CHPSO
California Hospital Patient Safety Organization

Patient Safety News
March 2012
Volume 4 Number 3

The New CHPSO/ECRI System — Upcoming Conferences

Sign-up now for PSO reporting system training sessions

These one-hour training sessions are designed for those who will have access to the PSO reporting system. Participants will learn how to enter events, edit events and print event reports. The same program will be presented three times: March 16 at 8 AM, March 19 at noon and March 21 at 1 PM. There is no need to sign up for these sessions. The login information will be distributed by email to all members.

Patient safety event reporting just got a whole lot easier!

A vital component of CHPSO's mission as your Patient Safety Organization is to collect and analyze safety event data. The Patient Safety and Quality Improvement Act of 2005 called for PSOs to form and required that data be standardization for event reporting based on the Common Formats developed and maintained by AHRQ. To better comply with these data standards, CHPSO has partnered with ECRI Institute.

Effective immediately, CHPSO members will send their patient-safety event data to ECRI Institute. Because many CHPSO members use Midas+ Care Management as their event reporting system, CHPSO will host a web seminar providing an overview of the Midas+ data collection and extraction process that fully supports the AHRQ Common Formats. During the seminar, we also will demonstrate how to upload the data extract file created using Midas+ to the ECRI Institute's system.

Please join us for this interactive demonstration and discussion on Wednesday, March 28 at 10 AM. There is no need to sign up for these sessions and **non-members are welcome**. The login information will be distributed by email to all newsletter recipients.

CHPSO/ECRI conferences

The new CHPSO/ECRI collaboration has already yielded several conferences for members — on Endoscopic Light Burns and Deep Dive: Medication Safety. More are scheduled through the year and are listed on the event calendar in this issue. Additionally, special conferences on select topics will be added and announced once the speakers have been confirmed. Sign up for any of these sessions by contacting Colleen Meacham at cmeacham@chpso.org or 916.552.7651.

Register Now for Annual Meeting

Accelerate patient safety initiatives at your hospital by joining your colleagues at CHPSO's Annual Meeting — Take a Stand for Patient Safety: Eliminate Preventable Harm — March 13, 2012, in Glendale. Nationally renowned experts will share patient stories, case studies and critical elements to achieving a culture of safety. The program is designed for hospital executives; quality, risk and patient safety leaders; and physician, pharmacist and nurse leaders.

Participants from CHPSO-member hospitals may register for $300. Non-members are $500.

Partners include the California Hospital Association, the Hospital Association of San Diego and Imperial Counties, the Hospital Association of Southern California and the Hospital Council of Northern California. Sponsors include the California HealthCare Foundation and Kaiser Permanente.

The brochure and registration form are available at www.chpso.org/images/201203bro.pdf . To register online go to www.cvent.com/d/8cq8p2/4W.

Attendees can receive 5.75 hours of continuing education credits through the National Association of Healthcare Quality (NAHQ) and the American Society for Healthcare Risk Management (ASHRM).

Check Your Medication Refrigerators

CDPH Alert

During Medication Error Reduction Plan (MERP) Surveys, CDPH pharmaceutical consultants continue to identify circumstances whereby refrigerated vaccines have not been properly stored in accordance with manufacturer's specifications. These occurrences involve refrigerators located in various areas, including emergency departments, in-patient pharmacies and out-patient clinics.

California regulation requires refrigerated medication storage temperature to be maintained between 2.2° Celsius (36° Fahrenheit) and 7.7° Celsius (46° Fahrenheit) — California Code of Regulations, Title 22, Section 70263 (q)(6).

For most vaccine manufacturers, the recommended refrigerated storage temperature is from 2° to 8° Celsius. Diphtheria, tetanus, hepatitis and pneumococcal vaccines have aluminum adjuvants: adjuvants are used to modify or augment the effects of a vaccine by stimulating the immune system to respond to the vaccine more vigorously. When these vaccines are stored below freezing temperatures, the immunogen separates from the aluminum reducing the vaccine's potency; repeated exposure to freezing temperature will render the vaccine ineffective. (For live vaccines, such as MMR, varicella, MMRV and yellow fever, potency loss is seen at higher temperatures.)

Survey findings

Findings by the CDPH are significant, and warrant further action. The following three scenarios illustrate this medication safety concern.

During one hospital MERP survey, 3,921 patients were identified who had received vaccines following storage at subzero (freezing) temperatures. Temperatures were determined to be out of range for over 32 months. Continued investigation revealed patients who had received improperly stored vaccine who later died from the disease the vaccine was otherwise intended to prevent.

Another MERP survey identified 6,471 patients who had also received vaccines after storage at subzero temperatures. Temperatures were determined to be out of range for approximately 16 months.

