ENFit syringe (left) has larger female tip than an oral syringe with a male tip (right).

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South Carolina medication error bill is **dangerously** off target

If we have learned nothing else about patient safety in the last two decades, it's that our response to medical errors can either propel our safety efforts forward or stop them dead in their tracks. An alarming proposed piece of legislation in South Carolina that we learned about last week seeks to permanently revoke a nurse's license after involvement in a fatal medication error. This clearly evokes the latter response and leaves us, and we hope others, deeply troubled regarding how little Sen. Kevin Bryant (R), who introduced the bill, and members of the medical panel subcommittee, who voted for the bill, understand human error, justice, and patient safety.

The proposed bill (S. 371, Samuel's Law) arose from the tragic, 2012 death of a 7-year-old boy, Samuel Cutliff, who received a 10-fold overdose of morphine—4 mL instead of 0.4 mL. We offer our heartfelt condolences to Samuel's family. In response to the error, the South Carolina Board of Nursing placed the nurse on probation for 1 year and ordered her to pay a civil penalty and complete several courses of study. We know little about the cause(s) of the error other than what is written in news reports, but the bill voted on last week is strangely focused on just one type of medication error and suggests that misreading a physician's order may have led to the error. The bill initially stated:

"Upon the board's findings that a licensed nurse misreads a physician's order and over-

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SAFETY briefs



Strength confusion over Zerbaxa. ZER-BAXA (ceftolozane and tazobactam) was approved by the US Food and Drug Administration (FDA) in December 2014 for use in combination with metroNIDAZOLE for the treatment of complicated intra-abdominal infections caused by susceptible organisms, and complicated urinary tract infections, including pyelonephritis. In at least five known incidents, pharmacists and pharmacy technicians have made mixing errors with the new combination cephalosporin/beta-lactamase inhibitor. In these reports, pharmacy staff have indicated the errors happened because they were more familiar with the labeling of the current combination products UNASYN (ampicillin and sulbactam) or ZOSYN (piperacillin and tazobactam), where the total amount of the two drugs (e.g., 1.5 g) is identified on the label. Instead, the Zerbaxa vial label expresses the strength of each individual ingredient, ceftolozane 1 g/tazobactam 0.5 g (**Figure 1**).



Figure 1. Unlike Unasyn (right) that expresses the product strength as the combined sum of each ingredient, Zerbaxa (left) lists each ingredient separately, which has led to confusion.

This difference in label style, although accurate in identifying the medications and strengths, has been confusing to prescribers who may order the drug the same way they order Unasyn or Zosyn, as the combined strengths of each ingredient—

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new ENFit syringes is supposed to begin in the current quarter. Any oral syringe currently in use (and any Luer-tipped syringe) will not work with the ENFit connector system. ENFit feeding tubes will begin distribution in the third quarter according to the published GEDSA timelines on stayconnected.org.

In our August 14, 2014 newsletter, we identified several unresolved process dilemmas that this changeover would trigger. Fortunately, these issues have been addressed, and we are happy to report that vendors have designed bottle adapters and straws (**Figure 2**), and syringe caps (**Figure 3**) to use with the ENFit syringes. However, ISMP has identified further safety issues for hospitals to consider as the connectors are introduced. When we recently received samples of the new devices and conducted simulations, we verified some measurement and administration issues reported to us.

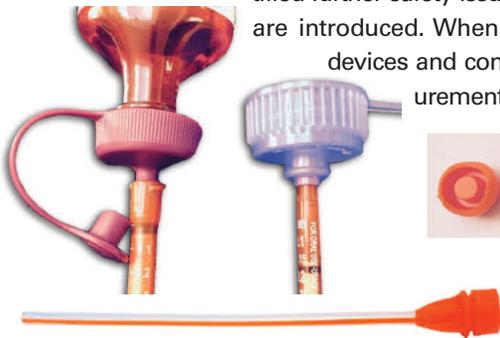


Figure 2. New bottle adapter and ENFit syringe on the left compared to the current style oral syringe and bottle adapter on the right (top). A straw-type device (bottom) will also be available. This can be used to draw up medication from a unit dose liquid cup.

syringe caps. We have highlighted in red the processes in the sections below that may present particular safety considerations.

