

## Wrong Blood in Tube

Humans cannot perform tasks correctly each time. Unaided, 98 percent correct performance is excellent. Nevertheless, when the consequences of error are severe, multiple system redesign steps may be needed to reduce the rate to an acceptable level. Achieving zero error may be impossible. Transfusion medicine provides a good example of the roadblocks to perfection.

Hospitals have taken vigorous steps to reduce the risk of major hemolytic transfusion reactions resulting from an incorrect crossmatch. In a recent paper (Ansari and Szallasi), the authors look at their success at eliminating discrepancies between the patient identified on the tube's label and the patient whose blood is in the tube (wrong blood in tube — WBIT).

In large-scale studies, the detected WBIT rate tends to be about 0.04 percent, but the real WBIT rate is even higher. Detection of the error only occurs when some red flag arises, such as a mismatch with an earlier recorded blood type, realization by the phlebotomist that he made a patient recognition error or post-facto analysis of an unexpected transfusion reaction.

The authors noted that their rate was similar to the typical rate, and WBITs persisted even when policies were changed to have two witnesses to patient ID and bedside tube labeling. They then added a second control, the two-tube/check-type method. This requires two different persons to draw blood from the same patient at two different times for patients who had no previously-recorded

blood type. This relatively simple step provides a “defense in depth,” adding a second, independent type check, markedly reducing the risk of WBIT.

With the two-tube/check-type method, a WBIT event will be caught when the ABO or Rh blood types are discrepant. However, WBIT may still occur when the two samples come from patients with the same major blood type (e.g., A+.) Then the crossmatch, which also screens for rarer incompatibilities, may still be in error. Indeed, the authors detected several potential errors by other means that were not detected by the two-tube/check-type method.

Further rate reductions may require more automation and innovations in patient and blood sample identification. To quote Richard Friedberg of Baystate Health System: “Absent a bar-code on the patient's forehead, the rest are all compromises.”

— Rory Jaffe, MD MBA, [rjaffe@chpso.org](mailto:rjaffe@chpso.org)

## Reference

Ansari S, Szallasi A. “Wrong blood in tube”: solutions for a persistent problem. *Vox sanguinis*. 2011;100(3):298-302.

## Just Culture Roadmap Progressing

A Just Culture Roadmap is in development for hospitals to use as a guide in developing, assessing and sustaining a Just Culture initiative tailored to their organizational needs. The Roadmap also will be used to identify needed resources

that can be placed into a comprehensive toolkit for members.

The initial draft was reviewed during the July 11 CHPSO Member Monthly Call with the focus being on tools and resources hospitals need and would like to see provided in the Just Culture toolkit. The objective is to have an updated Roadmap and an initial draft toolkit ready for the next CHPSO member call on August 8 at 10 AM.

Members provided some feedback on the July 11 call and via email. The takeaway from this call was the members would like an entire Just Culture program, all packaged with the capability to use their own logo on educational and communication materials. The review prompted more questions and additional requests for discussions. An informal work group will be created for those members that would like to provide additional feedback and that would like to share their tools or procedures that could be incorporated into the toolkit. The first informal work group meeting was by webinar on July 20 with the focus being on tools needed for the toolkit. Additional informal work group webinars are scheduled for August 17 and September 21, each at 10 AM.

Going forward after the comprehensive toolkit is completed and offered for implementation, future webinars or ad hoc calls may be scheduled for those members that would like an ongoing connection with the Roadmap Toolkit to discuss what is working and not working at their facility and allow an opportunity for the hospitals to share best practices and outcomes from their facility.

— Bobbie Dietz, [bdietz@chpso.org](mailto:bdietz@chpso.org)

## FDA Medical Device Clearance Process Criticized

The Institute of Medicine (IOM) released a study of the 510(k) clearance process for medical devices. Their answer to the question: “Does the 510(k) clearance process provide a reasonable assurance of safety and effectiveness?” was: “The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a premarket evaluation of safety and effectiveness as long as the standard for clearance is substantial equivalence to any previously cleared device.” As one of the committee members at the IOM briefing said, “510(k) logic is fundamentally flawed.”

Medical devices are divided into three classes that, roughly speaking, correspond to levels of risk and needed safety controls, Class I being lowest and Class III highest. 510(k) clearance allows Class II devices to come to market without a premarket approval (PMA) process. 510(k) clearance can also be used for certain Class I and Class III devices, but that is not extensively addressed by this report. Two-thirds of all new devices (typically Class I) are exempt from review. About one-third goes through 510(k) clearance. Only 1 percent of all new devices enter the market via the PMA pathway.

