Is the Patient Safety Movement Killing the Art of Medicine?

"I learned the discipline of flying in order to have the freedom of flight.…Discipline prevents crashes."—Captain John Cook, British Airways, Concorde Pilot

Much of the discussion in patient safety revolves around systems approaches to reducing the frequency and impact of human error—for example, standardization, checklists and forcing functions. To protect patients, these approaches often reduce provider autonomy.

Yet traditional health care training emphasizes individual artisanship and self-reliance. For physicians, this training occurs through the traditional master-apprentice relationship of internship and residency, drilling in the responsibility to apply knowledge and personal experience to the treatment of each individual patient.

Will provider autonomy have to go away, standardizing all health care? The short answer is that both artisanship and standardization are necessary. The criterion for selecting one over the other for any aspect of medical care is that which benefits the patient the most.

Some activities (e.g., preparation for surgery) are repetitive, involve teams of people, and have critical steps that cannot be missed. Those characteristics call out for measures to improve reliability, and for those repetitive steps, a checklist can be very beneficial. On the other hand, no one is advocating a checklist to guide the surgeon's hand during sur-gery—there, anatomy can be different, the location of the lesion may vary, and the choice of "best" practice may vary considerably from patient to patient.

Health care is a complex mixture of art and science. Those working to improve patient safety must recognize where human factors engineering benefits patients, and where it does not. And health care training needs to develop a more nuanced view of the practice of medicine, helping practitioners understand the inherent risks (and benefits) of individual autonomy in a field as complex and dangerous as health care.

Ultimately, an ideally designed, safe health care delivery system will provide the right mixture of discipline and freedom, and health care practitioners will still enjoy significant freedoms; knowing that systems will help the routine parts of health care proceed more safely.

—Rory Jaffe, MD rjaffe@calhospital.org

CHPSO Chooses Quantros as Technology Provider

The California Hospital Patient Safety Organization (CHPSO) has selected Quantros, a leading health care information software company, as its technology provider.

"A critical element in our selection was that the technology partner provides hospitals with a nearly effortless reporting system," said CHPSO Executive Director Rory Jaffe, MD. "We recognize the significant reporting burden hospitals currently bear, and do not want data reporting to be a barrier to CHPSO participation."

Quantros will store and secure CHPSO data, as well as provide an automatic secure transfer of Patient Safety Work Product (PSWP) data from those using Quantros SRM into the CHPSO database. The company also will provide a secure PSWP data upload process for health care facilities using either internally developed or commercial systems other than Quantros SRM. For hospitals with data solely on paper, Quantros will provide data entry screens for manual capture of PSWP data.

Quantros also will provide pre-built comparative reports that individual hospitals can access at any time, allowing them to view aggregate information about their own reports and compare their experience to comparable groups of hospitals—both within California and nationally. In addition, the company will provide free technical support for the upload, data entry and pre-built report processes.

More than 2,000 health care facilities use Quantros technology solutions, and many patient safety organizations are selecting Quantros as their technology partner. Quantros team members include physicians, nurses and health care professionals, as well as an experienced team of information technology specialists.

Join the Effort to Reduce CLBSIs

An estimated 250,000 central-line blood stream infections (CLBSIs) occur in hospitals each year and as many as 62,000 patients who get these infections die as a result. The Health Research and Educational Trust, through a contract with the Agency for Healthcare Research and Quality, and in partnership with the Johns Hopkins University Quality and Safety Research Group and the Keystone Center for Patient Safety and Quality of the Michigan Health & Hospital Association, will implement in more than 100 hospitals in 10 states nationwide a patient-safety program proven to dramatically reduce CLBSIs.

California has been selected as one of the states, and the California Hospital Association and CHPSO are proud to lead the effort. Three collaborative meetings are required as part of this project; much of the rest of the interactions will be by teleconference. To make the program available to as many hospitals as possible, the in-person meetings will be held in both the San Diego region and the Central Valley.

Information on the program, including details on participation requirements, is located on the CHPSO website at www.chpso.org/clbsi/index.asp. A teleconference will be scheduled to help hospitals assess whether they want to participate. To sign up for the teleconference, contact La Shon Tate at ltate@calhospital.org. Questions about participation may be sent to Rory Jaffe at rjaffe@calhospital.org, Judith Yates at jyates@hasdic.org or Mary Lopez at mlopez@hcncc.org.

