FIRST

Do No Harm

In this Issue:

- Lahey Clinic - Radiation Exposure & Medical Imaging
- Update on ASCs
- Faulkner Hospital - Solutions for Disruptive Behavior
- SQR Corner

Quality and Patient Safety Division, Board of Registration in Medicine

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RADIATION EXPOSURE AND MEDICAL IMAGING

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There are multiple types of medical imaging examinations that utilize ionizing radiation, including radiography, CT, angiography and fluoroscopy. CT and nuclear medicine procedures are the major contributors to growing medical radiation exposure in the United States. (Ref 1). CT has come under increased scrutiny because of its higher volumes and visibility. An estimated 80 million CT scans were performed in 2010 in the U.S. Many physicians and most patients are ill equipped to understand radiation biology and the potential effects of ionizing radiation. The American College of Radiology (ACR) White Paper (2007), stated emphatically that educating future physicians on radiation exposure during diagnostic imaging must occur during medical school. However, radiation biology and safety are not included in most medical school curricula, although this deficiency is slowly being recognized and corrected. Concern over the risks of CT scanning has been heightened by television sound bites, newspaper articles, and internet publications; these media have not covered these complex issues well. There is thus a real opportunity to enhance patient and physician education in the context of clinical care.

Radiation effects can occur from acute overexposure, typically a rare event. Several episodes of CT over-scanning during brain perfusion studies resulting in skin burns and hair loss were reported in the media over the past two years. These incidents likely resulted from technical errors that can be avoided by utilizing fixed preprogrammed protocols at the CT console. While these incidents thankfully affected a limited number of patients, they served as a "heads-up" to vendors and health providers to better safeguard patients against future occurrences. Of more widespread concern is the potential oncogenic effects posed by chronic radiation exposure. Most experts believe that there is overutilization of CT in the United States. This is driven by several factors: Practice variation due to lack of defined clinical pathways, defensive medicine, self-referral, and public expectation. There is also likely some underutilization in individual patients, in part due to fear of radiation exposure. The objective is to use ionizing radiation in a timely, appropriate fashion for each patient.

CT related cancer risk is small and must be viewed in context. CT has revolutionized the practice of medicine, and the benefits of both positive and negative studies in the management of disease are well known. It is also a valuable guidance tool in minimally invasive procedures. The Good News: When CT is used appropriately, its benefit to the patient will almost certainly outweigh its risk, as the likelihood of developing cancer from a single study is typically very small or immeasurable. Patients should not be denied a clinically indicated scan because of radiation fears. Radiation related risk of oncogenesis is hard to measure, especially in light of natural background radiation, baseline cancer risk, and long delay in any possible side effect. The normal lifetime risk of developing a cancer in the US is about 40%, and for a fatal cancer is about 22%. A single CT scan typically elevates this risk either minimally or immeasurably. This small possibility of hazard should be compared to the risk of *not* performing the scan in any given clinical scenario. Of note, significant cumulative radiation exposure is concentrated in a subset of patients. These patients are typically elderly and have a decreased life expectancy. A smaller group, (perhaps 4-15%) receive multiple serial CT scans that taken cumulatively, would yield measurable increased risk of developing cancer. (Refs 2,3)

Best radiation safety practice centers around use of the ALARA Principle, which states that medical diagnoses should be reached using radiation doses that are "as low as reasonably achievable." For the referring physician, this means asking "Do I really need a CT to answer this clinical question?. Can another modality with no radiation be used instead? Do I need an imaging test at all?" For the Radiologist, ALARA principles must be translated into Department policy, and ready consultation on individual patients when needed. In other words, attempts should be made to perform only appropriate studies, and each study should be performed with the least amount of radiation. The referring provider should provide a targeted history and clinical question to the radiologist, who then can choose the specific scan protocol that minimizes dose index and scan field.

Other steps we have taken include: regular review of CT scanning protocols; purchase and installation of iterative dose reduction software on our CT scanners; enrollment in the new ACR national dose registry; and development of clinical algorithms. ACR accreditation is also essential, as each scanner is evaluated for image quality and dose. Education of patients and physicians is key. We have developed a Radiation Consultation Service. Patients or physicians requesting information on radiation exposure can seek telephone or in-person consultation from a Medical Physicist and a Radiologist. After this session, a formal letter is generated to the patient and is placed into the medical chart. We are developing an on-line Radiation Safety self-learning module that

(Continued on page 2)

Radiation Exposure and Medical Imaging

(Continued from page 1)

will be used as part of the professional education process. We also closely monitor fluoroscopy-intensive procedures in the Interventional suites. Our nurses educate patients on the signs and symptoms of acute radiation reactions and they initiate post-procedure patient contact. Adherence to this policy is benchmarked regularly at our monthly Department QI meeting.

