

Misconnections

Challenge: Designed Environment

The April special supplement highlighted a high-risk medication safety program that was instituted after a tragic accidental injection of Vincristine into the CSF. A recent CHPSO alert highlighted the risk of accidentally connecting Viaspan to an intravenous line.

One common factor in these two instances is that if misconnections were impossible, these hazards would have been mitigated. Vincristine, in particular, has been a recurring cause of death in cancer patients due to the exact same error — injection into the CSF of a medication intended for IV use.

If the connectors for epidural lines were incompatible with intravenous lines; if the connector for Viaspan were incompatible with IV tubing, we would not need these warnings, and the harm from

such misconnections would become much rarer.

There is progress in the development of standards for connectors that would “force” users to connect lines properly. These are the ISO 80369 Small Bore Connectors Standards. The total standards package consists of seven parts: ISO 80369-1, General requirements; ISO 80369-2, Driving gases and breathing system ancillary ports; ISO 80369-3, Enteral feeding; ISO 80369-4, Urological; ISO 80369-5, Limb cuffs; ISO 80369-6, Neuraxial; and ISO 80369-7, Luer fittings (ISO 594 replacement).

The list represents a set of different uses that currently can be cross-connected. Misconnection often creates serious risks (e.g., driving gases and blood pressure cuff inflation lines cause air embolus when connected to an IV and local anesthetics for neuraxial use, such as subarachnoid or epidural may cause cardiac arrest given intravenously). Use may be fatal when given intravenously. Implementing forcing functions by making the

different classes of connectors incompatible with each other acknowledges that the best practitioners still will make occasional errors, and that error rate, low as it is, is still too high for our patients. By adding a mechanical barrier, these occasional errors will be much less likely to harm patients.

The UK is already moving to incompatible devices for neuraxial injections, as noted in the alert “Safer spinal (intrathecal), epidural and regional devices” (www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=65259), with the introduction of such devices for spinal use by April 2011 and for the other uses by April 2013. California law mandates that intravenous, epidural and enteral feeding connection devices shall be designed to not fit into connection ports other than the type for which they are intended: beginning January 1, 2013 for intravenous and enteral devices, and January 1, 2014 for epidural devices. Many of these devices should be appearing on the market — particularly after the ISO standards are finally released.

— Rory Jaffe, MD MBA rjaffe@calhospital.org

ISO 80369 Status as of 4/29/2010

Standard	Title	Status
80369-1	General requirements	Publication planned for November 2010
80369-2	Driving gases and breathing system ancillary ports	Publication planned for March 2011
80369-3	Enteral feeding	Proposed New Work
80369-4	Urological	Not yet active
80369-5	Limb cuffs	Proposed New Work
80369-6	Neuraxial	Publication planned for January 2012
80369-7	Luer fittings	Not yet active

Status updates are available at goo.gl/sZLx

Health Care Reform Includes PSO Provision

The Patient Protection and Affordable Care Act (PPACA), the health care reform bill, includes a Hospital Readmissions Reduction Program, which reduces payments for risk-adjusted excess readmissions for certain conditions and requires public reporting of readmission rates. In addition, PPACA includes an amendment to the Public Service Act

The PPACA addition to the Public Service Act regarding PSOs:

Sec. 399KK. Quality Improvement Program for Hospitals With a High Severity Adjusted Readmission Rate.

(a) Establishment. —

(1) In General. — Not later than 2 years after the date of enactment of this section, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 921(4)).

(2) Eligible Hospital Defined. — In this subsection, the term ‘eligible hospital’ means a hospital that the Secretary determines has a high rate of risk adjusted readmissions for the conditions described in section 1886(q)(8)(A) of the Social Security Act and has not taken appropriate steps to reduce such readmissions and improve patient safety as evidenced through historically high rates of readmissions, as determined by the Secretary.

(3) Risk Adjustment. — The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

(b) Report to the Secretary. — As determined appropriate by the Secretary, eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.

establishing a program for hospitals with high risk-adjusted readmission rates. This program will use patient-safety organizations, such as CHPSO. Until the Department of Health and Human Services issues the regulations, specifics of this program are unclear.

