PATIENT SAFETY AUTHORITY
An Independent Agency of the Commonwealth of Pennsylvania

PA PSRS
Pennsylvania Patient Safety Reporting System

PENNSYLVANIA PATIENT SAFETY ADVISORY

Produced by ECRI Institute and ISMP under contract to the Pennsylvania Patient Safety Authority

Vol. 5. No. 1

March 2008

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About the Pennsylvania Patient Safety Advisory

OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS), especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

PUBLISHING INFORMATION

The *Pennsylvania Patient Safety Advisory* (ISSN 1941-7144) is published quarterly, with periodic supplements, by the Pennsylvania Patient Safety Authority. This publication is produced by ECRI Institute and the Institute for Safe Medication Practices under contract to the Authority as part of the Pennsylvania Patient Safety Reporting System (PA-PSRS).

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SUBSCRIPTION INFORMATION

This publication is disseminated by e-mail at no cost to the subscriber. To subscribe, go to https://www.papsrs.state.pa.us/Workflow/MailingListAddition.aspx.

INDEX INFORMATION

The *Pennsylvania Patient Safety Advisory* is indexed in the Cumulative Index to Nursing and Allied Health Literature® (CINAHL®) print index and electronic database.

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The Pennsylvania Patient Safety Authority works with the Pennsylvania Medical Society to offer *AMA PRA Category 1 Credits*™ for selected portions of the *Pennsylvania Patient Safety Advisory* through the online publication *Studies in Patient Safety*. Go to http://www.pamedsoc.org to find out more about patient safety CME opportunities.

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Manuscripts consistent with the objectives of the *Pennsylvania Patient Safety Advisory* are welcome. For information and guidance about submission and instructions for authors, please contact the editor.

ACKNOWLEDGEMENTS

The PA-PSRS staff would like to thank the following individuals who graciously offered us their insight and/or reviewed selected articles for Vol. 5, No. 1:

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Leadership Series: Meaningful Engagement in Patient Safety Improvement

Ana Pujols-McKee, MD

Ana Pujols-McKee, MD
Chair, Pennsylvania Patient Safety Authority Board of Directors

The patient safety movement seems to generate themes as we continue to move forward. For 2008, the buzz phrase getting "boards on board" remains a prevailing theme generating much attention at national meetings. One can barely hear a presentation on patient safety without hearing the discussion of the importance of the board of trustees' active commitment and fiduciary responsibility to quality and patient safety.

There is no debate on the need to increase the board of trustees' involvement, but there is no real consensus on how to reach a meaningful level of engagement. Does it add value to educate trustees on probability coefficients? Are dashboards the best way to tell what is really going on? Throughout the year you will continue to hear many strategies and potential solutions, and Pennsylvania should be at the cutting edge and leading the nation in this initiative.

Legislation enacted in 2002 created an opportunity for Pennsylvania hospitals to significantly advance and engage their governing bodies on their path to improving patient safety. Act 13 of 2002, the same law that authorized the Patient Safety Authority, required hospitals, ambulatory surgical facilities, and birthing centers in the Commonwealth to develop patient safety committees whose membership may include a member of the board of trustees. In addition, it required patient safety committees to provide quarterly reports to the organization's administration and governing body. The Act also provides detail about the contents of these reports, which include the number of Serious Events and Incidents, but more importantly, the committee's *recommendations to eliminate future Serious Events and Incidents.*

Admittedly, legislation is not always the most comfortable way to initiate change, but when these processes are properly implemented, they can afford an organization a tremendous opportunity to achieve the correct level of engagement, an appropriate level of sharing, and a significant return of value to the community served.

Moving forward in 2008, I invite each of you to look within your organizations and ask yourselves if you have made the most of this opportunity afforded by Act 13.

For our part, the Patient Safety Authority is committed to increasing trustee awareness of patient safety through education regarding their role in governing an organization dedicated to quality. The Authority's Board of Directors included facility board education as one of its strategic initiatives, and the Authority has begun work to adopt an appropriate curriculum for Pennsylvania. More information will be provided as it becomes available.

Wishing all of you a great year in making it safer!

Information for Boards

Dr. Pujols-McKee and the rest of the Pennsylvania Patient Safety Authority Board of Directors call attention to the importance of board-level leadership for patients to have a safe medical experience. She has raised the issue of how boards can reach that objective. Clearly, the Authority believes that reporting is one of the tools. "You can't improve what you don't measure." However, becoming aware of errors does not fix them. Improvement comes from redesigning systems, not making providers aware of their errors and the consequences.

Board committees may wish to consider the following recent articles among many that discuss patient safety from the perspective of the board:

Pronovost PJ, Berenholtz SM, Needham DM. A framework for health care organizations to develop and evaluate a safety scorecard. *JAMA* 2007 Nov 7;298(17):2063-5. Dr. Pronovost and colleagues recommend rate-based measures of outcomes and processes related to outcomes, plus other measures of the culture of safety in the organization. Because patient safety reporting systems are vulnerable to reporting bias and lack denominators, the authors recommend using them to identify, but not measure, errors.

Shortell SM, Singer SJ. Improving patient safety by taking systems seriously. *JAMA* 2008 Jan 30;299(4):445-7. The authors emphasize the importance of having systems for reliably delivering medical care, both within organizations and across organizations.

Clarke JR, Lerner JC, Marella W. The role for leaders of health care organizations in patient safety. *Am J Med Qual* 2007 Sep-Oct;22(5):311-8. Myself and others from ECRI Institute reviewed critical "patient safety literacy" for board members, including high reliability organizations, culture of safety, decreasing unjustified variability in care, at-risk behavior, an emphasis on system design rather than provider performance, and disclosure. Twenty actions are cited that are appropriate for board consideration, including reporting, monitoring, and benchmarking against past performance.

—John R. Clarke, MD, Editor

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Letter to the Editor

Surgical Complication Incidence

In our hospital Patient Safety Committee, we recently had a discussion about the incidence of surgical complications and specifically whether there is any variation according to the day of the week. There is a commonly held belief that in manufacturing, more errors occur on Mondays.