— Rory Jaffe, MD rjaffe@calhospital.org

Safety and Quality Collaborative Focuses on Maternity Care in California

California Maternal Quality Care Collaborative (CMQCC) is a multi-stakeholder organization of physicians, nurses, midwives, administrators and public health leaders devoted to eliminating preventable maternal death and injury, and promoting equitable maternity care in California. CMQCC's collaborative approach brings resources, tools, measures and quality-improvement techniques to maternity services throughout the state. CMQCC was formed in July 2006 by the California Department of Health, Maternal Child and Adolescent Health Division, and California Perinatal Quality Care Collaborative.

CMQCC, with the Maternal Child and Adolescent Health Division, recently formed the first-ever California Pregnancy-Associated Maternal Mortality Review (CA-PAMR) Committee to examine why **maternal mortality rates over the past six years have doubled in the state** and identify what to do about it. For more information, visit the CMQCC website at www.cmqcc.org/maternal_mortality.

Based on the CA-PAMR reviews, one of the leading causes of maternal deaths with a strong chance to have altered outcomes is obstetric hemorrhage. A statewide taskforce recently finished a set of tools to improve the readiness, recognition, response and reporting of hemorrhages. The tools are available on the CMQCC website at www.cmqcc.org, which also offers background material on maternal-quality improvement.

Developing a set of best-practice documents and guidelines is only the first step in leading change. Thus, two major efforts are currently underway to support hospital and clinician implementation of the developed tools. First, CMQCC is hosting a multi-hospital learning collaborative that will offer quality-improvement training, expert and peer mentoring, and training in safety drills over a 12-month period. Second, CMQCC is providing technical support to the Los Angeles County Health Department's OB hemorrhage project within the Local Assistance for Maternal Health (LAMH) pilot project. For more information, visit the CMQCC website at www.cmqcc.org/committees_projects/lamh_local_assistance_for_maternal_health.

Another quality-improvement initiative that CMQCC is leading is the elimination of non-medically indicated elective deliveries prior to 39 weeks in San Bernardino County. Currently, seven hospitals have been collaborating on the LAMH project for a year and have begun to make changes in clinical practices in their county. There is significant neonatal and maternal morbidity that can be prevented. There also will be a new statewide learning collaborative with the March of Dimes and other partners for this topic.

For questions regarding CMQCC, visit the website at www.cmqcc.org/about/contact_us or call Debra Bingham at 650.723.5763.

—Elliott K. Main, MD main@cmqcc.org and Debra Bingham, DrPH, RN bingham@cmqcc.org

IJ Corner

The California Department of Public Health (CDPH) is authorized to administer an administrative penalty in a situation where a noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to a patient. Fines are up to $50,000 for the first penalty, up to $75,000 for the second and up to $100,000 for subsequent violations. To date, 83 administrative penalties have been issued. Medication safety leads the list with 33 penalties.

Medication safety can be improved by the annual review and updating of the Medication Error Reduction Plan (MERP) mandated in 2000. The MERP is required to:

1. Evaluate, assess and include a method to address each of the procedures and systems, including those related to professional practice, or health care products, procedures and systems, including, but not limited to, prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use to identify weaknesses or deficiencies that could contribute to errors in the administration of medication.

2. Include an annual review and modification to assess the effectiveness of the implementation of each of the procedures and systems listed in #1, and make appropriate changes.

3. Describe the technology to be implemented and how it is expected to reduce medication-related errors.

4. Include a system or process to proactively identify actual or potential medication-related errors.

5. Include a multidisciplinary process to regularly analyze all identified actual or potential medication-related errors, and describe how the analysis will be utilized to change current procedures and systems to reduce medication-related errors.

6. Include a process to incorporate external medication-related error alerts to modify current processes and systems as appropriate.