A third hospital had administered improperly stored hepatitis B vaccine to 1,636 newborn babies over a 6-month period (investigation revealed five mothers who were positive for hepatitis B).

In each instance, corrective action, including appropriate follow-up with the patients and/or their families was required.

System failures

All three hospitals had common system failures around monitoring their medication refrigerator temperatures. These failures included: inadequate understanding of the monitoring system; lack of accountability in ensuring temperatures were properly maintained; and, inappropriate, or no action taken when temperatures were found out of range.

Inadequate understanding of the monitoring systems is especially problematic around electronic monitoring thermometer systems. Many of these systems can be set with temperature out-of-range parameters which trigger built in alarms to alert users. In one case, the hospital had set an out-of-range alert parameter for four hours. As set, the alarm would only go off when the temperature had been out of range after four hours. In another case, while the alarm went off, the staff was unaware of its purpose and it was ignored. Another hospital used temperature wheels, also an electronic system, whereby temperatures are logged on a paper wheel; however, staff did not know how to correctly interpret the recorded data.

Lacking clear accountability in ensuring that refrigerator temperatures are properly maintained is also problematic. One hospital did not have an assigned primary person, or a designated backup person for monitoring temperatures; it was believed the maintenance department would take care of the refrigerators. When maintenance department staff members were interviewed, they indicated the pharmacy department was responsible.

Finally, there were hospitals which took inappropriate action for out of range medication refrigerator temperatures. One institution, after discovery of improper storage, returned the vaccines to inventory and dispensed the reduced potency vaccines. Another hospital had staff monitoring for, and documenting to, subzero temperatures. Nevertheless, they failed to act upon the temperature excursions.

Subscription service: www.chpso.org/lists/
Questions or comments: Rory Jaffe, MD MBA rjaffe@chpso.org

Recommendations

CDPH recommends each facility review its process and procedures for ensuring refrigerated medication, including vaccines, are adequate to achieve storage within the appropriate temperature at all times. CDPH further recommends designation of primary and backup personnel for temperature monitoring, including scheduled visual inspection of storage areas, to include preventive maintenance and testing of refrigerators and monitoring devices.

If you have any questions, please contact Loriann De Martini, PharmD, Chief, Pharmaceutical Consultant at 916.552.8645 or Loriann.demartini@cdph.ca.gov.

— Loriann De Martini, PharmD, CDPH, Loriann.demartini@cdph.ca.gov

Minimizing Bias in Clinical Peer Review

From QA to QI

In my last column, I reviewed the basics of extracting valid measures of clinical performance during case review. It turns out that such measures can be of great benefit in minimizing bias in peer review. The key is to remember that measures of clinical performance require an aggregate view over multiple cases. They are not reliable enough to justify harsh corrective action based on a single case. This fits well with the QI model for peer review. When each case review is not a threatening, high-stakes exercise and the rating scale captures all shades of gray, life is easier.

This is worth emphasizing. A common misconception is that bias can be minimized by parsing peer review findings into a small number of categories. Such thinking stems from confusion between reliability of a measure and agreement between raters. Agreement is an illusion if the reliability of a measure is low. For example, we can agree that the standard of care was not met, but be wrong for having overlooked a key factor in our case review.

In the language of quality improvement, we can think of bias as a variety of special cause variation that degrades the reliability and validity of measurement. In the context of peer review, bias commonly arises in relation to the clinical outcome or the reviewer. Less commonly, there may be combined reviewed physician and reviewer bias as in cronyism and bad faith peer review. Such conflicts of interest are generally obvious and readily avoided by judicious program design and review assignment. Finally, case selection is a potential source of bias that has not been formally studied. This possibility could be minimized by standardizing case identification mechanisms, as well as any applicable pre-review screening activity to create a level playing field.

Cases with bad outcomes are judged more harshly than the same care which results in an acceptable outcome. While our mental model holds that serious adverse events are more likely to be associated with substandard care, it is not a simple relationship. Good physicians can have bad outcomes, even if, other things being equal, we expect them to have fewer bad outcomes than their less capable counterparts. This makes the case for measuring clinical performance through a standardized process that emphasizes data aggregation and routine constructive feedback. If case reviews are evenly distributed to members of the review committee without regard to clinical subject matter, this approach also helps to mitigate the potential bias from reviewer factors such as being too critical or lenient.

Reviewer bias is also reduced when committee discussion serves to validate review findings. Those who work together tend to develop common standards. Training, particularly an exercise in duplicate case review and discussion, can further reduce biases. See my white-paper on this subject for more detail: QatoQI.com/wp_bias.htm. Similarly, if reviewers understand the risk of outcome bias, the committee can develop the habit of explicitly discussing the issue.