A manufacturer can obtain 510(k) clearance by notifying the FDA that the device is substantially equivalent to an older, approved Class II device (predicate). The new device would then be cleared for marketing subject to the same requirements as the predicate device. To be substantially equivalent, the device has to be for the same intended use as the predicate, with the same technological characteristics (or different characteristics that are

### Case Study: Biliary Stents in Peripheral Vasculature

“There are small stents whose size makes them suitable for application both in bile ducts and in peripheral vasculature. Because the former indication involves using a product in patients who have advanced cancer and short life expectancies, the long-term durability of the product is not critical with a biliary stent, and the FDA allows biliary stents to be cleared via the 510(k) process. The same stent, if used in peripheral vasculature, would require PMA because long-term risks posed by the device are of greater concern in this patient population. As a result of having multiple premarket-review pathways — 510(k) and PMA — available for a single device, it was possible for manufacturers to circumvent the PMA process for stents used in peripheral vasculature by clearing them through the 510(k) process and then having them be used off-label in peripheral vasculature. It was estimated that up to 90 percent of biliary-stent use was for off-label application in treating peripheral vascular disease.” — IOM

demonstrated to be as safe and effective as a predicate) and does not raise different questions of safety and efficacy than the predicate device.

The primary criticism by the IOM is that the clearance process does not include an evaluation, either pre-market or post-market, of the product’s safety. In cases in which the product is truly a clone of a currently marketed device, substantial equivalency is not necessarily an incorrect standard. However, substantial equivalence does not guarantee that the device poses the same risks and performs similarly to an older device, particularly when the device is a chimera of multiple predicates. And the manufacturer can use as a predicate an old, discontinued device or a device that was approved but never marketed.

There have been instances where a new 510(k) device, though based on a predicate, was found in practice to have a different risk profile. For example, many metal-on-metal hip systems were approved via 510(k), but the FDA is now conducting further review ([goo.gl/jBpZZ](http://goo.gl/jBpZZ)) based

upon adverse events in both the USA and the UK.

The IOM committee recommends increased premarket and postmarket regulation of these devices. To avoid tying up all new devices in the more costly and lengthy PMA process, the premarket review needs to be appropriate to the projected risk of the device. The report emphasizes the importance of postmarket surveillance — both to assure that the primary use is same as the predicate and to rapidly identify new risks. Improved postmarket surveillance may allow a quicker premarket process without needlessly increasing risk to patients. With appropriate surveillance, postmarket detection may occur after the same number of adverse events as it would in a large premarket study.

Motivation for assurance of primary use comes partially from the marketing rules. Marketing for “off-label use” is different for devices than drugs. While the FDA regulates and restricts off-label promotion of prescription drugs and restricted devices (typically Class III devices), the

Subscription service: Colleen Meacham [cmeacham@chps.org](mailto:cmeacham@chps.org)

Questions or comments: Rory Jaffe, MD MBA [rjaffe@chps.org](mailto:rjaffe@chps.org)

Copyright © 2011 [California Hospital Patient Safety Organization](http://CaliforniaHospitalPatientSafetyOrganization.org)

This newsletter may be freely distributed in its original form.

Opinions expressed by the authors are their own and not necessarily CHPSO’s.

Federal Trade Commission regulates promotion of virtually all Class II devices. The report includes the example of biliary stents, where the primary use in practice systematically differed from the 510(k) application.

Many facilities, including hospitals, are required to report to the FDA and/or manufacturer when a device has or may have caused or contributed to a patient's death, serious illness or serious injury (21CFR803.3 through 803.33). While the initial report may go to either the manufacturer or the FDA, an annual report of these events goes to the FDA. Providers can enhance the FDA's ability to monitor devices by not only identifying required events but also others that may indicate emerging device issues. Members can report these events to CHPSO. CHPSO is collecting the experience of many hospitals and will be looking for areas of concern.

— Rory Jaffe, MD MBA, [rjaffe@chpso.org](mailto:rjaffe@chpso.org)

## Reference

Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process. *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*. Washington, D.C.: National Academies Press; 2011:245.

## Brief Notes

### *CHPSO in the news*

The Agency for Healthcare Research and Quality (AHRQ) latest issue of webM&M highlights Patient Safety Organizations. There are two articles, one by Bill Munier, Director of AHRQ's Center for Quality Improvement and Patient Safety ([goo.gl/KiNSY](http://goo.gl/KiNSY)), and one by Rory Jaffe discussing the evolution of CHPSO ([goo.gl/nr4hu](http://goo.gl/nr4hu)).

### *Sending protected information*

When sending confidential messages to CHPSO, please use a secure method. In addition to the automated system for feeding incident reports to the CHPSO database, acceptable methods include:

**Encrypted email:** Each CHPSO employee has a public encryption key attached to their emails. Most email clients (e.g., Outlook, Thunderbird) have native support for this encryption method — no special software needed. Contact us for instructions and a copy of the key.

**Secure fax:** Our fax machine is both physically and electronically secured. Send faxes to 916.554.2299. After sending the fax, please notify Colleen Meacham at [cmeacham@chpso.org](mailto:cmeacham@chpso.org), as faxes will be held in the machine unprinted until a password is entered.

**US mail or other courier service,** such as UPS or FedEx: Documents can be sent to CHPSO, 1215 K St Ste 800, Sacramento, CA 95814.

**Confidential Discussion and Collaboration Site:** Please contact Colleen Meacham for access instructions. Messages posted on this site are visible to other CHPSO members.

### *Retained Surgical Items*

The Michigan Hospital Association PSO has joined our effort to identify and mitigate causes of retained surgical items, particularly “bits and pieces” intentionally left behind, such as micro-needles or broken drill bits. Broadening the effort to include other states will particularly help for learning from rare events such as these.