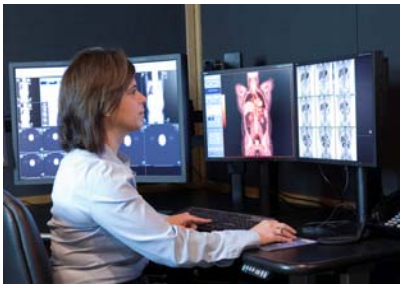
In summary, while radiation exposure is of growing concern, organizational dedication to ALARA principles can optimize patient care and minimize risk. Education of both patient and physician should be an important element of an institution's approach to this issue.

References:

(1) National Council on Radiation Protection & Measurements. "Medical Radiation Exposure Of The U.S. Population Greatly Increased Since The Early 1980s." *ScienceDaily*, 3 Mar. 2009. Web. 23 Nov. 2011.

(2) Brenner DJ, Shuryak I, Einstein AJ. Impact of reduced patient life expectancy on potential cancer risks from radiologic imaging. *Radiology* 2011 Oct;261(1):193-8. Epub 2011 Jul 19.

(3) Sodickson A, Baeyens PF, Andriole KP, Prevedello LM, Nawfel RD, Hanson R, Khorasani R. Recurrent CT, cumulative radiation exposure, and associated radiation-induced cancer risks from CT of adults. *Radiology 2009* Apr; 251(1):175-84.



Lahey Clinic Department of Radiology

AMBULATORY SURGICAL UPDATE

QPSD staff from left: Maureen Keenan, Mary Ann Mark, and Tracy Gay. QPS Committee member, Dr. Dinesh Patel, accompanied the team.

A series of workshops to inform licensed Ambulatory Surgical Centers (ASCs) of the unique, collaborative role of the Quality and Patient Safety Division (QPSD) in healthcare quality oversight, and of the Patient Care Assessment reporting requirements, was completed in September. The forums were a valuable opportunity for learning and sharing by both ASC attendees and the QPSD. Licensed ASCs will now receive QPSD communications including, Newsletters, Alerts and Advisories.

An ASC weblink has been created on the Quality and Patient Safety Website: www.mass.gov/massmedboard/qps . Click on the link for Ambulatory Surgical Centers and Clinics for relevant materials, specific to ASCs.

All licensed ASCs are required to have an approved Patient Care Assessment (PCA) Plan [243 CMR 3.03]. December 31, 2011 is the deadline for the PCA Plan submissions. The PCA Plan document must describe the ASC's Quality and Safety program, be unique to the facility and services provided, and comply with the PCA regulations. The areas of PCA Plan compliance are summarized in the "Patient Care Assessment Plan for ASCs and Clinics," found on the ASC website link above.

The first ASC Semi Annual and Annual Reports [243 CMR 3.07 and 3.12] are due by March 30, 2012. The Guidelines for reporting and the reporting schedule can also be found on the ASC website. There is no required format for the reports. The QPSD will accept formats that may already be in place.

The Safety and Quality Review Form and instructions for the reporting of unexpected serious events [243 CMR 3.08] are available on the ASC website.

All data reported to the QPSD is provided extensive safeguards of confidentiality by law [MGL c. 111 § 204 & 205]. The QPSD works independently from the Department of Public Health and the other divisions of the Board of Registration in Medicine. Until further notice, to assure confidentiality, all reports should be mailed to the QPSD.

Through the use of various tools, including reporting feedback to individual ASCs, sharing of de-identified lessons learned, statewide data analysis, workshops, newsletters and alerts, the QPSD will strive to maintain open communications and assist in the recognition and response to ASC issues.

FINDING "SYSTEM LEVEL" SOLUTIONS FOR DISRUPTIVE BEHAVIOR

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Faulkner Hospital

While fans of the fictional TV character, Dr. Gregory House, may find his sarcastic outbursts to be amusing, studies show that his real-life counterparts are more likely to be labeled as disruptive, and to find themselves on the receiving end of a summons and complaint alleging malpractice. Studies about the association between physician behavior and the likelihood of being sued support what is common knowledge among risk managers: physicians who engage in disruptive behavior can expect to see more claims than their colleagues. Plaintiff attorneys, too, understand that when they ask potential clients why they decided to sue, the response will often include complaints about the physician's behavior and poor communication.