Some authors distinguish hindsight bias (Monday morning quarterbacking) from outcome bias, that is, having knowledge of the outcome tends to make one over-confident in one's ability to have predicted it. Hindsight bias can be most productively addressed in the process of identifying potential strategies to prevent recurrence of an error or adverse event. It may be of less concern for the process of clinical performance measurement *per se*.

With this background, we should be ready for a deeper dive into effective event analysis.

Coming Next: Learning from Defects

— Marc T. Edwards, MD MBA, QA to QI Consulting, marc@QAtoQI.com

Responding to Serious Adverse Events

The Institute for Healthcare Improvement recently released an important document: Respectful Management of Serious Clinical Adverse Events (2nd ed). This is the fourth in a series of articles discussing crisis management.

The four hallmarks of a strong crisis response are immediacy, transparency, apology and accountability. Internal and

external communications around serious clinical events are essential.

The following is excerpted, with permission, from the webinar *Moving from Increased Awareness to Changed Behaviors* by Jim Conway and from the IHI Whitepaper *Respectful Management of Serious Clinical Adverse Events (Second Edition)*.

Reimbursement and Compensation

Bishop Desmond Tutu said, "If you take my pen and say you are sorry, but don't give me the pen back, nothing has happened." Amends or damages are due. In approaching this essential and challenging area, key concepts for leaders are service recovery, reimbursement and compensation

Definitions for Compensation, Reimbursement and Service Recovery:

Compensation: A financial remedy accorded to an individual who has sustained an arguably avoidable loss in order to replace the loss caused by the arguably inappropriate act with the intention of making the injured party whole.

Reimbursement: The act of paying someone for expenses with or without an admission of fault.

Service Recovery: The process used to "recover" dissatisfied members or patients by identifying and fixing the problem or making amends for the failure in customer or clinical service.

Service recovery, including reimbursement, should be an immediate proactive response to all adverse events; patients and family members should not have to ask. Reimbursement can include out-of-pocket expenses (housing, parking, child care, transportation, meals or lost wages) for the patient and/or family. COPIC's 3Rs program (recognize, respond, resolve) represents one of the earliest systematic approaches, demonstrating the value of service recovery, empathy, etc., to preserve relationships and prevent litigation. The Coverys (formerly ProMutual Group) comprehensive REACT (respond effectively and communicate timely) seven-state disclosure program also includes a reimbursement component.

The offer of financial compensation to patients and families injured through medical error has historically been delegated to risk and claims managers, lawyers, and the courts. The decision-making process has occurred far from the organization's clinical and administrative leaders, playing out over long periods of time. In 2003 and 2004 monographs, the American Society for Healthcare Risk Management wrote that effective and successful disclosure provides patients and families with opportunities to get information needed to make next-step decisions, including the possibility of seeking appropriate compensation. Richard Boothman of the University of Michigan notes, "Not every patient wants compensation and not all compensation is financial, but the inability or unwillingness to offer it signals insincerity and suggests that apologies are really affectations or strategies, not an integrated step borne of a commitment to honesty."

In the United States, a relatively few early, innovative and promising developments are linking disclosure with resolution that includes compensation. Published examples of these programs include the early work of the VA Medical Center in Lexington, Kentucky, and the University of Michigan. While different in details, commonalities include the following:

- All begin with an organizational policy of full disclosure of adverse events and training and support for clinicians to aid them in making disclosures.

- All share a general philosophy of risk management that holds that being candid about medical injuries, apologizing when appropriate and providing for the patient's financial needs (in at least a limited way) through a quick, accessible process will eliminate the impetus for most patients or families to sue and will spur institutional learning and safety improvement.

- The models diverge in their specific approaches to compensation.

According to Frank Testa, System Director for Risk Management at Cook Children's Health System, "Over the past five years we have had great success with this approach to respectful management of serious events. We have used this approach to settle claims and believe this approach has provided significant savings and is an effective litigation avoidance strategy. We believe it is our ethical and moral responsibility to disclose adverse events in a timely and compassionate manner, apologize for any harm, and provide appropriate accommodation to the child and parents."

Key Points:

- Key concepts for leaders are service recovery, reimbursement and compensation

- Immediate proactive response to all adverse events

- Service recovery, including reimbursement

— Bobbie Dietz, bdietz@chpso.org

Wrong-Site Surgery: Contributing Factors

From *Quarterly Update on Preventing Wrong-Site Surgery*, Pa Patient Saf Advis 2012 Mar;9(1):28-34.

"The two major causes of wrong-site surgery are misinformation and misperception. Ensuring the completeness and accuracy of information from the surgeon's office is the first step in preventing misinformation from leading to wrong-site surgery. Three wrong-site surgeries, one near miss with cancellation of the operation, and three other reports of near misses during the past quarter underline the importance of the surgeon's office providing accurate information."