I am hoping that the *Pennsylvania Patient Safety Advisory* may have the information to answer this question as it may have some impact upon staffing paradigms for hospitals. It does have implications for hospital and resident staffing.

Chris D. Tzarnas, M.D.
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Editor's Note

The PA-PSRS' analysts thought your question would be of general interest and have information available from prior analyses that can partially answer the question you pose. We had reviewed 1,784 reports of technical errors by surgeons in the operating room between June 28, 2004, and June 30, 2005. Looking at the date of the event by day of the week, we note no apparent difference in distribution, except weekends:

Sunday: 3%

Monday: 18%

Tuesday: 20%

Wednesday: 20%

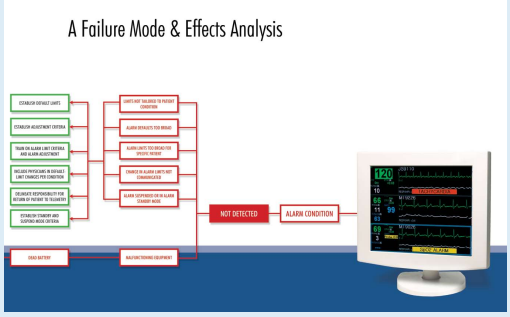
Thursday: 19%

Friday: 17%

Saturday: 4%

We do not have denominators indicating the number of procedures done on each day, so there remains a possibility that the rates are different in the unexpected event that the number of operations fluctuates noticeably among weekdays.

Supplement: Alarm Interventions during Medical Telemetry Monitoring



Between June 2004 and October 2006, PA-PSRS received 277 reports related to alarm response during medical telemetry monitoring. All of the reports described events in which patients were not consistently monitored for physiologic conditions, and three events resulted in patient death. Telemetry physiologic monitoring systems generate visual and audible alarm signals based on changes in patient physiologic conditions that exceed alarm limits established for a specific patient or a particular patient population. When a clinician does not respond or delays response to an alarm, appropriate patient care may be compromised, possibly resulting in a poor patient outcome.

PA-PSRS analysts conducted a failure mode and effects analysis (FMEA) on alarm interventions during medical telemetry monitoring because of the potential for serious patient harm or death. FMEA is a proactive risk assessment method used to evaluate a system or process in order to identify potential failures and develop and implement mitigation strategies to reduce or eliminate failures before they occur. Healthcare facilities can use the published results of this FMEA to understand telemetry monitoring alarm response processes and similar process failures and as an aid to develop facility-specific risk reduction strategies. The complete monograph, "Alarm Interventions during Medical Telemetry Monitoring: A Failure Mode and Effects Analysis," is available on the Pennsylvania Patient Safety Authority's Web site at http://www.psa.state.pa.us.

In order to provide open critique and feedback, the *Pennsylvania Patient Safety Advisory* welcomes letters to the editor, either in response to previous published articles or as questions or comments or alternative opinions consistent with the objectives of the *Advisory*. Correspondence should be addressed to PA-PSRS, P.O. Box 706, Plymouth Meeting, PA 19462-0706, USA, or support_papsrs@state.pa.us.

All correspondence must include the author's names and contact information. All letters will be acknowledged. The decision to publish a letter is at the discretion of the editor, who also reserves the right to edit the correspondence. Authors will have to state any potential conflict of interest prior to publication of any correspondence as well as conform to the confidentiality, formatting, and style requirements of the *Advisory*.

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Diagnostic Ionizing Radiation and Pregnancy: Is There a Concern?

ABSTRACT

Both pregnant patients and physicians may overestimate the risk of an ionizing diagnostic radiation examination on the conceptus. Fetal health effects of ionizing radiation vary according to the radiation dose absorbed and gestational phase at the time of exposure. The effects of ionizing radiation are cumulative. Performing multiple diagnostic radiation procedures on a pregnant woman may place the conceptus at risk for negative health effects. PA-PSRS has received more than 90 reports of pregnant patients being exposed to diagnostic ionizing radiation since the program's inception in June 2004. Many involved performing a radiologic procedure on a patient who was unaware of the pregnancy. Risk reduction strategies include delaying nonurgent radiographs; using a diagnostic examination not involving ionizing radiation; ensuring radiographic equipment is in proper working order; and encouraging open communication among the healthcare team and patient to ensure that the most appropriate study is used to obtain the maximum amount of information while reducing exposure to the fetus. (Pa Patient Saf Advis 2008 Mar;5[1]:3-15.)

While medical uses of radiation have improved diagnostic, treatment, curative, and palliative capabilities, radiation may also be damaging or lethal[1] to an embryo or fetus in certain circumstances. PA-PSRS has received more than 90 reports of pregnant patients being exposed to diagnostic ionizing radiation (see "Ionizing Radiation Exposures Reported to PA-PSRS"). The PA-PSRS reports show that many women are not aware they are pregnant during diagnostic radiology procedures.[2] About 50% of pregnancies in North America are unplanned.[3] Therefore, the possibility of unanticipated radiation exposure to an embryo/fetus may occur when women of childbearing age undergo diagnostic radiation procedures.

This article will present the effects of x-ray radiation, estimated fetal radiation doses of common diagnostic procedures, background incidence of fetal complications, risk reduction strategies, and resources. The article will not encompass nuclear medicine procedures, radiation therapy, or occupational exposure to x-rays. Moreover, in this article, the term "conceptus" is used to refer to any stage of conception: pre-embryo, embryo, or fetus.

What is Ionizing Radiation?

Radiation is energy that is emitted from sources[4] including heat and light from the sun, microwaves from an oven, or x-rays from an x-ray tube. The characteristics of the radiation depend on its energy. Ionization refers to the process in which the radiation has sufficient energy to remove an electron from an atom (e.g., gamma rays, x-rays) to form a pair of charged particles (i.e., ions). Lower energy radiation (e.g., radio waves, visible light) has insufficient energy to cause ionization. The resulting ions can be very destructive to biological material since they can break chemical bonds. Two types of cell damage occurs; the cell can die or be damaged. In the event of cell death, the damage to the overall organism will only be significant if a sufficient number of cells are killed. Cell death will occur with a sufficient dose. Cell damage is more complicated. The cell may simply become nonviable and eventually die. Alternatively, the damage to the genetic code may be repaired. In the event that the repair is flawed and the cell remains viable, then mutations may result, eventually manifesting as cancer many years later.[5,6] Carcinogenesis may or may not occur.

