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PATIENT SAFETY NETWORK

The Wrong Channel

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The Case

A 28-year-old woman in labor began receiving treatment with magnesium sulfate for preeclampsia. Initial dosing started at 50 mL/hour using a multi-channel medication pump (Figure). Additional infusions from the pump included lactated ringers (125 mL/hour) and Pitocin (12 mL/hour). The three pump chambers were located side by side on the device. Following placement of epidural anesthesia, a fetal heart rate deceleration occurred due to maternal hypotension. A fluid bolus with lactated ringers was ordered. The nurse increased the pump rate to 500 mL/hour, but within 20 minutes, the patient reported feeling warm, weak, short of breath, and flushed.

While checking the pump, the nurse realized that she had inadvertently increased the magnesium sulfate rate instead of the lactated ringers. The infusion was stopped immediately. The patient remained weak and areflexic for about 20 minutes, prompting administration of calcium gluconate. She was monitored closely until her symptoms fully resolved. Afterward, she successfully delivered a healthy infant.

The Commentary

We have all seen “someone else” turn on the wrong burner on the stove and burn themselves. Many of us have seen “other people” futilely try to unlock the door of the wrong automobile that looks like theirs. All of us have known a few men who have inadvertently strolled into—and then scampered out of—the women’s bathroom. These are everyday examples of slightly hazardous mix-ups between similar things. As we read about them (luckily, they never happen to *us*, of course), we are prompted to ask: Which stoves are the most confusing? What time of day do people mistake another car for theirs? Does the subtlety of the bathroom sign play a role in this embarrassing gender gaffe?

Luckily, these mix-ups, and the steps taken to prevent them, can help point the way to preventing the type of mix-up we see in the multi-channel infusion pump case. What do we know about design flaws with infusion pumps that made this adverse event more likely? More important, what can medical device companies, health care organizations, and *you* do about reducing the incidence?

Scope of Infusion Pump Safety Issues

Observational studies of infusion pump and intravenous (IV) medication safety illustrate some unpleasant realities. Husch and colleagues (1) prospectively observed and detected that 59% of IV medication administrations over a 9-hour period involved an error. The article cites 37 “rate deviation” errors but did not specifically mention any infusion pump channel mix-ups. Their definition of error was strict, in that it included any preventable event that may cause or lead to inappropriate IV medication use or patient harm. When they compared the error rates seen under direct observation with those reported through the institution’s incident reporting system, they found a 600-fold difference!

Other prospective studies demonstrate a wide variety of infusion pump adverse events, pointing to many design and process issues. One multi-method study (2) mentions several types of “wrongly routed” flows, but there were no specific data about multi-channel infusion pumps. Another project that observed nurses administering IV medications found 265 so-called mistakes, slips, and violations.(3) The authors’ detailed analysis pointed to “inadequate use of technology” and “design failures” as common culprits, but they found no specific infusion pump channel mix-ups like the one seen in our case.

Human Factors Engineering Analyses

Human factors engineering (HFE) methods provide a complementary approach to identifying design flaws in infusion pumps and other devices.(4) Because of their potential to predict adverse events related to design, HFE methods (eg, heuristic evaluation and usability testing) have become standard device development processes supported by biomedical device national standards organizations (5) and the United States Food and Drug Administration (FDA).(6)

In an HFE study on an infusion pump, a heuristic (expert) evaluation was accomplished by 4 raters, who used 14 human factors design guidelines to find 231 violations.(7) Heuristic evaluation is a systematic “benchtop” inspection method.(8) Human factors engineering experts use a set of principles or list of design guidelines to review physical appearance, design of controls and displays, and even warning labels and accompanying training and trouble-shooting guides. The investigators found many design violations that might be relevant to this case, since potential problems were often identified in the parts of the infusion pump where doses are changed and drug settings are confirmed.

Ginsburg also applied heuristic evaluation and HFE usability testing to three infusion pumps.(9) In usability testing, 17 typical infusion pump users attempted several realistic clinical scenarios on 3 infusion pump types. Performance analysis focused on errors, and trained users of the 3 pumps had a total of 10, 18, and 42 critical, yet unnoticed, errors in 40-minute sessions. The paper did not reveal if any were of the channel-confusion type.

A Magician’s Dream

Another viewpoint arises when we start looking at devices, software, and even architecture through a more critical HFE lens. Most likely, in this case, the sets of tubing, the connection points, and the infusion pump channels had similar color, texture, and shape. The controls and displays for each channel were likely the same. Moreover, most components and content of the fluid system are nearly invisible, the system is attached to an opaque patient, and all of it is located in a cluttered, noisy, and oft-interrupted environment.

This is a magician’s dream set-up. Unfortunately, those being “tricked” are often unable to simply return to their seats in the audience.