Beginning in January 2009, as part of the licensure survey, CDPH began reviewing hospital MERPs. To date, the deficiencies issued fall into one of the following categories: 1) failure to address all statutory elements of the MERP; and 2) failure to implement polices and procedures related to medication safety and MERP. Hospitals are encouraged to review the MERP statute (Health and Safety Code Section 1339.63), review the hospital MERP plan to ensure all elements are addressed and the annual review of the MERP is documented, and that policies and procedures are implemented and understood by staff.

—Debby Rogers drogers@calhospital.org

Reliable Patient-Centered Care

There is a growing chorus calling for health care that is customized based on patient needs and preferences. The belief is that this will not only improve patient-provider relationships, but will also empower patients to help eliminate unwanted or unnecessary services, and improve outcomes.

In response to this call, some have suggested that system-based quality measures should be scrapped because clinicians must either orient their behaviors to be patient-centered or system-centered. While I understand their concern about patients becoming nothing more than a body associated with a medical record number, I think there is ample evidence in the marketplace that a patient-centered **system** is the optimum approach.

For example, when you walk into your local Starbucks, you are greeted by a dizzying array of choices and almost endless variation. So what has Starbucks done to make a reliable system that is highly customized?

- Scripting: Baristas are trained to greet the customer with prescriptive, that is pre-scripted, language. By asking you "What drink can I get started for you today?" they are focusing you away from the food items for now, and onto the drinks.

- Tools: As you give them your order, they take the order on the cup that they'll serve your drink in. The cup is designed for efficiency and accuracy, but has ample options for complete flexibility.

- Personalization: Instead of giving you a number, the barista asks you for your name. Once completed, your name is called, and the drink that arrives in your hand has your name on it. It's fully custom(er)ized.

High-reliability organizations don't try to behave like boutiques, and health care can't afford to function as such. Quality outcomes demand consistency of process; but those processes can, and should, be highly patient-centric. Health care is far more complex than the neighborhood Starbucks, and the outcomes are far more important than the quality of the brewed beverage of choice. These truths make it essential that health care organizations thoughtfully apply best practices, such as scripting, hard-wired tools and personalization, to realize the promise of patient-centered care.

—Steven Montague lifewings@verizon.net, Vice President, LifeWings

CHPSO Workgroup Addresses Patient-Safety Action Priorities

As part of its ongoing goal to help hospitals develop effective strategies for improving patient safety, the California Hospital Patient Safety Organization (CHPSO) is evaluating resources (toolkits, action plans, etc.) to assist with patient safety action priorities.

The priorities under discussion are: surviving sepsis; improving surgical care; improving PE and VTE prevention; improving medication management safety; reducing *Clostridium difficile* and multi-drug resistant organism infections; preventing hospital-acquired pressure ulcers; reducing patient harm from falls; preventing central-line blood stream infections; and preventing ventilator-associated pneumonia.

Hospitals are encouraged to send comments and suggested resources to CHPSO.

— Rory Jaffe, MD rjaffe@calhospital.org

CDPH ALERT—Check Your Medication Refrigerators

To enhance communication, CHPSO invited the California Department of Public Health (CDPH) to publish notices or articles in this newsletter. This article directly represents the viewpoint of the CDPH.

CDPH has identified a number of situations in which the storage of refrigerated medications has not protected the health and safety of patients.

The situations have involved refrigerators located on clinical units (e.g. emergency department) and in the pharmacy where the noted refrigerator temperature was outside of the acceptable range.

Refrigerator temperature shall be between 2.2° Celsius (36° Fahrenheit) and 7.7° Celsius (46° Fahrenheit) in accordance with California Code of Regulations (CCR), Title 22, Section 70263 (q) (6).

In all cases the failure to maintain an appropriate temperature range was over an extended period of time (e.g. months) and involved both elevated temperatures (greater than 8° Celsius) and lower temperatures (below 2° Celsius).

Common findings included:

- Failure to act when the recorded temperature was noted to be outside of the acceptable range. In one case the temperature was noted to be above 8° Celsius(C) for two consecutive months with no action. The refrigerator was located in the main in-patient pharmacy and pharmacy staff was noting the excessive temperature on a daily basis in the temperature log. In another case, five months prior to a CDPH visit, the hospital had implemented an electronic monitoring system for its numerous refrigerators (approximately 70). Upon review of the monitoring data there were multiple incidents of unacceptable temperature range readings on multiple refrigerators with no action noted.