Measurement

Radiation is measured using different terms according to the aspect of radiation that is being measured. This includes exposure, absorbed dose, and effective dose (see Table 1). When measuring radiation exposure, one can directly measure the amount of ionization, which is the number of ions produced in a volume of air. When SI units (metric) are used, exposure is measured in coulomb per kilogram (C/kg). In the United States, exposure is traditionally measured in roentgen (R).

The biological effects from ionizing radiation depend upon the total energy of radiation absorbed (in joules) per unit of mass (in kilograms) in the sensitive organs or tissues.[7,8] This amount is called the absorbed dose. Absorbed dose is expressed in gray (Gy). One gray equals the absorption of 1 joule of radiation energy by 1 kg of matter. The gray was adopted internationally in 1976.[9] Calculation of absorbed doses of radiation provides a foundation upon which the probability of radiation-induced effects can be evaluated. In the United States the absorbed dose is often referred to as radiation absorbed dose (rad). One rad equals 10 mGy.[8,9] The absorbed dose is important when considering the short term, or deterministic, effects of radiation.

To assess the biological risk of ionizing radiation after partial exposure of the body, other factors must be considered, such as the type of radiation, the varying sensitivity of different tissues, and absorbed doses of different organs.[8,9] This risk is expressed as the effective dose. The metric unit is the sievert (Sv). Traditionally in the United States, the roentgen equivalent man (rem) is used instead of the sievert. One Sv equals 100 rem.[8,9] The effective dose is used to assess the long-term, or stochastic, risks associated with radiation exposure.

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Ionizing Radiation Exposures Reported to PA-PSRS

PA-PSRS has received more than 90 reports of pregnant patients being exposed to diagnostic ionizing radiation. Here are a few edited examples:

A patient was asked if she could be pregnant and the date of her last menstrual period. The patient responded that she receives contraception injections and does not get periods. The patient signed a release indicating she was not pregnant. An x-ray of the abdomen was performed, which revealed a fetus.

A patient presented to the [emergency department (ED)] *with a chief complaint of back pain. She was asked if she was pregnant, and she stated no. X-ray films were read, revealing a fetus of over 31 weeks. The patient was notified of the pregnancy, at which time she stated her last menstrual period was seven months ago.*

A patient was scheduled for a [computed tomography (CT) scan] *of the abdomen and pelvis to rule out a mass. The patient was interviewed and signed a form indicating she was not pregnant. The patient stated she had a negative pregnancy test 10 days ago. The CT study was performed with contrast. The scan was aborted as soon as an image of fetus appeared.*

A patient received a CT scan of the abdomen and pelvis in 60 slices. Prior to the procedure, she stated she did not believe she could be pregnant. The CT scan showed a viable fetus of 12 weeks gestation.

Over a seven-week period of time, a 19-year-old patient received the following studies: abdomen x-ray, CT scan of the abdomen and pelvis with and without contrast, retrograde x-ray, chest x-ray, and cystogram. For each visit, the patient was asked if she was or could be pregnant, and she denied pregnancy each time. At the end of the seven weeks, an ultrasound showed a viable intrauterine pregnancy of seven weeks and one day.

The patient had a CT scan of the abdomen and pelvis, and the radiologist's interpretation revealed a fetus.

A patient presented to the ED with fever and abdominal pain. The patient had a history of [inflammatory bowel disease] *and tubal ligation three years ago. The patient also reported her last menstrual period was within the past month. The patient had a CT scan of the abdomen, which revealed an intrauterine pregnancy. Upon notification, the patient stated she had been at another hospital the previous week and had an x-ray of the abdomen. The patient was seen by an obstetrician, and an ultrasound was performed, indicating an intrauterine pregnancy of 15 weeks gestation.*

A patient was sent to the imaging department for a CT scan due to abdomen/pelvis bloating. She responded "no" when asked if there was a chance she could be pregnant, and she signed the consent form. The CT scan revealed an intrauterine pregnancy.

An ED patient [underwent] *an x-ray of the abdomen. The patient had not voided prior to the x-ray, but the patient stated, when asked by the ED staff and the x-ray technician, that she had a period two weeks earlier and that she felt she was not pregnant. After the x-ray, the patient voided, and the dipstick was positive for pregnancy. A follow-up ultrasound indicated twins.*

An ED patient denied the possibility of pregnancy and stated she had a miscarriage one month prior to admission. An abdominal CT scan was done, after which a urine specimen was obtained that was positive for pregnancy. A transvaginal ultrasound confirmed an intrauterine pregnancy. The patient is planning to terminate the pregnancy.

This article will refer to mGy and rad as units of measure (10 mGy = 1 rad).

Perceptions

When a pregnant patient is exposed to radiation during diagnostic radiology procedures, lack of knowledge may result in great anxiety after exposure and misinterpretation of the risk.[10] A woman may believe she should abort her fetus after any exposure to ionizing radiation.[7] One study revealed that up to 25% of exposed women believed their infants were at risk for major malformations after exposure to diagnostic imaging.[11] Twenty-three percent of pregnancies in Greece were terminated because of unfounded concerns about fetal teratogenicity after the nuclear reactor accident in Chernobyl.[12]

In Canada, the Motherisk Program conducted a survey of pregnant women who were told that the baseline risk of major malformations in the general population was about 3%. They were asked their perceptions of risk for fetal malformations when a pregnant woman underwent a diagnostic imaging procedure. The

Table 1. Measurement of Radiation

QUANTITY	METRIC (SI)	CONVENTIONAL	CONVERSION	COMMENT
Exposure	Coulomb per kilogram (C/kg)	Roentgen (R)	1 R = 2.58×10^{-4} C/kg	Directly measured
Absorbed dose	Gray (Gy)	Radiation absorbed dose (rad)	10 mGy = 1 rad	Deterministic effects
Effective dose	Sievert (Sv)	Roentgen equivalent man (rem)	1 Sv = 100 rem	Stochastic effects