Administering Liquid Medications Via An Enteral Feeding Tube

ENFit syringe to ENFit connection. If a dose of liquid medication must be administered via a feeding tube with the new enteral connector, an ENFit syringe must be used. In a recent guidance document, FDA suggested the syringes should be marked “Feeding/Medication Only.” An oral syringe will no longer connect to the feeding tube.

Measuring an enteral medication dose in pharmacy. An ENFit bottle adapter (**Figure 2**) should be affixed to the bulk bottle of liquid medication, and the correct dose should be withdrawn from the bottle using an ENFit syringe. If medicine must be withdrawn from a unit dose cup, an ENFit straw (**Figure 2**) is available. It is important to note that dose measurement with an ENFit syringe is from the base of the syringe tip (where the gradation marks begin) to the correct gradation mark on the syringe (**Figure 4**). In this regard, no changes were made to gradient markings or how to measure a dose when compared to an oral syringe. A cap meant for an ENFit syringe should be securely placed on the filled ENFit syringe prior to transport (**Figure 3**).



Figure 4. Doses for feeding tube administration are measured in between the arrows, from the base of the syringe tip to the proper gradation on the syringe scale.

Measuring an enteral medication dose in patient care units. While ISMP strongly recommends that liquid medications for patients with feeding tubes be prepared and dispensed in exact doses by the pharmacy, there may be times when healthcare professionals in patient care units must use an ENFit syringe to draw liquid medication from a

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Zosyn 4 g/0.5 g prescribed as 4.5 g. For a “Zerbaxa 1.5 g” order, just one vial (1 g ceftolozane and 0.5 g tazobactam) should have been used. However, staff prepared the dose based on the amount of ceftolozane alone because the total amount of combined drug was not listed on the vial label. Subsequently, 2 vials of ceftolozane/tazobactam were mixed, and the contents of 1½ vials were placed into an infusion bag. This mixing error was found before the drug was administered to a patient. But there have also been three incidents in which a 3 g dose was ordered, and in two cases, the patients received 4.5 g of the drug (3 vials), although they did not experience an adverse reaction.

Although the drug is new and it’s possible it might be ordered before pharmacy and therapeutics (P&T) committees have had a chance to completely review it, any new medication used in the hospital should receive some type of expedited review by the P&T committee or the pharmacy. Cubist, the manufacturer, says it is evaluating possible preventative actions in follow-up to these cases. FDA is also aware of these issues based on reports from the manufacturer and ISMP. We think the best action would be to list the strength similar to the way it has been done in the past with the other combination products mentioned.



PCA basal infusion overdose. By telephone, a physician prescribed patient-controlled analgesia (PCA) for a postoperative patient using **HYDRO**morphone demand doses of 0.3 mg, a lockout interval of 10 minutes, and a basal infusion of 1.5 mg per hour. The new order was entered on the medication administration record (MAR), but the basal infusion was misread as 15 mg/hour and, thus, entered incorrectly. The original order was used as reference when first programming the pump, so the correct basal dose of 1.5 mg was programmed. Then, after the patient ambulated to the bathroom, the pump was not plugged back into the electrical socket. The pump ran out of battery power, and instead of plugging the pump in, a

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unit dose liquid cup. When that happens, dead space in the tip of the ENFit syringe must be considered if an ENFit straw *isn't* used. This dead space measures from 0.15 to 0.2 mL, and while this may not seem like much, it can be significant for certain drug doses, particularly in pediatric and neonatal populations.

Because of the dead space, when a practitioner uses the ENFit syringe and begins to draw up a medication directly from a unit dose liquid cup, there will be a small bubble of about 0.15 mL to 0.2 mL of air (**Figure 5**) that moves into the syringe first. To measure doses exactly, nurses must remove the air bubble and attempt to accurately measure the dose without

allowing fluid to remain in the syringe tip, thus filling the dead space. Flicking the syringe to remove the air

bubble may lead to some minor spillage as the medication sprays out of the wide female connector. Thus, as nurses first become familiar with the new syringes, there may be several attempts to withdraw the correct amount of medication from the cup into the ENFit syringe, each time requiring removal of an air bubble. The process can be messy and tedious, and can lead to incorrect dosing if the bubble isn't removed.