Industry’s Role

Fortunately, industry and other stakeholders have begun to absorb this message. The ANSI/AAMI HE-74 (5) is a guide to less error-prone design of devices, including infusion devices. The guide is being adopted in industry and taught in universities. AdvaMed, a device industry group, has partnered with the FDA to create human factors design standards for all future infusion devices.(10) Designing efficient, yet safer, devices will require that industry fully embrace HFE methods and that it receive the type of assistance from health care organizations and providers described below.(11,12)

The Role of Health Care Organizations

Health care organizations can use HFE to select and deploy safer infusion pump technology—and help avoid the adverse event depicted in this case. Some health care systems are using heuristic evaluation to guide procurement and signal to industry their commitment to HFE aspects of design.(13) Other hospitals are employing usability testing to compare several infusion pump models prior to purchase.(9)

Even if an infusion pump system is not being replaced, an organization can use HFE methods to make its existing system safer. Biomedical engineers and nurses, if armed with general training in HFE principles, can detect and suggest fixes for many potential vulnerabilities.(14) Usability testing can aid in the improved design of pump labels and other cognitive aids (eg, quick-reference cards).(4) For instance, a color-matching or text-labeling method for the IV tubing and bag could be developed with usability testing and then standardized across the institution. Usability testing can also guide the focus and content of in-service training on infusion pumps. A facility could identify the installation and operational steps that most often lead to infusion pump channel confusion and emphasize those steps over others.

Your Role (“Homework”)

FDA regulations, industry standards, and HFE methods will never be sufficient. All of them depend on you, the health care provider. Many of you can support the organizational roles listed above (for example, to learn basic HFE principles and participate in analyses of new technologies). You can also help participate in analyses of adverse events and report any infusion pump events or near misses that you see.(15) You can also report areas of vulnerability. When you see infusion pump devices that remind you of the confusing stove, the similar cars, or the vaguely labeled bathroom, that can serve as your signal to help all the stakeholders see the design-related safety issues hiding in plain sight.

The “Perfect” Infusion Pump?

Many industry and academic groups have tried the usual brainstorming and focus group methods to revolutionize infusion pump design. What is needed and described above is a fresh approach that stares directly at the naked truth of how bad things have become in error-prone areas like IV medication administration through infusion pumps. More creative design can make it obvious—even to the proverbial kids on the street—which IV medication is coming from which IV bag, through which infusion pump channel, at what rate, and into where.

Specifically, I would recommend the following design considerations: (i) improve displays on the status of multiple channels or multiple pumps, (ii) make it more obvious how fluid is flowing from each IV bag all the way to the IV catheter—beyond simply placing a label every 6 inches, and (iii) be savvy and humble enough to learn from other industries that also try to avoid mix-ups—creative answers can be found nearly everywhere (eg, even bartender equipment might hold design lessons).

Take-Home Points

- Confusion between multiple infusion pump channels is just one type of several adverse events that occur frequently (>50%) when IV fluid and medications are administered through these devices.
- There are many conceptual and HFE reasons for channel confusion, but little explicit literature or direct studies address the problem.
- An increasing number of people in industry, government, academia, and practice are applying HFE to infusion pump design vulnerabilities.
- Providers play a key role in addressing this and other medical device problems, since individual efforts by other stakeholders are insufficient.

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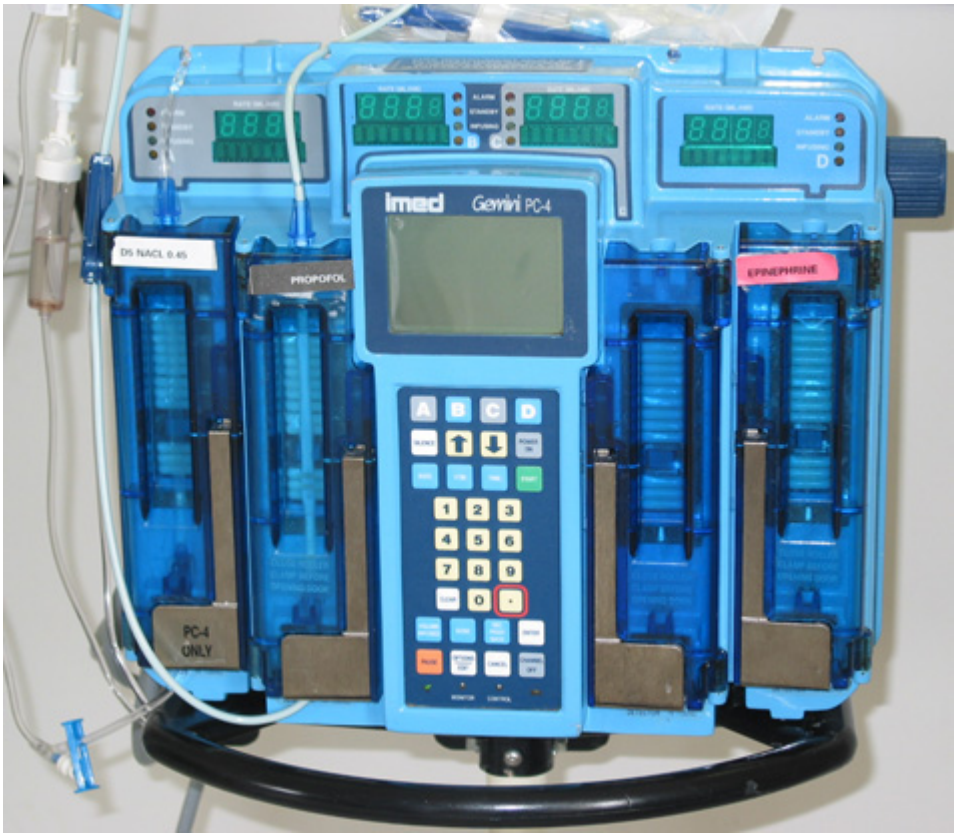
Figure

Figure. Multi-Channel Infusion Pump



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