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pregnant women who had been actually exposed to a diagnostic imaging procedure estimated the teratogenic risk as 25.5%. The nonexposed pregnant control group perceived the risk as 15.7%.[13] This fear of radiation and misinterpretation of the effect on the fetus may persist even when evidence-based data of the safety of low-dose radiation exposure is provided.[10]

Physicians may also overestimate this risk. One study[13] indicated that physicians caring for pregnant women have unrealistically high perceptions of the teratogenic risk associated with abdominal radiographs/computed tomography (CT) scans administered during early pregnancy. This misperception might result in delay of necessary diagnostic procedures or inappropriate medical advice resulting in unnecessary termination of pregnancy.[14]

A survey of family physicians and obstetricians in Israel revealed that 40% of responding family physicians and 70% of obstetricians recommended therapeutic abortion for women exposed to radiation from a diagnostic imaging procedure in early pregnancy.[13] In another survey in Ontario, Canada, of randomly selected family practitioners and obstetricians, the respondents were informed of the baseline risk of major fetal malformations (1% to 3%) without medical diagnostic imaging. They were asked about their perceptions of fetal risk associated with the following two imaging procedures at six weeks gestation: (1) radiograph (kidneys, ureters, bladder) and (2) abdominal CT scan.

More than 30% of the responding facility practitioners and 20% of the responding obstetricians would have overestimated the risk of major malformations as a result of this radiation exposure.[13] The physicians' misperceptions might have produced increased anxiety among women seeking counseling, unnecessary pregnancy terminations, and/or delays in necessary diagnostic procedures for pregnant women.[13]

Risks in the General Population

In order to understand the risks to the conceptus associated with exposure to diagnostic x-rays, one needs to understand the risks to the conceptus without exposure to diagnostic radiation. It is also important to know the conceptus usually receives less that 1 mGy (0.1 rad) of natural background radiation during a nine-month gestation.[2] This background radiation is from four major sources: cosmic radiation, solar radiation, external terrestrial sources (e.g., rocks, soil), and radon gas.[4] Table 2 specifies the incidence of the risks to the fetus associated with pregnancy *without* acute radiation exposure. The general population's total risk of spontaneous abortion, major malformations, mental retardation, and childhood malignancy is approximately 28.6% (286 per 1,000 deliveries).[6]

Table 2. Background Incidence of Conceptus Complications without Diagnostic Imaging Radiation

RISKS	INCIDENCE
Spontaneous incidence of major malformations	Approximately 1% to 3%
Intrauterine growth restriction	4%
Spontaneous abortion	At least 15%
Genetic disease	8% to 10%
Mental retardation (intelligence quotient less than 70)	Approximately 3%
Severe mental retardation (unable to care for self)	0.5%
Heritable effects	1% to 6%
Spontaneous risk of childhood leukemia and cancer (ages 0 to 15)	0.16%
Children developing cancer up to age 15 (United Kingdom)	0.15%
Children developing leukemia only to age 15 (United Kingdom)	0.03%
Lifetime risk of contracting cancer	33%
Lifetime risk of contracting fatal cancer	20%

Sources: ACOG Committee on Obstetric Practice. ACOG Committee Opinion. Number 299, September 2004 (replaces No. 158, September 1995). Guidelines for diagnostic imaging during pregnancy. ***Obstet Gynecol*** 2004 Sep;104(3):647-51; Brent RL. The effects of embryonic and fetal exposure to x-ray, microwaves, and ultrasound. In: Brent RL, Beckman DA, editors. ***Clinics of perinatology, teratology.*** Vol 13. Philadelphia (PA): Saunders;1986:613-48; Coakley F, Gould R. Guidelines for the use of CT and MRI during pregnancy and lactation. Chapter 5. In: UCSF imaging of retained surgical objects in the abdomen and pelvis section handbook [online]. University of California, San Francisco Department of Radiology. 2005 [cited 2007 Jun 6]. Available from Internet: http://www.radiology.ucsf.edu/instruction/abdominal/ab_handbook/05-CT_MRI_preg.html; Harding LK, Thomson WH. Radiation and pregnancy. ***Q J Nucl Med*** 2000 Dec;44(4):317-24; International Commission on Radiological Protection. Radiation and your patient: a guide for medical practitioners. ***Ann IRCP*** 2001;31(4):5-31; International Commission on Radiological Protection (ICRP). ***Biological effects after prenatal irradiation (embryo and fetus).*** ICRP Publication No. 90. Kidlington, Oxford (United Kingdom): Elsevier; 2003; International Commission on Radiological Protection (ICRP). ***Pregnancy and medical radiation.*** ICRP Publication No. 84. Kidlington, Oxford (United Kingdom): Elsevier; 2000; Ratnapalan S, Bona N, Chandra K, et al. Physician's perceptions of teratogenic risk associated with radiography and CT during early pregnancy. ***AJR Am J Roentgenol*** 2004 May;182(5):1107-9; Ratnapalan S, Bona N, Koren G. Ionizing radiation during pregnancy. ***Can Fam Physician*** 2003 Jul;49:873-4; Sharp C, Shrimpton JA, Bury RF. Diagnostic medical exposures: advice on exposure to ionizing radiation during pregnancy [online]. Chilton, Didcot, Oxon (UK): National Radiological Protection Board. 1998 [cited 2007 Jul 19]. Available from Internet: http://www.e-radiography.net/regsetc/nrpb_asp8/Diagnostic Medical Exposures Advice on Exposure to Ionising Radiation during Pregnancy.htm; Timins JK. Radiation during pregnancy. ***N J Med*** 2001 Jun;98(6):29-33; Toppenberg KS, Hill DA, Miller DP. Safety of radiographic imaging during pregnancy. Am Fam Physician [online]. 1999 Apr 1 [cited 2008 Jan 21]. Available from Internet: http://www.aafp.org/afp/990401ap/1813.html.

For sources associated with specific values, contact the ***Pennsylvania Patient Safety Advisory*** staff.