For these enteral doses, one way to minimize the bubble and measure an accurate dose from a cup would be for nurses to use the ENFit straw attached to the ENFit syringe (**Figure 2** on page 2). This allows the nurse to minimize the dead space and promote easier dose measurement. Of course, this means hospitals must supply ENFit straws in patient care areas and educate nurses about the need to use them and how to use them.

Again, doses meant for a feeding tube are measured only using the syringe scale, and should not include a syringe tip full of medication, which can be avoided by using the bottle adapter (for enteral doses prepared in the pharmacy) or straw device on nursing units. With doses given via a tube, the dead space in the syringe should always be cleared of fluid during measurement of the dose and should also be clear of fluid when attaching the syringe to an ENFit connection on the feeding tube. If there

is an accumulation of medication in the syringe tip when measuring a feeding tube dose from a medication cup (**Figure 6**), some of that may leak out when connected to the feeding tube or be injected via the tube, which may constitute a small amount of excess medicine reaching the patient. The volumes appear to vary depending on liquid viscosity, volume of fluid in the dead space, and force of injection caused by the syringe plunger when connected via the ENFit connector to the feeding tube.

As already mentioned, measuring a dose for administration via an ENFit feeding tube is only accurate if there is no medication in the dead space both before and after adminis-

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Figure 5. Air (circled) is drawn into a syringe when drawing an oral liquid from a cup without an ENFit straw device. The air bubble must be removed to measure an accurate dose.



Figure 6. The ENFit syringe tip (circled) must be cleared when measuring doses and before connecting to an ENFit (male) feeding tube (left). If fluid remains, some leakage may occur and a small amount of extra medication may be administered.

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new pump was used. This time, the MAR was used to guide the programming, and the pump was set to deliver 15 mg, not 1.5 mg of **HYDRO**morphone each hour. An hour later, the patient was found unresponsive. He was given naloxone and transferred to a critical care unit, where he required another dose of naloxone and recovered.

Despite the transcription error that resulted in entering a basal dose of 15 mg/hour instead of 1.5 mg/hour on the MAR, use of a smart pump with dose error-reduction software (DERS) would have alerted the nurse to the error while programming the pump. In fact, a basal dose of 15 mg/hour should result in a hard stop without the ability to override the warning. An independent double-check of the PCA settings also may have caught the error. Because the syringe of **HYDRO**morphone was obtained from an automated dispensing cabinet, there was no pharmacy label listing the patient-specific basal dose of 1.5 mg/hour for reference. Basal infusions are not recommended in opioid-naïve patients. (It is uncertain if this patient was opioid-tolerant, but if not, even a 1.5 mg dose per hour would likely be enough to cause serious problems, given its equivalence to more than 10 mg of morphine per hour.)

Further, it appears the patient was not being monitored as recommended by the Anesthesia Patient Safety Foundation (APSF) using continuous electronic monitoring of oxygenation (pulse oximetry, monitored from a central location if possible) and intermittent nurse assessments. Other modalities that measure ventilation and airflow adequacy (e.g., capnography) should be employed for patients who need supplemental oxygen to maintain acceptable oxygen saturation levels. Nurses should also be educated regarding safe dose ranges with the opioids used for PCA. Finally, use of a preprinted order set may help guide an appropriate dosing regimen for PCA.

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tration. This is a fundamental change in the way that nurses must measure medication doses for feeding tubes while using unit-dose cups since a straw must be used in the process. The added complexity has the potential to contribute to dosage error when very small amounts of liquid are needed for a dose, such as for infants.

ENFit syringe product vendors are aware of the issue of bubble formation and dead space when preparing doses directly from a cup of liquid and they are prepared to introduce solutions that may mitigate this concern. ISMP has not received anything to test and cannot comment on the safety or accuracy of what may be forthcoming.

Administering the medication. Once procedures have been followed to verify placement and/or flushing of the feeding tube, the ENFit syringe's female connector should be attached to the compatible male connector on the feeding tube, and the medication should be administered (**Figure 6** on page 3).

Administering Liquid Medications by Mouth

Measuring and administering an oral dose of medication. For now, it would be safest to use an oral syringe to measure the dose and administer the medication by mouth, using the same techniques and devices currently in place.