The American Medical Association defines disruptive behavior as: "Personal conduct, whether verbal or physical, that negatively affects or that potentially may negatively affect patient care. (This includes but is not limited to conduct that interferes with one's ability to work with other members of the health care team)."

The Joint Commission notes that certain behaviors threaten patient safety by undermining team work. These may include overt actions such as verbal outbursts and physical threats, and passive activities such as reluctance or refusal to answer questions, return phone calls, or pages.

Dr. Gerald Hickson, a leading expert on physician behavior and its connection to malpractice, has examined why a small number of physicians have a disproportionate number of malpractice claims. He found that these physicians did not treat sicker or more litigious patients, nor did they demonstrate significant differences in technical competence. He found that the physicians who were at higher risk for being sued more often received a greater number of unsolicited patient complaints about their care. Dr. Hickson and others have observed a link between poor communication skills and poor outcomes. Increased risk of being sued appears to be related to patient dissatisfaction with the physician's ability to establish rapport, provide access, administer care and treatment by managing expectations, and to communicate effectively. Hickson, G.B. et al., Patient Complaints and Malpractice Risk, JAMA 2002; 287 (22); 2951-2957. More recent studies by others support Dr. Hickson's early findings about the correlation between poor provider communication and the likelihood of being sued. Rosenstein, Alan H., The Quality and Economic Impact of Disruptive Behaviors on Clinical Outcomes in Patient Care, American J Medical Quality, published online 21 April 2011; DOI: 10.1177/1062860611400592.

Hospital staff members also have identified concerns about the negative effects of disruptive behavior on care. A 2008 study of more than 4500 respondents from more than 100 hospitals showed that staff perceived a strong link between disruptive behaviors by a very small number of physicians and the occurrence of adverse events, medical errors, and compromises in patient safety and quality. More than half reported that 1-3% of medical staff exhibits disruptive behavior. Rosenstein, A., O'Daniel, M., A Survey of the Impact of Disruptive Behaviors and Communication Defects in Patient Safety, Jt Comm J Qual Patient Saf., 2008, 34; 464-471. Leape and Fromson estimate that the incidence of disruptive physician behavior is between 3-5% of physicians. Leape, L.L. and Fromson, J.A., Problem Doctors: Is There a System-Level Solution?, Annals of Internal Medicine, 2006. 144 (2); p. 107-115.

The Joint Commission, recognizing the threat of disruptive behavior to patient safety, published a Sentinel Event Alert in 2008, entitled, Behaviors That Undermine a Culture of Safety. In 2009, a new Joint Commission Leadership Standard went into effect, requiring hospitals to maintain a code of conduct that defines disruptive behaviors and to create a process to manage such behaviors. Recently, the Joint Commission dropped the term "disruptive" and instead now focuses upon behaviors that represent a patient safety threat by interfering with effective team work.

Leadership teams at Brigham and Women's Hospital (BWH) and Faulkner Hospital have responded to this mandate. Both institutions have developed a Code of Professional Conduct. In addition, there is recognition that disruptive behavior may be triggered by exhaustion, undue stress, or personal problems that require support. BWH has created the Center for Professionalism and Peer Support. The center offers physicians peer support, training in professionalism, and leadership workshops on how to provide difficult feedback. The center also offers a tiered approach in responding to disruptive behavior. The initial steps include feedback and support to help the physician cope with underlying issues that may be contributing to the behavior, as well as setting expectations for change. Additional support in coping with underlying problems is also available as part of any intervention.

In 2010, Faulkner Hospital conducted a hospital-wide survey to capture staff perceptions about the prevalence of disruptive behavior. Based upon the results of that survey, the hospital created an interdisciplinary task force, facilitated by Maureen Fischer, a Faulkner risk manager. The committee developed a hospital-wide initiative to identify and address disruptive and unprofessional behavior. There also is a strong educational component. Dr. Andy Whittemore, Chief Medical Officer for BWH addressed the Faulkner medical staff on the subject of disruptive behavior in 2010, and Dr. Jo Shapiro of

(Continued on page 4)

Finding "System Level" Solutions For Disruptive Behavior

(Continued from page 3)

the BWH Center for Professionalism and Peer Support presented this topic at Faulkner's Tri-Annual meeting of the medical staff in October 2011. Physician training in professionalism is scheduled at the Faulkner in December.