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Approximate Fetal Radiation Doses of Common Diagnostic Procedures

The majority of diagnostic procedures provide a fetal dose much less than 50 mGy (5 rad).[15] (Table 3 presents the approximate fetal doses of common diagnostic procedure using ionizing radiation.) These estimated fetal doses, however, could vary by a factor of 10 to 100 for the same study, based on the techniques and equipment used.[1,7,15,16] Variables include

Table 3. Approximate Fetal Radiation Doses of Common Diagnostic Procedures

PROCEDURE	mSv	MEAN DOSE mGy (rad)*	MAXIMUM DOSE mGy (rad)*
X-ray			
Abdomen	1	1.4 (0.14)	4 (0.4)
Kidney, ureter, and bladder	1.7	2.9 (0.29)	15 (1.5)
Chest	0.02	less than 0.01 (0.001)	less than 0.01 (0.001)
Intravenous urogram/ pyelogram	10 to 20	1.7 (0.17)	10 (1); 0.37 to 2.64 (0.037 to 0.264)
Lumbar spine	1.3	1.7 (0.17); 0.9 (0.09)	10 (1)
Pelvis	0.7	1.1(0.11); 3.4 (0.34)	4 (0.4); 22 (2.2)
Skull	0.07	less than 0.01(0.001); 0.04 (0.004)	less than 0.01 (0.001)
Thoracic spine	0.7	less than 0.01 (0.001)	less than 0.01 (0.001); 0.03 (0.003)
Dental		less than 0.001 (0.0001); less than 0.01 (0.001)	
Upper/lower extremity	less than 0.01	0.01 (0.001)	
Mammogram	0.6	less than 0.05 (0.005)	0.2 (0.02)
Hip	0.3		0.51 to 1.4 (0.051 to 0.14)
Computed Tomography			
Abdomen	10	8 (0.8); 7.6 (0.76)	49 (4.9); 26 (2.6)
Chest	8	0.06 (0.006)	0.96 (0.096); less than 1 (0.1)
Hand		less than 0.005 (0.0005)	less than 0.005 (0.0005)
Lumbar spine		2.4 (0.24); 7.5 (0.75)	8.6 (0.86); 40 (4)
Pelvis**	7.1	25 (2.5)	79 (7.9)
Head	2.3	less than 0.005 (0.0005)	less than 0.005 (0.0005)
Pelvimetry		0.2 (0.02)	0.4 (0.04)
Fluoroscopy			
Upper GI		1.1 (0.11)	5.8 (0.58); 0.56 (0.056)
Barium enema**	7	6.8 (0.68); 10 (1)	24 (2.4); 130 (13)
Barium swallow	15	1.1 (0.11)	5.8 (0.58)

* Duplicate values represent different estimations in the literature.

** Highlighted rows indicate potential exposures of more than 50 mGy.

Sources: Centers for Disease Control and Prevention. Prenatal radiation exposure: a fact sheet for physicians. [emergency preparedness & response fact sheet online]. 2005 Mar 23 [cited 2008 Jan 21]. Available from Internet: http://www.bt.cdc.gov/radiation/prenatalphysician.asp; Cohen-Kerem R, Nulman I, Abramow-Newerly M, et al. Diagnostic radiation in pregnancy: perception versus true risks. *J Obstet Gynaecol Can* 2006 Jan;28(1):43-8; De Santis M, Di Gianantonio E, Straface G, et al. Ionizing radiation in pregnancy and teratogenesis: a review of literature. *Reprod Toxicol* 2005 Sep-Oct;20(3):323-9; Hamilton PM, Roney PL, Keppel KG, et al. Radiation procedures performed on U.S. women during pregnancy: findings from two 1980 surveys. *Public Health Rep* 1984 Mar-Apr;99(2):146-51; International Atomic Energy Agency. Radiologic protection of patients: pregnancy and radiation in diagnostic radiology. [online]. [cited 2008 Jan 21]. Available from Internet: http://rpop.iaea.org/RPoP/RPoP/Content/SpecialGroups/1_PregnantWomen/PregnancyAndRadiology.htm; International Commission on Radiological Protection. Radiation and your patient: a guide for medical practitioners. *Ann IRCP* 2001; International Commission on Radiological Protection (ICRP). *Biological effects after prenatal irradiation (embryo and fetus).* ICRP Publication No. 90. Kidlington, Oxford (United Kingdom): Elsevier; 2003; International Commission on Radiological Protection (ICRP). *Pregnancy and medical radiation.* ICRP Publication No. 84. Stockholm (Sweden): ICRP; 2000; Ionizing radiation during pregnancy [online]. 2003 Nov 5 [cited 2006 Sep 7]. Available from Internet: http://www.perinatology.com/exposures/Physical/Xray.htm; Kusama T, Ota K. Radiological protection for diagnostic examination of pregnant women. *Congenit Anom (Kyoto)* 2002 Mar;42(1):10-14; Lockwood D, Einstein D, Davros W. Diagnostic imaging: radiation dose and patients' concerns. *Cleve Clin J Med* 2006 Jun;73(6):583-6; Ratnapalan S, Bona N, Koren G. Ionizing radiation during pregnancy. *Can Fam Physician* 2003 Jul;49:873-4; Sharp C, Shrimpton JA, Bury RF. Diagnostic medical exposures: advice on exposure to ionizing radiation during pregnancy [online]. Chilton, Didcot, Oxon (UK): National Radiological Protection Board. 1998 [cited 2007 Jul 19]. Available from Internet: http://www.e-radiography.net/regsetc/nrpb_asp8/Diagnostic Medical Exposures Advice on Exposure to Ionising Radiation during Pregnancy.htm; Smits AK, Paladine HL, Judkins DZ, et al. Clinical inquiries. What are the risks to the fetus associated with diagnostic radiation exposure during pregnancy? *J Fam Pract* 2006 May;55(5):441-2,444; Timins JK. Radiation during pregnancy. *N J Med* 2001 Jun;98(6):29-33.