- Failure to implement an effective monitoring system to identify unacceptable temperature ranges. In one case the electronic monitoring system was set with an acceptable lower temperature range of −1.11° C. The electronic monitoring system would not "alert" unless the temperature fell below −1.11° C. This was done on multiple refrigerators including the one located in the pharmacy.

- Failure to monitor refrigerator storage during monthly medication room inspections. During inspection the CDPH surveyor noted several vials of vaccines with "tiny clumped particles." The vaccine should be clear and if discolored it's to be discarded, according to the manufacturer's information. It was later identified that the medications in that refrigerator along with three others were noted to be below 2° C going back more than four months. There was no evidence that the pharmacist monitored the refrigerator during their required monthly medication room inspections. Had the pharmacist inspected the refrigerators they may have identified the unacceptable temperatures and useable vaccines. The requirement for a pharmacist to conduct a monthly inspection of all drugs maintained on nursing stations is found at CCR Title 22 Section 70263 (q) (10).

Failure to store medications at the appropriate temperature, as specified by the manufacturer, can have significant impact on patient care. Some medications are particularly susceptible to fluctuations in temperatures that upon exposure render them unusable. This is particularly so for most vaccines.

According to the World Health Organization (WHO), the document titled, "Temperature Sensitivities of Vaccines" it's indicated, "More than two million deaths were averted by immunization, as well as an additional 600,000 hepatitis-B-related deaths that would otherwise have occurred in adulthood … However, despite this, more deaths could be prevented and illnesses avoided, if vaccines which are sensitive both to excessive heat and excessive cold, were transported and stored correctly … Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, *Haemophilus influenzae* type b, IPV and their combinations

should not be frozen.… When a vaccine containing an antigen adsorbed to an aluminum adjuvant (e.g. hepatitis B, tetanus toxoid,..) is damaged by freezing, the loss of potency can never be restored; the damage is permanent.… Freezing affects the adsorbed vaccines through changing their physical form.… Freezing brings changes in the structure and morphology of the adsorbed vaccines… ice crystals formed during freezing force aluminum particles to overcome repulsion, thereby producing strong interparticle attraction resulting in aluminum particle coagulation/agglomeration.… The size of the granules seems to increase on repeated freezing and thawing cycles."

The [Morbidity and Mortality Weekly Report, Dec 8, 2006](#) indicated the following medication storage recommendations:

- Diphtheria-tetanus, or pertussis-containing vaccines: Do not freeze (Aluminum adjuvant—irreversible loss of potency with exposure to freezing temperature).

- Hepatitis A and B vaccines: Do not freeze (Aluminum adjuvant—irreversible loss of potency with exposure to freezing temperature).

- Pneumococcal conjugate or polysaccharide vaccine: Do not freeze (re: conjugate vaccine, Aluminum adjuvant—irreversible loss of potency with exposure to freezing temperatures).

Vaccines exposed to freezing temperatures are no longer useable and administration to a patient will not afford them an expected immunity against the specified disease. During one investigation it was noted over a four month period several refrigerators storing vaccines were registering temperatures below 2° C to a recorded low of −7.8° C. The facility identified that over 500 patients had received vaccines (e.g. Tetanus, Hepatitis B and Pneumococcal) stored in those identified refrigerators during the same time period.

CDPH recommends you review your process and procedures for ensuring medications, requiring refrigeration, are adequate to achieve storage within the appropriate temperature at all times.

If you have questions, please contact Loriann De Martini, Pharm.D. Chief Pharmaceutical Consultant at 916.552.8645 or [loriann.demartini@cdph.ca.gov.](mailto:loriann.demartini@cdph.ca.gov)

— Loriann De Martini, Pharm.D. loriann.demartini@cdph.ca.gov

New LinkedIn CHPSO Group

CHPSO has opened a public forum on the LinkedIn social network. This network is useful for getting news updates, networking with peers, sharing ideas and learning from others. However, public forums are not appropriate places to discuss confidential information. Please respect everyone's privacy rights by not discussing specific cases.

To participate in the CHPSO LinkedIn group, go to www.linkedin.com/groups?gid=2174322.