The Faulkner Risk Management and Credentialing departments share a commitment to promote and sustain a culture of professionalism among its medical staff. In supporting efforts to address disruptive behavior, risk managers work to achieve the common goals of promoting patient safety and reducing risk of liability. In addition, Faulkner has developed criteria for ongoing and focused professional practice evaluations. The evaluations include an assessment of each provider's professionalism as a core competency required as part of the credentialing and re-credentialing process.

Here is a Glimpse of what some hospitals are reporting in their Semi-Annual Reports....

- The following measures were implemented in response to a case involving a patient who developed propofol-related infusion syndrome (PRIS): (1) educational videos on BIS monitoring, paralysis, and PRIS uploaded to the hospital intranet for mandatory viewing; (2) development of Propofol administration guidelines; and (3) approval of enhanced laboratory monitoring (triglycerides and creatinine kinase) for patients receiving propofol infusions.

- A study of its standing sliding scale insulin orders resulted in a finding that less than 50% of patients were at their glucose level, leading to the hospital's development of two new insulin order sets.

- Following review of outlier cases for VTE prophylaxis, this rehabilitation hospital's Coumadin order form was revised to include a dosing guideline. If a medication with a known interaction is ordered, the patient's INR is to be checked within 3 days. A recent audit of the new order form showed 100% compliance with the dosing guideline.

- One hospital now provides patients with a pamphlet describing the role of hospitalists, which also includes pictures of the hospitalists on staff. The patients are provided with the business card for the hospitalist assigned to their care.

- A Root Cause Analysis (RCA) performed following a retained foreign body (RFB), associated with an obstetrical procedure, resulted in the following improvements: standardization of the equipment setup in the labor and delivery rooms and the sponge count process; staff education in procedure revisions; and a change in equipment that counts sponges.

- Following any activation of its Rapid Response Team (RRT), this rehabilitation hospital reviews the patient's condition and treatment during the 72 hours prior to the RRT to determine whether anything was missed or the attending physician should have been called sooner.

- In response to a "near miss" involving a potentially toxic dose of acetaminophen from administering analgesic medications with Tylenol (Percocet and Fiorocet), the hospital removed analgesics containing more than 325 mg of acetaminophen from its formulary and now requires physicians to write for oxycodone and acetaminophen as separate orders.

- A multidisciplinary team (physicians, nurses, pharmacy and IT) developed hospice order sets to facilitate ordering of medications for hospice patients.

- Responding to a 2011 FDA MedWatch Alert about association between the use of sodium polystyrene sulfonate (SPS) in sorbitol and cases of intestinal necrosis, one hospital's Pharmacy and Therapeutics committee recommended: (1) a SPS product without sorbitol; and (2) that the medication be dispensed in an oversized container to allow for dilution of the medication (with water or juice) immediately prior to administration.

Lahey Clinic Hospital began using pink wristbands to identify patients as at "risk for bleeding." Criteria for use of these wristbands include patients on therapeutic doses of anticoagulants, thrombolytics, platelet aggregation-inhibiting agents, and patients with an INR of $\geq$ 2 or with a platelet count of < 50,000/uL.

SQR CORNER

The Event -Burn in the OR

The QPSD thanks Baystate Franklin Medical Center for sharing this report.

A flash burn occurred during the use of a cautery in the operating room, resulting in a minor burn to the patient's face. The cautery used was a hand-held high temperature nitrous/oxygen mix (70/30). The sevoflurane oxygen source had been removed prior to the cautery use. The mask was not on the patient's face while cautery was used.

Immediately following the surgery, the surgeon disclosed what had happened to the patient. The patient received topical treatment for the burn and was discharged home as planned.

The Hospital's Response

The Director of Quality contacted the patient within the first week post-op and then again following internal review, to follow-up, to apologize, and to share the plan for improvement. A Root Cause Analysis identified communication among staff regarding use of cautery as an area for improvement. Orientation and education of staff regarding fire safety in the OR was also noted to be an area for improvement, particularly among surgeons and anesthesiologists, who had no requirement for ongoing education on this topic. Coincidentally, there was an inservice on this topic that day for OR nurses and technicians. It was the quick reaction of the technician that prevented the spread of fire and additional injury to the patient.

There was considerable discussion regarding the use of battery powered high temperature cautery. A review of literature did not find one as superior to the other as all have the potential to be a source of ignition. The hand held high temperature nitrous/oxygen mix 70/30 cautery used for this patient was immediately removed from service and replaced with a different cautery tool.