Using ENFit syringes as the sole device. Even with excellent communication between nursing units and the pharmacy, it may be impossible for pharmacy to always know which patients can swallow and can use an oral syringe, and which have a feeding tube and will need an ENFit syringe. For patients with feeding tubes, medication orders should specify "via tube." But even so, some patients may later have their tubes removed before pharmacy is notified, while others with feeding tubes can still swallow liquid medications orally. For simplicity, some hospitals have told us that they hope to be able to use ENFit syringes for both feeding tube administration as well as oral administration by mouth, thus eliminating the need for a second type of syringe without a Luer tip. But going with only ENFit syringes alone poses safety considerations, particularly for doses in small volumes, less than 2 mL, as described below.

Administering an oral dose via ENFit syringe. When a medication intended for oral administration has been drawn into an ENFit syringe via a bottle adapter or ENFit straw, if the dose is given orally and not connected to a feeding tube, the patient will not receive the full amount of liquid, and thus an incomplete dose. This is because fluid will remain in the dead space after delivering the medication into the patient's mouth (**Figure 7**). For volumes above 2 mL, this would not be clinically significant since only 0.15 mL to, at most, 0.2 mL would remain (under 10%). Most liquid doses for adults are usually well above that amount, so this should rarely be a problem for them. However, for neonatal, infant, and some pediatric patients, this could represent a significant underdosing, especially since some infant liquid medication doses can be under 0.25 mL (e.g., concentrated morphine, digoxin, and others). When infants, small children, or others are receiving very small volumes of liquid orally, we recommend using oral syringes for oral doses.

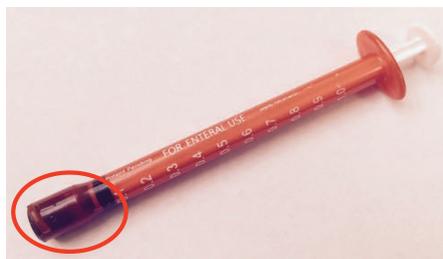


Figure 7. Medication remains in the syringe tip if using an ENFit syringe to administer an oral dose.

Finally, if an ENFit syringe by itself (no straw) is used by nurses to draw up liquid from a unit dose cup for oral use, the bubble should be removed and the syringe should be com-

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medicates or undermedicates a patient, the board shall revoke the person's license to practice in this State."¹

It appears that an equally troubling and amended version of the bill will be voted upon by the full Senate Committee on Medical Affairs at the end of April:

"Upon a finding by the board that a person licensed under this chapter acted in a willful, wanton, or grossly negligent manner by misreading a physician's order causing a patient to be over-medicated or under-medicated and resulting in the patient's death, the board shall revoke the person's license to practice nursing in this State. As used in this subsection, "willful, wanton, or grossly negligent" means an act or course of action, or inaction, which denotes a lack of reasonable care and a conscious disregard or indifference to the rights, safety, or welfare of others and which does or could result in death."²

Shockingly, Sen. Bryant who introduced the bill is a pharmacist who claims he has "never heard of an overdose of this magnitude."³ Anyone who has followed national media reports, read ISMP newsletters, or is remotely familiar with the medical literature is well aware that 10-fold overdoses caused by inaccurate prescriber orders or misreading or misinterpreting orders have happened repeatedly. Revoking a nurse's license will do nothing to reduce this confusion, nor will it reduce the risk of misreading physician's orders or prescriptions—two longstanding *system-based* causes of medication errors that have tripped-up even the most experienced and vigilant nurses and pharmacists.

Sen. Bryant has also been quoted to say, "This is similar to a drunk driver killing someone, and we give them a restricted license for a year."³ It is truly a sad day in healthcare when misreading a physician's order is likened to driving under the influence of alcohol—the former is clearly human error, and the latter, reckless behavior.

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pletely filled to the appropriate dose, keeping the fluid that accumulates in the syringe tip dead space. This same amount will remain in the dead space after releasing the medicine into the mouth. Therefore, a dosing error will not result.