There are several ways to participate in the network after joining the group. For example, to submit a news article that would be interesting to others, go to the "News" tab, select "Submit a news article" and paste in the URL for the article.

To ask a question or share an interesting idea, go the "Discussions" tab, select "Start a discussion" and follow the directions.

— Rory Jaffe, MD rjaffe@calhospital.org

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.

September

2: *SCPSC* (Southern California Patient Safety Collaborative): *Clostridium difficile*-Associated Diseases, High Alert Medications, Hospital Acquired Pressure Ulcers and Medication Safety. Industry Hills.

11: (Date change—was September 18) *CAPSAC* (California Patient Safety Action Coalition): California Patient Safety Action Coalition Meeting. Napa.

29: *HASD&IC* (Hospital Association of San Diego & Imperial Counties): ICU Sedation Task Force Meeting. San Diego.

October

12: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. La Jolla.

13: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Newport Beach.

22: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Redding.

23: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Sacramento.

29: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Fresno.

30: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Glendale.

November

4: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Fremont.

5: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Los Angeles.

10: (Date change—was November 3) *SCPSC*: Central Line Blood Stream Infection, MRSA, Sepsis Mortality, and Surgical Care Improvement Project. Industry Hills.

12: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Orange.

13: *CHPSO & CAPSAC*: Just Culture Event Investigation Training. Palo Alto.

17: *HASD&IC*: ICU Sedation Task Force Meeting. San Diego.

December

4: *CAPSAC*: California Patient Safety Action Coalition Meeting Los Angeles.

15: (Date change—was December 3) *SCPSC*: *Clostridium difficile*-Associated Diseases, High Alert Medications, Hospital Acquired Pressure Ulcers and Medication Safety. Industry Hills.

January

28: *HASC*: Southern California Patient Safety Colloquium. Pasadena.

For further information on these events:

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

CHPSO: Rory Jaffe info@chpso.org

HASC: Catherine Carson ccarson@hasc.org

HASD&IC: Erin Curtis erin.curtis@cardinalhealth.com

Just Culture Event Investigation: www.chpso.org/just/eventinv.pdf

SCPSC: Catherine Carson ccarson@hasc.org

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 will be archived on the CHPSO website (www.chpso.org). Send subscription requests (additions, deletions) to ltate@calhospital.org. Submit articles to rjaffe@calhospital.org.

CHPSO will:

- Offer health care providers a secure environment—protected by legal privilege and confidentiality—to conduct patient safety activities so that health care providers can analyze quality and safety issues to improve care and reduce risk to patients.

- Encourage health care providers to voluntarily submit and share information, which will be de-identified and used to track patient safety trends nationwide.

- Give feedback to health care providers on ways to reduce risk and improve patient quality and safety.

- Publicize the achievements of member hospitals and the regional collaboratives.

To join, hospitals sign a contract that includes a business associate agreement and the privacy and privilege protections. The contract enables participation, but hospitals retain the flexibility to participate or not in each of CHPSO's program offerings.

Frequently Asked Questions About Working With CHPSO

Why do we need to sign a contract? The contract outlines the responsibilities of both CHPSO and providers to protect the confidentiality of the shared data. Also, CHPSO is a business associate, so a HIPAA business associate agreement is needed.

If we sign up, can we still opt out of any CHPSO activity? Yes, you can choose which activities you participate in. Everything is voluntary, even after signing a contract.

What are "common formats?" The PSO rule envisions the aggregation of deidentified reports from PSOs to develop a National Patient Safety Database from which we will learn how to make care safer for our patients. The common formats allow the aggregation. AHRQ developed the formats through a national consensus process. Current incident report system users should find the common formats easy to use.

When we work with CHPSO, can we discuss quality problems with other hospitals? Yes you can, and that information will continue to be privileged and confidential. However, you cannot identify any of the providers without a signed consent from that person.

If another hospital tells us of an incident there, can we share that information with our workforce? Yes, but with these conditions: 1) you do not identify the hospital or any of the named providers (except with written consent from each that you identify); 2) you do not identify the patient; and 3) you only use that information for quality-improvement and patient-safety purposes.