Many CHPSO hospitals are already participating and sending reports of their near-misses and retained items using the

brief information collection form. All CHPSO hospitals are welcome to join this effort. Contact Colleen Meacham ([cmeacham@chpso.org](mailto:cmeacham@chpso.org)) for more information and instructions.

## Calendar

The following upcoming events are still open for enrollment. For more information or to enroll, use the contacts listed below.

### *August*

**8:** CHPSO: Members Call. Just Culture Roadmap and Toolkit; Demonstration of Confidential Collaboration and Communication Portal. 10–11 AM

**9:** SCPC (Southern California Patient Safety Collaborative): Track I — Hospital Acquired Infections in the ICU Setting, Sepsis and Surgical Care Improvement Project. Industry Hills.

**17:** CHPSO: Just Culture Roadmap and Toolkit workgroup call. 10 AM

**23:** SCPC: Perinatal Monthly Webinar. 12:15 PM

**24:** PSCSD&IC (Patient Safety Council of San Diego & Imperial Counties): Ending Elective Deliveries Before 39 Weeks Gestation. San Diego.

**30:** PSCSD&IC: Standardizing Dosing Limits. San Diego.

### *September*

**9:** CAPSAC: California Patient Safety Action Coalition meeting. Sacramento.

**12:** CHPSO: Members Call. 10–11 AM

# CHPSO Patient Safety News

August 2011 ≈ Page 4

**13:** SCPSC: Track II — Pressure Ulcers, Readmissions and Transitions of Care. Industry Hills.

**13:** PSCSD&IC: Preventing Rehospitalizations Network (PRN). San Diego.

**14:** PSCSD&IC: Preventing Rehospitalizations Network (PRN). San Diego.

**21:** CHPSO: Just Culture Roadmap and Toolkit workgroup call. 10 AM

**27:** SCPSC: Perinatal Monthly Webinar. 12:15 PM

**27:** PSCSD&IC: HAI Elimination. San Diego.

## October

**10:** CHPSO: Members Call. 10–11 AM

**20:** PSCSD&IC: Standardizing Dosing Limits. San Diego.

**25:** SCPSC: Perinatal Monthly Webinar. 12:15 PM

## November

**2:** PSCSD&IC: Preventing Rehospitalizations Network (PRN). San Diego.

**8:** SCPSC: Track I — Hospital Acquired Infections in the ICU Setting, Sepsis and Surgical Care Improvement Project. Industry Hills.

**14:** CHPSO: Members Call. 10–11 AM

**15:** SCPSC: Track III — Perinatal Care. Industry Hills.

**15:** PSCSD&IC: Ending Elective Deliveries Before 39 Weeks Gestation. San Diego.

## December

**2:** CAPSAC: California Patient Safety Action Coalition meeting. Torrance.

**12:** CHPSO: Members Call. 10–11 AM

**13:** SCPSC: Track II — Pressure Ulcers, Readmissions and Transitions of Care. Industry Hills.

**13:** PSCSD&IC: HAI Elimination. San Diego.

**15:** PSCSD&IC: Standardizing Dosing Limits. San Diego

*For further information on these events:*

CAPSAC: John Keats [John.Keats@CHW.edu](mailto:John.Keats@CHW.edu) or [www.capsac.org](http://www.capsac.org)

CHPSO: Rory Jaffe [rjaffe@chpso.org](mailto:rjaffe@chpso.org)

PSCSD&IC: Lindsey Wade [lwade@hasdic.org](mailto:lwade@hasdic.org)

SCPSC: Julia Slininger [jslininger@hasc.org](mailto:jslininger@hasc.org)

## Subscribe Now

Newsletter subscription is free and open to all. If you wish to receive this newsletter and other email updates from CHPSO, contact Colleen Meacham ([cmeacham@chpso.org](mailto:cmeacham@chpso.org)) and include your name, email address, organization and position.

## About This Newsletter

CHPSO *Patient Safety News* provides lessons learned from reviews of patient-safety events and news of patient-safety

activities in this state. We hope you will find it useful in your efforts to improve patient outcomes. This newsletter may be freely distributed in its original form. Copies of each newsletter are archived on the CHPSO website ([www.chpso.org](http://www.chpso.org)).

Prospective authors may submit articles to Rory Jaffe, MD, MBA: [rjaffe@chpso.org](mailto:rjaffe@chpso.org), 916.552.7568. Typical articles will be brief — between 200 and 600 words. A completed [publication agreement form](#) must be submitted prior to publication.

## Contact Information

Rory Jaffe, Executive Director, [rjaffe@chpso.org](mailto:rjaffe@chpso.org) 916.552.7568

Bobbie Dietz, Director Quality & Patient Safety, [bdietz@chpso.org](mailto:bdietz@chpso.org) 916.552.7599

Colleen Meacham, Administrative Assistant, [cmeacham@chpso.org](mailto:cmeacham@chpso.org) 916.552.7651

CHPSO office, [info@chpso.org](mailto:info@chpso.org) 916.552.2600, secure fax 916.554.2299