A timely system must be established to notify the pharmacy of all medication doses needed via ENFit syringes due to feeding tubes (or oral syringes when feeding tubes are discontinued). For example, prescribers should be required to order medications by the correct route (i.e., oral, enteral) so the pharmacy knows what type of syringe to use. There should also be other ways to communicate route of administration, such as via electronic messaging. However, in practice, this may be difficult to reliably implement and align with the type of syringe the pharmacy dispenses. Even with such a policy, hospitals should anticipate that some rework will occasionally be needed. Of course, the route of administration should always be reflected in the medication administration record.

A Note About Proprietary Enteral Systems

Devices meant specifically for the neonatal population that do NOT meet the ISO 80369-3 standard for enteral connectors, but have their own proprietary design, are also on the market. These devices will not connect to small bore Luer connectors. However, concern has been expressed that hospitals may not have a fallback system to rely on if a shortage or recall of manufacturer-specific equipment occurs since the proprietary system would not be compatible with ISO-designed ENFit connectors.

Conclusions

If an ENFit syringe is connected to an ENFit bottle adapter or straw for syringe filling, then it must be attached to an ENFit feeding tube in order to administer an accurate dose, particularly liquid doses under 2 mL. If an ENFit syringe is filled directly from a cup without an ENFit straw, then as long as it is not connected to an ENFit device for administration, and instead is delivered directly into the patient's mouth, the dose will be accurate. Problems can exist if an ENFit adapter or straw is used to fill the syringe with small amounts of medicine but the dose is given orally. Problems can also exist if liquid is drawn directly into a syringe from a cup (no straw) then attached to an ENFit feeding tube. The key point to remember is that the volume in the tip of the syringe (the dead space) before and after administration needs to be the same. If the tip is full of medicine before administration, it must be full after administration. If the tip is empty before administration, it must be empty after administration (Figures 8-11).

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Figure 8. Medication drawn up from a cup without an ENFit connector and delivered by mouth. The volume of medication in the syringe tip at the start and end of administration is the same, so dosing is accurate.

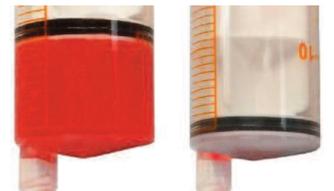


Figure 9. Medication drawn into an ENFit syringe in the pharmacy using an ENFit adapter, and then given via an ENFit device. The volume of medication in the syringe tip is the same before and after administration, so dosing is accurate.



Figure 10. Medication drawn from a cup but administered into an ENFit device can lead to over-delivery of medication. The volume of medication in the tip of the syringe differs before and after administration. The full dose plus the extra in the dead space was administered.



Figure 11. Medication drawn into a syringe using an ENFit adapter but given by mouth leads to under-delivery of medication. The volume of medication in the tip of the syringe differs before and after administration. The dose minus the drug leftover in the dead space was administered.

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The proposed bill may be especially troubling to the South Carolina Hospital Association, which has been encouraging the adoption of a Just Culture throughout the state and sponsoring Just Culture Certification courses as recently as January 2015. In a Just Culture, everyone is held equally accountable for their behavioral *choices*. But human error is not a behavioral *choice*. It is inadvertent action or inaction that occurs frequently in all aspects of life, and it is not amenable to disciplinary action. The best way to reduce the risk of human error is to design systems that make it hard or impossible to do the work wrong. In regards to this event, perhaps an electronic ordering system, use of a leading zero (0.4) when expressing decimal doses, prescribing doses in mg and not mL, special precautions for opioids, and many other system-design changes could have a much larger impact on preventing similar errors.

While the intent of the legislation is presumably laudable—to prevent fatal medication errors—the means of achieving the goal are contrary to current national thinking on responding to errors and are counterproductive. Threatening the loss of license for misreading prescriber's orders will do nothing to prevent the event and will instead worsen the risk of errors given that nurses, or other professionals, will no longer report such events, particularly when patient harm is absent, not serious, or not clearly linked to the error. Crucial opportunities for learning will be lost.