Following literature review of surgical fire prevention evidence and risk assessment tools, a new process was implemented where the circulator nurse reports a fire risk score during time-out. The process change was communicated to all nursing and ancillary staff, physicians and vendors. The PDSA (plan-do-study-act) model is being used to test the change.
Orientation and education on this topic is now mandatory for all OR personnel, including surgeons and anesthesiologists. Mock drills will be performed and will include evacuation of the patient from the OR while surgery is in progress. The hospital also took steps to ensure implementation of best practices regarding anesthesiology, draping, patient preparation, equipment and environment of care.

The Event - Hospital acquired Stage III pressure ulcer.

This patient was admitted with an acute middle cerebral artery cerebrovascular accident (CVA). Her past medical history included coronary artery disease, morbid obesity, diabetes, acute renal and respiratory failure, and obstructive sleep apnea. She was intubated and admitted to the Critical Care Unit (CCU), where a reddened area was documented on her coccyx. A wound care nurse (WCN) consult on HD#2 assessed the area as a 2 Stage II ulcer. Upon reassessment on HD# 5, the WCN noted that the area had advanced to a Stage III ulcer.

The Hospital's Response

The patient was placed on the Pressure Ulcer Prevention protocol on admission. She was supported nutritionally, frequently repositioned, and was on a bariatric specialty bed with low air loss feature. However, she had multiple risk factors, including mechanical ventilation, sedation, vasopressors, morbid obesity and heart disease. She also had "friction and shear," from agitation related to the stroke.

The hospital reviewed its pressure ulcer program and took the following actions.

1. Pressure ulcer data and findings were discussed at the Critical Care staff meeting.
2. Braden scores <18 are now audited to assess documentation and compliance with Pressure Ulcer policies.
3. The Critical Care nursing director participates in interdisciplinary rounds to ensure that skin care issues are being addressed.
4. The WCN conducted educational programs for each department and shift.
5. The WCN now monitors inpatient length of stay and focuses on patients in the CCU to assure appropriate skin care interventions. Review will also occur for Medical/Surgical patients with length of stay greater than 7 days.

"Gain Full Value From Your Root Cause Analysis" Workshop

Held September 8th in Marlborough

The Quality and Patient Safety Division in co-sponsorship with the Massachusetts Hospital Association, the Massachusetts Society for Healthcare Risk Management and the Massachusetts Medical Society held a full day workshop in Marlborough on September 8th. The workshop was facilitated by Patrice Spath, BA, RHIT, of Brown-Spath & Associates.

Ms. Spath described the elements of a "thorough" root cause analysis, discussing what is often missing from investigations. She presented the analytical tools caregivers need to identify the event's root cause and latent conditions and how to determine if these issues have been found. Lastly, Ms. Spath discussed how to identify strategies for designing sustainable corrective actions and follow-up monitoring activities.

Examples of Safety and Quality Review Reports

- Lost laboratory specimen
- Wrong-site pacemaker wire implant
- Aspiration during anesthesia induction
- Delayed "decision to incision" c-section
- Pressure ulcer from tracheotomy tapes
- Renal complications related to vancomycin

CONTACT THE QPSD

To be added to the QPSD Newsletter and advisory mailing list, update hospital contact information, submit an article, request an SQR form, or obtain additional information, contact QPSD: Jennifer.Sadowski@state.ma.us or (781) 876-8296.

Send mail to Massachusetts Board of Registration in Medicine, QPS Division, 200 Harvard Mill Square, Suite 330, Wakefield, MA 01880.

QPS NOTES

Watch for a **Special Supplement to FIRST** on the Peer Review Conference held last June 2011.

An **Executive Summary of the Breast Reconstruction Expert Panel Report** is published in the Journal of the American College of Surgeons (December 2011). The link to the article is at: http://www.journalacs.org/article/S1072-7515(11)01027-1/fulltext.

The QPSD needs your help! We would like to have accurate contact information for your facility's leadership; we also want to update our description in the annual health care facility report of the services your facility provides, its licensed bed size and average census. If you receive an email asking for this information, please respond by the date requested.

GME Programs and the Patient Safety Culture. The QPSD is interested in learning about innovative ways in which hospitals ensure that residents and other trainees are active participants in their patient safety programs. If you would like to share your experiences, please contact us.

The QPSD Newsletter, FIRST Do No Harm, is a vehicle for sharing quality and patient safety initiatives of Massachusetts healthcare facilities and the work of the Board's Quality and Patient Safety Division and Committee. Publication of this Newsletter does not constitute an endorsement by the Board of any studies or practices described in the Newsletter and none should be inferred.