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filtration, presence of a grid, and x-ray parameters. Moreover, in fluoroscopy-based exams, fetal doses are difficult to calculate because it may be unknown how long the conceptus is actually in the primary beam, which the radiologist may move during the procedure. Additional factors affecting fluoroscopy doses include magnification, grid use, and whether conventional or pulse fluoroscopy is used. Fetal dose is also greatly affected by such patient anatomical factors as thickness of the patient, anteversion or retroversion of the uterus, and distension of the bladder.[1]

Effects of Ionizing Radiation

Because chemicals and drugs are metabolized and transported through the placenta to the conceptus, there can be variations in how they affect different mammalian species. However, ionizing radiation affects the conceptus directly. As a result, the effect of ionizing radiation in studies using animal models is more directly applicable to humans.[10]

General Effects

Ionizing radiation passing through living matter produces physical and chemical changes at various levels: molecular, cellular, tissue, and the whole organism.[16] Two types of effects can be produced by ionizing radiation: deterministic effects and stochastic effects.[7,15,17] (Refer to Table 1.)

Deterministic. These effects occur above a certain threshold dose of ionizing radiation.[7,15,17] Below this threshold, the effects in exposed populations are similar to control populations who have received only background radiation.[4] Deterministic effects are caused by cell killing, and the severity of the effect increases as the dose above the threshold increases.[7,18,19] Cell killing can produce death; growth retardation; abnormal brain/central nervous system (CNS) development, including mental retardation and behavioral disorders; abortion; malformation; and cataracts.[16,19]

Stochastic. Stochastic effects can occur after any exposure and involve damage to the nuclear material in cells, causing hereditary mutations or radiation-induced cancer including leukemia.[8,15-17] For such DNA damage or misrepair, there is no threshold dose below which the chance of these effects is zero.[7,17,19] Stochastic effects also increase with radiation dose.

Effects on the Conceptus

Ionizing radiation can produce the following effects on the conceptus, which depend upon the fetal dose absorbed and the phase of gestation at the time exposure occurs.[18,20] Exposing a fetus to 5 mGy (0.5 rad) adds about 0.17 cases per 1,000 deliveries (or about 1 case per 6,000 deliveries) to the general population's risks of spontaneous abortion, major malformation, mental retardation, and childhood malignancy.[7] Harmful effects can be categorized as follows: cell/intrauterine death, teratogenicity, carcinogenicity, and genetic/mutation/heritable effects.[14,20]

Effects According to Stages of Pregnancy

During the entire gestation, mammalian embryos and fetuses are radiosensitive. The type and severity of most induced biological effects depend on the developmental stage of the conceptus during which radiation exposure occurs.[21] Most of the effects of ionizing radiation can be considered according to the following stages of pregnancy: pre-implantation, organogenesis, and fetal development.

Pre-implantation. The pre-implantation stage begins from the moment the egg is fertilized until the fertilized egg attaches to the uterine wall (zero to two weeks postconception).[22]

Organogenesis (embryonic). During the organogenesis stage (two weeks postconception until seven to eight weeks postconception), cell migration of multipotential progenitor cells forms the major organs.[22]

Fetal development. In the fetal development stage (eight or nine weeks to delivery), differentiated organs undergo cellular growth. The three phases are as follows: early, mid, and late.[22]

Table 4 presents possible health effects to the conceptus, according to radiation dose and stage of pregnancy.

Severe mental retardation. While most major organs form and differentiate during the organogenesis phase of pregnancy, the CNS continues to differentiate during the organogenesis, early fetal, and mid-fetal stages of pregnancy.[22] The risk of severe mental retardation varies with the stage of pregnancy. Table 5 displays the variations in this risk to the conceptus during gestation. During early fetal development (8 to 15 weeks), 50 mGy is associated with IQ reduction.[23] This dose can be reached by a single CT scan of the abdomen and pelvis or by a barium enema (refer to Table 3).

Carcinogenicity (radiation-induced cancer and leukemia). Radiation has been shown to cause many types of cancer and leukemia in adults and children.[1,24] However, the estimates of cancer risk related to diagnostic radiation vary considerably. Therefore, the risk of diagnostic-radiation-induced cancer and leukemia remains unclear. More recent, well-designed studies do not replicate an association between childhood malignancies and in utero diagnostic radiation exposure found in earlier studies.[2,25] A recent analysis (ICRP 90) concludes that the relative risk of childhood cancer is 1.37 per 10 mGy (1 rad) of exposure.[21]

Genetic/mutation/heritable effects (alteration of germ cell lines). Radiation increases the frequency of mutations above mutations naturally occurring in the general population. However, no radiation-induced gene mutations have been demonstrated unequivocally in humans when the conceptus is exposed to diagnostic radiation.[20] Therefore, the exposure risk is considered to be the same as the risk after birth, 1 in 4,200 per 10 mGy (1 rad), compared to the estimated

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Table 4. Effects of Ionizing Radiation on Conceptus

PREGNANCY PHASE	WEEKS POST CONCEPTION	RADIATION EXPOSURE	POSSIBLE CONCEPTUS HEALTH EFFECTS
Pre-implantation	0 to 2 weeks	Diagnostic exposure (less than 100 mGy [10 rad])	Embryo implantation failure; embryo death by cytogenic damage
		Greater than 100 mGy (10 rad)	Lethality
Organogenesis	2 to 7/8 weeks	Less than 50 mGy (5 rad)	No increase of significant congenital malformations above background incidence
		Greater than 100 mGy to 150 mGy (10 rad to 15 rad)	Malformations due to cell killing; growth retardation; cataracts; skeletal anomalies; central nervous system abnormalities: microcephaly, mental retardation (risk of severe mental retardation is not increased over background levels)
Fetal Development			
Early	8/9 weeks to 15 weeks	Less than 50 mGy (5 rad)	Cancer is the only detectable health risk
		50 mGy to 500 mGy (5 rad to 50 rad)	Dose dependent growth retardation; IQ reduction
		Greater than 500 mGy (50 rad)	Increased risk of growth retardation/spontaneous abortion; major malformation; IQ reduction; severe mental retardation
Mid	16 weeks to 25 weeks	Less than 50 mGy (5 rad)	Cancer is the only detectable health risk
		50 mGy to 500 mGy (5 rad to 50 rad)	Not likely to produce health risk except cancer
		Greater than 500 mGy (50 rad)	Increase in major malformations and spontaneous abortions; dose dependent growth retardation; IQ reduction; severe mental retardation
Late	26 weeks to delivery	Less than 500 mGy (50 rad)	Cancer is the only detectable health risk
		Greater than 500 mGy (50 rad)	Dose dependent neonatal death and spontaneous abortion; major functional anomalies or malformations unlikely