While there are countless arguments we could make regarding the devastating impact that the bill will have on medication and patient safety, a *prima facie* argument can be made that the very definition of *willful, wanton, or gross negligence* in the amended bill language precludes *misreading an order*. Misreading an order is unintended and does not meet the definition of willful, wonton, or gross negligence as a conscious disregard for the rights,

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We urge product vendors to make samples of ENFit syringes, caps, bottle adapters, feeding tubes, straws, and administration sets available as soon as possible. Companies have yet to announce when the enteral devices will be available, but delivery of the samples must be well in advance of new supplies of ENFit devices to allow for evaluation by staff and training. It is only through simulations that practitioners will fully understand the issues described above and pinpoint where errors may happen based on hospital practices. Time for staff inservicing before actual use is also needed, and that can't be done adequately without seeing the supplies that will be used. Of utmost importance is the ability for frontline nurses, pharmacists and technicians to examine the devices. During the development of future products, early versions of the products should be tested by frontline personnel so potential problems can be identified during development rather than when products are about to reach the market.

We also urge GEDSA companies to work closely with each other and with frontline practitioners to understand how these devices will be used in practice. This will require a lot of hard work on everyone's part in order to reduce the risk of dosing errors when using the new devices. In the end, though, this is a worthwhile endeavor to eliminate the risk of tragic errors in which enteral liquids are given by the wrong route.

ISMP expresses our gratitude to NeoMed for providing us with samples of the new ENFit devices for simulation in preparing this article. We would also like to express our appreciation to Jamie Sklar, RN, MS, CCRN, and Sean O'Neill, PharmD, both from The Children's Hospital of Philadelphia, for their assistance during preparation of this article.

→ Special

Announcements

ISMP webinars

Join us on **April 30** for *The Human Dimension: When Being Human Gets in the Way of Medication Safety*. During this webinar, a model of the brain's information processing system will be presented, along with the perceptual and cognitive tendencies that influence behavior, including change bias, inattention blindness, and others. The focus of the program will be on the conditions, both human and system, that degrade performance, and strategies to reduce their impact on safety. For details, visit: www.ismp.org/sc?id=349.

New ISMP CE Opportunities—FREE for pharmacists and nurses

ISMP is now offering two ways to earn **FREE** CE credit. Pharmacists can download a monograph on IV preparation and administration errors that discusses failure to consider overfill when preparing certain IV drug infusions, unnecessary dilution of IV meds at the bedside, and unsafe use of syringes, needles, and vials. The monograph is available as a PDF and several electronic formats (i.e., iPad, Nook, Sony Reader, and Kindle). Pharmacists and nurses can also gain **FREE** CE on perioperative medication safety through a convenient on-demand webinar that addresses often-unrecognized problems, actual cases where errors have occurred, relevant regulatory and accreditation requirements, and how one organization successfully implemented risk-reduction strategies in the surgical setting. To access the new CE, go to: www.ismp.org/sc?id=509.

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safety, or welfare of others. There can be no *conscious* disregard without intent toward the action (intentionally misreading the order) or pre-existing knowledge of the mistake. There is a huge difference between human error and willful, wanton, and gross negligence.

Sen. Bryant's blogs and news reports have been filled with comments in response that argue against the bill, including the sentiment that all parts of the medical profession should be treated equally, and that it is unfair to single out nurses. While we agree with the need for equality, the real issue is fairness to the workforce and impact on patient safety. Simply put, it is not fair to revoke a nurse's license if human error leads to patient harm, and sweeping punitive action has been proven to only worsen patient safety, not improve it. Yes, we couldn't agree more that the system failed Samuel. But the bill, with its extreme and unjust sanctions for human error and its incongruent and mistaken linking of human error to gross negligence will only weaken the healthcare system.

Like Sen. Bryant and the medical panel, we agree that more can be done to prevent errors like the one that led to Samuel's death. In order to do this we must fix the system—the tools, processes, and environment in healthcare—and not levy harsher sanctions against human beings whom *the healthcare system allowed* to make a terrible mistake.

References

- 1) S. 371. General Bill. South Carolina General Assembly, Senate Committee on Medical Affairs. January 28, 2015. www.ismp.org/sc?id=506
- 2) Samuel's Law update s.371. Senator Kevin Bryant, Blog from the Backbench. April 6, 2015. www.ismp.org/sc?id=507
- 3) Brown K. S.C. Senate panel passes 'Samuel's Law.' Independent Mail. March 25, 2015. www.ismp.org/sc?id=508

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