Once details emerge, CHPSO will include the new program in its work plan as part of its service to member hospitals.

— Rory Jaffe, rjaffe@calhospital.org

An Amazing Assumption

While attending the AORN Congress last month, I took part in a session about applying lean principles in the OR, an area of interest because I’ve spent considerable time integrating human factors concepts with lean concepts. One of the session exercises, designed to demonstrate that “value” is defined by the ultimate customer, asked audience members to pair up and discuss this prompt: “*What I really want from an airline is...*”

Approximately three minutes of discussion later, audience members queued at the microphone and shared their responses:

- “Get me there on time”
- “Don’t lose my bags, especially if you’re going to charge me extra”
- “Keep us informed about our arrival time”

- “Don’t lie to us about the weather we have Internet on our phone”

- and so on...

Likely the only active airline pilot in the room, and one of relatively few who regularly flies more than 100,000 miles a year as a passenger, I was intrigued by the glaring omission in the list above. Have you noticed it?

Not one person said, “Get me there safely.” It was just assumed, and that’s a great thing. If this session had been held in the 1980s, or even the 1990s, I’m fairly certain that “Don’t kill me” would have been mentioned.

James Anderson, CEO of Cincinnati Children’s Hospital, has a great quote about what patients and their families really want. “*Don’t hurt me, make me better, and be nice to me. Without the first two, the third one doesn’t matter.*” To paraphrase Mr. Anderson, it’s my experience that what a patient truly desires is patient safety, quality outcomes and patient satisfaction, in that order. It will be a great day for health care when people forget to mention patient safety because the data supports the assumption that they are indeed safe.

— Steven Montague lifewings@verizon.net, Vice President, [LifeWings](http://LifeWings.net)

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FDA Initiates Infusion Pump Safety Program

Challenge: Designed Environment

The Food and Drug Administration (FDA), in recognition of a number of significant adverse events involving infusion pumps, is changing the way it is regulating and approving the pumps. Notably, the FDA is emphasizing human factors issues. Where there is a risk of misuse, the manufacturer must identify an appropriate response to that risk, and the response should not be merely training for the user. The FDA provided a sample list (see page 4) of human factors issues to address, with the notation that the list is not necessarily complete. However, it does give us a set of questions we should be asking about our current infusion devices.

The FDA also warned manufacturers against using user preference as an indication that their interface is safe. High-user preference does not necessarily equate with safety — evaluation of hazardous equipment should go beyond user preference to an evaluation of the how the manufacturer addresses the risks. It is not yet clear whether the manufacturer's risk-mitigation analysis will be publicly available. Such an analysis would be a great aid to purchasing decisions. However, hospitals can conduct their own analysis of the equipment, and the FDA's list is a good start. The FDA's guidance includes not only human factors risks, but also the other types of risks associated with external infusion pumps, and can be found at www.chpso.org/pumps/index.asp, along with information on risk reduction strategies and selection and use of smart pumps.

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Calendar

Following is a list of upcoming events that are still open for enrollment. For more information or to enroll, use the contacts listed below.

May

11: SCPSC (Southern California Patient Safety Collaborative): Track I: Surgical Care Improvement Project, Sepsis, Hospital-Acquired Infections in the ICU Setting. City of Industry.

13: BEACON.: Leadership Council. Location to be determined.

June

2: HASD&IC (Hospital Association of San Diego & Imperial Counties): San Diego Patient Safety Council; Sepsis. San Diego.

11: CAPSAC: California Patient Safety Action Coalition Meeting Pasadena.

29: (Date change — was June 15) SCPSC: Track II: Pressure Ulcers. City of Industry.

July

27: BEACON: Quarterly Meeting. Location to be determined.

August

10: SCPSC: Track I: Surgical Care Improvement Project, Sepsis, Hospital-Acquired Infections in the ICU Setting. City of Industry.

12: HASD&IC: San Diego Patient Safety Council; Sepsis. San Diego.

September

1: SCPSC: Track II: Pressure Ulcers. City of Industry.

