A Matter of Conscience: A Call to Action for System Improvements Involving Epidural and Spinal Catheters

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“To err is human, to repent divine, to persist devilish.”

—Benjamin Franklin

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nesthesiologists are continually engaged in self-assessment, and our specialty has been defined by its commitment to minimizing errors and ensuring the safety of all patients.1 Anesthesiologists were pioneers in safety and continue to be seen as leaders in improving quality of care and outcomes.2 This is well illustrated by the Anesthesia Patient Safety Foundation, which has led efforts in anesthesia-related safety.3 Notwithstanding this history, 2 related areas of potentially dangerous practice continue despite numerous previous warnings. What are these dangers? The first is the accidental administration of IV drugs into epidural or intrathecal space. The second is the even more dangerous administration of epidural drugs into the circulation via the IV catheter. With this editorial, we challenge the anesthesiology community, along with the relevant industry and regulatory agencies, to take urgent action and eliminate an unnecessary and preventable risk to our patients.

A CRITICAL OVERSIGHT

Safety in anesthesia is now embraced internationally. In the early 1990s, following major safety initiatives in the United States, European safety efforts were also launched. The International Taskforce on Anaesthesia Safety set a goal to augment, enhance, and support published standards,3 and in 2007 the Safe Anaesthesia Working Group was convened to review the International Standards for a Safe Practice of Anaesthesia.4 In addition to the essential practice standards, the safe anesthesia section in the World Health Organization Guidelines for Safe Surgery 2008 also includes presentations on the importance of the safe administration of medications.5

Surprisingly, these documents contain no mention of the potential catastrophic complications resulting from accidentally injecting IV medications into the intrathecal or epidural space, or of injecting epidural medication into the IV. Although the incidence of these complications is relatively rare, millions of epidurals are placed each year and the risk to patients (as evidenced by continuing case reports, legal cases, and articles in the lay press) continues. Recently, the popular press has once again reported the heart-wrenching case of a laboring woman who became paralyzed after the accidental injection of a nonanesthetic solution (the powerful antiseptic chlorhexidine) into her epidural space.6 In previous reports, the offending agents were an antibiotic,7 neuromuscular blocker,8 antihypertensive or vasopressor agents,7 anesthesia induction agents,8 and even tranexamic acid.9

The National Reporting Learning Service in the United Kingdom continues to receive regular reports of wrong route errors in anesthesia involving cross-connectivity between neuraxial catheters and Luer devices.10,11 In response to these reports, the UK National Patient Safety Agency (NPSA) issued a Patient Safety Alert and recommended that starting April 1, 2011, all intrathecal bolus doses should be administered, and all lumbar puncture samples obtained, using only syringes, needles, and other devices with connectors that do not connect with IV equipment.12 However this deadline has passed, the goal has not been met in either the United States or the United Kingdom, and the risk thus continues. Ignoring this risk is irresponsible, and from a patient safety perspective, a seismic oversight.

DEVELOPING AND TESTING SOLUTIONS

Other accidental or incorrect-route drug administrations have been eliminated over the past decades by developing intelligent solutions, for instance, pin key-index systems to prevent administration of the wrong volatile agent, and other methods to prevent the proverbial round peg from

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being placed within the square hole. Although these remedies also have been proposed for use with epidurals and spinals, they have not been developed or evaluated. Although solutions being considered are as yet imperfect, the larger problem is that there has not been the necessary consensus, pressure, and motivation in the United States or Europe to address the problem.

While the United States has been somewhat silent on the subject of incorrect-route drug administration, the United Kingdom has taken notice, although progress has been glacially slow. The elimination of this source of harm was 1 of 4 specific targets for harm reduction in the UK Chief Medical Officer’s report, “An Organisation with a Memory,” published in 2000.1 In 2004, the NPSA recommended that non-Luer compliant connectors be used for all neuraxial procedures, and that new designs be tested before introduction into practice.12 In 2006, 3 connector prototypes were described, but only 1 of them has successfully completed laboratory, simulation, and clinical assessment stages.13 In 2009, the UK Parliamentary Health Select Committee expressed frustration with the delayed introduction of a non-Luer spinal needle. In response, the NPSA convened an External Reference Group on Safer Neuraxial Devices to oversee the introduction of non-Luer connectors. A number of manufacturers have now developed devices, which, although welcome, potentially introduce new risks from a multiplicity of non-Luer connectors. Furthermore, it seems that the design of a useful non-Luer connector is not as simple as many, including ourselves, might think. The small-scale evaluation of 2 of these systems has yielded some important lessons. In initial evaluation, both non-Luer systems scored significantly lower than standard equipment for overall performance of spinal and epidural procedures, although the performance of non-Luer systems was mostly rated as “adequate or better.”13 More critically, both non-Luer connectors could cross-connect with 1 or more other Luer connectors, but this design shortcoming has purportedly since been eliminated following feedback to the manufacturers. The authors of the evaluation commented wryly that, “introducing equipment that is fully compliant with the National Patient Safety Agency alert poses a significant challenge to manufacturers and clinicians.” The authors concluded that before introducing any non-Luer device into widespread use, independent, formal evaluation should be performed.13 That, unfortunately, has not yet occurred.

A GLOBAL RESPONSE IS NEEDED

Why do these catastrophic errors continue to occur? Humans are fallible, particularly when distracted or under stress. No matter how conscientious the clinician, errors will always occur.14 The more difficult question—what are we waiting for before we remedy this risk—is much harder to answer. It is irresponsible for the anesthesiology community to wait for industry to come up with the remedy.

We need to work together to develop one uniform, non-interchangeable system.15 No fix will be perfect, as there will always be some degree of inconvenience if the gauge of the epidural or spinal catheter connector does not match a standard syringe. Assessing whether the ultimate solution involves changing the size of the epidural connector or switching from a female to a male end is not the major barrier. What is essential at this point is that all concerned parties must meet, that a consensus regarding the most effective solution be developed, and that all epidural and spinal kits use this new safer alternative to epidural catheter design. Further, standardization of equipment, not only in one city or one country but across the entire globe is necessary to improve patient safety. Despite the fact that globalization is clearly evidenced throughout our daily lives, there appears to be little interaction between various countries when it comes to fixing this problem. Preliminary efforts are underway in several countries involving numerous, mutually exclusive solutions.

Will development and implementation of a new non-Luer epidural catheter increase costs? Of course, but in the words of John F. Kennedy, “there are risks and costs to a program of action, but they are far less than the long-range risks and costs of comfortable inaction.” Uncomfortable as it may be, the time has come for action. **

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