Sources: Centers for Disease Control and Prevention. Prenatal radiation exposure: a fact sheet for physicians. [emergency preparedness & response fact sheet online]. 2005 Mar 23 [cited 2008 Jan 21]. Available from Internet: http://www.bt.cdc.gov/radiation/prenatalphysician.asp; De Santis M, Di Gianantonio E, Straface G, et al. Ionizing radiation in pregnancy and teratogenesis: a review of literature. ***Reprod Toxicol*** 2005 Sep-Oct;20(3):323-9; International Atomic Energy Agency. Radiologic protection of patients: pregnancy and radiation in diagnostic radiology. [online]. [cited 2008 Jan 21]. Available from Internet: http://rpop.iaea.org/RPoP/RPoP/Content/SpecialGroups/1_PregnantWomen/PregnancyAndRadiology.htm; International Commission on Radiological Protection. Radiation and your patient: a guide for medical practitioners. ***Ann IRCP*** 2001;31(4):5-31; International Commission on Radiological Protection (ICRP). ***Biological effects after prenatal irradiation (embryo and fetus).*** ICRP Publication No. 90. Kidlington, Oxford (United Kingdom): Elsevier; 2003; Lowe SA. Diagnostic radiography in pregnancy: risks and reality. ***Aust N Z J Obstet Gynaecol*** 2004 Jun;44(3):191-6; Timins JK. Radiation during pregnancy. ***N J Med*** 2001 Jun;98(6):29-33; Toppenberg KS, Hill DA, Miller DP. Safety of radiographic imaging during pregnancy. Am Fam Physician [online]. 1999 Apr 1 [cited 2008 Jan 21]. Available from Internet: http://www.aafp.org/afp/990401ap/1813.html.

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background frequency of genetic mutation and heritable (refer to Table 2).[19,21]

Low-dose radiation exposure. While low-dose diagnostic radiation is generally considered not harmful to the conceptus, some studies have indicated certain problems (refer to Table 6). Many of these studies have been criticized because of failure to control certain variables, the need to use retrospective methodology, study size, and/or lack of biological plausibility.[26]

Risk Reduction Strategies

Because some of the effects of ionizing radiation are cumulative, performing multiple diagnostic radiation procedures on a pregnant woman may place the conceptus at risk. Several strategies can be used to reduce this risk.

Justification

The physician justifies each use of medical radiation during pregnancy—the benefits must outweigh the risks.[1,6,7,16,17,26] Whenever possible, both parents are included in this decision-making process.[6] There are, of course, two individuals involved in this evaluation.[1] While the mother may receive direct benefit from the diagnostic procedure, her fetus may be exposed without direct benefit. But, if the mother's medical problem is serious, diagnostic radiation may lead to lifesaving medical interventions that may directly benefit the fetus.[1] Another consideration is determining whether the diagnostic procedure is useful—will its outcome strengthen confidence in the diagnosis and influence patient intervention.[7] The physician balances the medical needs against potential radiation risks on a

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Table 5. Fetal Effects of Ionizing Radiation: Severe Mental Retardation

PREGNANCY PHASE	WEEKS POST CONCEPTION	RADIATION EXPOSURE	RISK OF MENTAL RETARDATION
Organogenesis	2 to 8 weeks	Diagnostic radiation	No increased risk
		100 mGy to 200 mGy (10 rad to 20 rad)	Mental retardation
		1,000 mGy (100 rad)	Reduction of IQ (25 to 30 points); severe mental retardation in 40% of cases
		1,500 mGy (150 rad)	Severe mental retardation in 60% of cases
Fetal development			
Early	8/9 to 15 weeks	Diagnostic radiation	No increased risk
		200 mGy (20 rad)	Malformation of forebrain producing mental retardation
		1,000 mGy (100 rad)	Reduction of IQ (25 to 30 points); severe mental retardation in 40% of cases
		1,500 mGy (150 rad)	Severe mental retardation in 60% of cases
Mid	16 to 25 weeks	Diagnostic radiation	No increased risk
		Above diagnostic radiation	Less risk of IQ reduction and severe mental retardation
Late	26 to delivery		Central nervous system is relatively radioresistent

Sources: ACOG Committee on Obstetric Practice. ACOG Committee Opinion. Number 299, September 2004 (replaces No. 158, September 1995). Guidelines for diagnostic imaging during pregnancy. ***Obstet Gynecol*** 2004 Sep;104(3):647-51; De Santis M, Di Gianantonio E, Straface G, et al. Ionizing radiation in pregnancy and teratogenesis: a review of literature. ***Reprod Toxicol*** 2005 Sep-Oct;20(3):323-9; Harding LK, Thomson WH. Radiation and pregnancy. ***Q J Nucl Med*** 2000 Dec;44(4):317-24; Henshaw SK. Unintended pregnancy in the United States. ***Fam Plann Perspect*** 1998 Jan-Feb;30(1):24-9, 46; International Atomic Energy Agency. Radiologic protection of patients: pregnancy and radiation in diagnostic radiology. [online]. [cited 2008 Jan 21]. Available from Internet: http://rpop.iaea.org/RPoP/RPoP/Content/SpecialGroups/1_PregnantWomen/PregnancyAndRadiology.htm; International Commission on Radiological Protection. Radiation and your patient: a guide for medical practitioners. ***Ann IRCP*** 2001;31(4):5-31; International Commission on Radiological Protection (ICRP). ***Biological effects after prenatal irradiation (embryo and fetus).*** ICRP Publication No. 90. Kidlington, Oxford (United Kingdom): Elsevier; 2003; International Commission on Radiological Protection (ICRP). ***Pregnancy and medical radiation.*** ICRP Publication No. 84. Kidlington, Oxford (United Kingdom): Elsevier; 2000; Timins JK. Radiation during pregnancy. ***N J Med*** 2001 Jun;98(6):29-33; Toppenberg KS, Hill DA, Miller DP. Safety of radiographic imaging during pregnancy. Am Fam Physician [online]. 1999 Apr 1 [cited 2008 Jan 21]. Available from Internet: http://www.aafp.org/afp/990401ap/1813.html.