10: CAPSAC: California Patient Safety Action Coalition Meeting Napa.

10: BEACON: Key Contacts Meeting. Location to be determined.

23: BEACON: Physician Leadership Meeting. Location to be determined.

24: BEACON: CNE Meeting. Location to be determined.

October

6: HASD&IC: San Diego Patient Safety Council; Sepsis. San Diego.

November

16: SCPSC: Track I: Surgical Care Improvement Project, Sepsis, Hospital-Acquired Infections in the ICU Setting. City of Industry.

December

2: SCPSC: Track II: Pressure Ulcers. City of Industry.

3: CAPSAC: California Patient Safety Action Coalition Meeting. Torrance.

15: (Date change — was December 1) HASD&IC: San Diego Patient Safety Council; Sepsis. San Diego.

For further information on these events:

BEACON: Pamela Speich pspeich@hospitalcouncil.net or www.beaconcollaborative.org

CAPSAC: Theresa Manley manleyt1@pamf.org or www.capsac.org

HASD&IC: Lindsey Wade lwade@hasdic.org

SCPSC: Catherine Carson ccarson@hasc.org

Infusion Pump Use Hazard Examples (from the FDA draft guidance for industry and FDA staff)

Hazard	Corresponding Risk(s) to Health	Potential Cause(s)
User does not understand how to initiate pump operation	Delay of therapy	User interface design is confusing. User confused by pump operation, instructions for use insufficient or lacking, training insufficient or lacking. Note: Can apply to lay users particularly.
The pump is programmed incorrectly	Overdose Underdose Delay of therapy Incorrect therapy	User believes “piggy back” is accounted for in set up but it is not.
		The instructions for use are confusing for the user.
		The user specifies incorrect configuration parameters (blood glucose reading, drug concentration, etc.)
		The user accidentally touches the pump console, presses the wrong key or key “bounces” when hit, changing or mistakenly programming pump settings.
Infusion stopped prematurely	Underdose Delay of therapy	The user forgets to resume the pump after suspending it.
		User is unaware of battery capacity.
The user fails to detect or understand pump notifications	Overdose Underdose Delay of therapy Incorrect therapy	Background noise or nuisance alarms cause user to fail to detect or to ignore them.
		The user muffles the pump’s speaker or other audio devices, either intentionally or unintentionally
Wrong medication or concentration is delivered	Incorrect therapy Delay of therapy	User selects and sets up pump with incorrect medication or incorrect concentration.
		Medication is correct but user selects incorrect concentration or delivery rate for that medication.
Physical set up, such as routing of tubing or selection of appropriate tubing set is incorrect	Overdose Underdose Delay of therapy	User believes infusion is occurring but it is not.
		User is required to perform excessive programming task sequences or perform them repeatedly.
		User is confused about pump set-up, troubleshooting, or operation tasks.
		Physical set-up of pump components is difficult.
User “works around” or “bypasses” software limits on drug/dose parameters	Overdose Underdose	Software configuration, possibly user-defined configuration, is not applicable to current treatment and user is compelled to “work around” or “bypass it”.
		“Work around” or “bypass” requirements are required so often the user does not attend to displayed limits.
User ignores or misinterprets software-generated “warnings”	Overdose Underdose Incorrect therapy	Warnings are displayed so often that user ignores them.
		Warning statements are not sufficiently informative, meaningful or appropriate for the condition
User misinterprets or misunderstands pump status or operational mode	Overdose Underdose Incorrect therapy Delay of treatment	Pump operates differently than expected.
		Pump operational mode indications are absent or not communicated effectively.
		Display characters not distinguishable.
The pump is disconnected	Underdose Delay of therapy Exsanguantion	The user’s motions cause the pump to be disconnected from the user.
Excessive bolus administration due to too many bolus requests from the user	Overdose	The user forgets previously received boluses, and requests for unnecessary boluses without consulting with bolus history records.
(Drug) Leakage	Underdose Trauma Allergic response	The user does not follow instructions to disconnect the pump.
The drug reservoir is detached during normal pump use	Underdose Delay of therapy	The user’s motions cause the reservoir to be disconnected.