Differences in Agreement with Statements on a Culture of Safety Survey by Operating Room Personnel between Facilities with No History of Wrong-Site Surgery and a History of Wrong-Site Surgery

	percentage answering yes		
	no wrong-site surgery	wrong-site surgery	*p* value for difference in agreement
Agreement with the Following Statements was Significantly More Likely with No Wrong-Site Surgery than with Wrong-Site Surgery			
I know the first and last names of all the personnel I worked with during my last shift.	88	61	0.000
It is easy for personnel in the operating rooms (OR) here to ask questions when there is something that they do not understand.	79	63	0.001
Working in this hospital is like being part of a large family.	65	51	0.001
There is widespread adherence to clinical guidelines and evidence-based criteria regarding patient safety here.	79	59	0.001
Patient safety is constantly reinforced as the priority in the ORs here.	86	72	0.001
I know the proper channels to direct questions regarding patient safety in the ORs here.	89	81	0.002
Staff/attending physicians in the ORs here take responsibility for patient safety.	74	58	0.002
Medical errors are handled appropriately in this hospital.	83	72	0.003
I would feel safe being treated here as a patient.	83	72	0.003
Decision making in the OR utilizes input from relevant personnel.	66	46	0.004
Important issues are well communicated at shift changes.	71	56	0.004
Briefings are common in the OR.	67	51	0.005
I receive appropriate feedback about my performance.	73	53	0.005
The culture in the ORs here makes it easy to learn from the errors of others.	66	54	0.007
This hospital does a good job of training new personnel.	69	55	0.011
The levels of staffing in our ORs are sufficient to handle the number of patients.	50	36	0.014
Nurse input about patient care is well received in the OR.	78	63	0.014
I am encouraged by my colleagues to report any patient safety concerns I may have.	83	70	0.024
I have the support I need from other personnel to care for patients.	76	67	0.024
Hospital administration supports my daily efforts.	50	37	0.027
Information obtained through incident reports is used to make patient care safer in the ORs here.	65	58	0.028
Agreement with the Following Statements was Significantly More Likely with Wrong-Site Surgery than with No Wrong-Site Surgery			
High levels of workload are common in the ORs here.	77	92	0.000
I have made errors that had the potential to harm patients.	4	18	0.004
In the ORs here, it is difficult to speak up if I perceive a problem with patient care.	16	28	0.005
I have seen others make errors that had the potential to harm patients.	26	41	0.006

CHPSO Calendar Notes

Except as noted, these events are for CHPSO members only.

March

12: *CHPSO*: Members Call. Cancelled due to annual meeting.

13: *CHPSO*: Annual Meeting. Glendale. *Open to all.*

16: *ECRI*: PSO Reporting System Training Session. 8:00–9:00 AM

19: *ECRI*: PSO Reporting System Training Session. 10:00–11:00 AM

21: *ECRI*: PSO Reporting System Training Session. 1:00–2:00 PM

20: *CHPSO and NCQC* (North Carolina Center for Hospital Quality and Patient Safety): Safer Handoffs. 9:30–10:30 AM (Please note date change from March 27)

28: *ECRI and MIDAS*: Data Flow to PSO Reporting System using MIDAS. 10:00–11:00 AM *Open to all.*

April

16: *CHPSO*: Members Call. 10–11 AM (Please note date change from April 9)

16: *CHPSO/ECRI*: User Group Meeting, Topic Insulin. 11:30–12:30 PM

24: *CHPSO and NCQC*: Safer Handoffs. 9:30–10:30 AM

May

14: *CHPSO*: Members Call. 10–11 AM

21: *CHPSO/ECRI*: User Group Meeting, Topic Infrastructure. 11:30–12:30 PM

June

11: *CHPSO*: Members Call. 10–11 AM

July

9: *CHPSO*: Members Call. 10–11 AM

16: *CHPSO/ECRI*: User Group Meeting, Topic Training. 11:30 AM–12:30 PM

August

13: *CHPSO*: Members Call. 10–11 AM

20: *CHPSO/ECRI*: User Group Meeting, Topic Same name alerts; look-alike. 11:30–12:30 PM

September

10: *CHPSO*: Members Call. 10–11 AM

October

8: *CHPSO*: Members Call. 10–11 AM

15: *CHPSO/ECRI*: User Group Meeting, Topic TBD. 11:30–12:30 PM

November

12: *CHPSO*: Members Call. 10–11 AM

19: *CHPSO/ECRI*: User Group Meeting, Topic TBD. 11:30–12:30 PM

December

10: *CHPSO*: Members Call. 10–11 AM

For further information on these events:

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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).

Prospective authors may submit articles to Rory Jaffe, MD, MBA: 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.

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