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case-by-case basis, rather than solely on numerical calculations.[1] Radiographs that are ordered will ideally not only meet the criterion of medical necessity but also be in accordance with appropriate published guidelines.[6,7]

Usually, the risk of not making a correct diagnosis is greater than the radiation risk involved.[7,27] If the mother's condition requires x-rays, there usually should be no hesitation in ordering a needed study.[6]

Delay

If radiographic information is not likely to alter immediate medical management, it may be prudent to delay nonurgent radiographs, particularly during the sensitive CNS period of early fetal development from 8 to 15 weeks after conception.[6] Any delay until after pregnancy must be considered in light of the clinical status of the mother and unborn child, balancing the risks and benefits to both.[7,17]

Because of some studies linking maternal, prenatal dental x-rays with low-birth-weight babies, the American Dental Society recommends that pregnant women postpone elective dental x-rays until after delivery.[28]

Avoidance

Avoid studies in pregnant patients that do not influence patient care.[29] Moreover, consider whether follow-up diagnostic studies involving ionizing radiation are medically necessary.[29] Also, consider whether repeat studies are necessary if such studies were recently performed at another hospital or outpatient setting.[7]

The following diagnostic studies may be medically unjustified during pregnancy:[7]

- Lower lumbosacral radiographs in patients with stable degenerative conditions of the spine
- Routine chest x-rays at hospital admission or before surgery in the absence of cardiac or pulmonary disease/insufficiency

The World Health Organization concluded that routine screening chest x-rays during pregnancy are not indicated unless there is a high incidence locally of clinically silent chest disease.[1] CT of the fetus should be avoided in all trimesters of pregnancy.[30]

Moreover, x-ray pelvimetry is of limited medical value and should not be performed on a routine basis.[1] There is a poor statistical correlation between pelvic measurements and the course of labor. If x-ray pelvimetry is medically necessary, the reasons should be clearly documented.[1]

Alternatives

If a patient is pregnant, consider whether another diagnostic examination can be substituted.[18,20] Ultrasound and magnetic resonance imaging (MRI) have no known risks to a developing fetus and do not

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Table 6. Fetal Effect of Low-Dose Diagnostic Ionizing Radiation Exposure

STUDY	RADIATION DOSE	FETAL HEALTH EFFECT
Jacobson and Mellemgaard	Low dose	Eye anomalies
Kinlen and Acheson	Low dose	No increased rate of malformations or spontaneous abortions
Bohnen et al.	Diagnostic radiation of greater than 0.3 rad during second or third trimester	Significant reduction of infant head circumference
	Diagnostic radiation of greater than 0.3 rad during first trimester	No effect
Hamilton et al.	Diagnostic radiation	Lower birth weight babies
Hujoel et al.	Dental radiographs during pregnancy (threshold dose 0.4 mGy [0.04 rad])	Increased risk of low birth weight babies
Boice et al., De Santis et al.	Diagnostic radiation with thyroid exposure during first trimester (threshold dose 0.4 mGy to 0.9 mGy [0.04 rad to 0.08 rad])	Slight reduction of birth weight

Sources: Bohnen NI, Ragozzino MW, Kurland LT. Brief communication: effects of diagnostic irradiation during pregnancy on head circumference at birth. ***Int J Neurosci*** 1996 Nov;87(3-4):175-80; Boice JD Jr, Stovall M, Mulvihill JJ, et al. Dental x-rays and low birth weight. ***J Radiol Prot*** 2004 Sep;24(3):321-3; De Santis M, Straface G, Cavaliere AF, et al. First trimester maternal thyroid X-ray exposure and neonatal birth weight. ***Reprod Toxicol*** 2005 May-Jun;20(1):3-4; Hamilton PM, Roney PL, Keppel KG, et al. Radiation procedures performed on U.S. women during pregnancy: findings from two 1980 surveys. ***Public Health Rep*** 1984 Mar-Apr;99(2):146-51; Hujoel PP, Bollen AM, Noonan CJ, et al. Antepartum dental radiography and infant low birth weight. ***JAMA*** 2004 Apr 24;291(16):1987-93; Jacobsen L, Mellemgaard L. Anomalies of the eyes in descendents of women irradiated with small X-ray doses during age of fertility. ***Acta Ophthalmol (Copenh)*** 1968;46(3):352-4; Kinlen LJ, Acheson ED. Diagnostic irradiation, congenital malformations and spontaneous abortion. ***Br J Radiol*** 1968 Sep;41(489):648-54.

involve ionizing radiation.[7,16,18,20,24] In certain circumstances, direct visualization of the mother's pathology (e.g., using endoscopy or laryngoscopy) may promote accurate diagnosis.[29] Diagnostic alternatives may be appropriate when cost, waiting time, or organizational difficulties are not prohibitive.[7]

For example, if pelvimetry must be done, the obstetrician can obtain adequate information by ultrasound or MRI, thus avoiding ionizing radiation.[1,30] For acute appendicitis during the first and second trimester, MRI and/or ultrasound can be considered instead of obtaining a CT scan.[30] Ultrasound is the initial study of choice to identify renal calculi.[30] For trauma, ultrasound may be sufficient, but CT may be necessary if specific anatomic injuries are suspected.[30]

Optimization/Minimization/Protection

When a pregnant patient requires x-ray, the examination should be optimized to provide good diagnostic quality for the least possible exposure to the fetus.[1,18] Medically necessary radiography or fluoroscopy of areas remote from the fetus (e.g., head, chest, extremities) can be safety performed at any time during the pregnancy if x-ray equipment is shielded properly, x-ray beam collimation is used, proper technique/procedures are followed, and the equipment is in proper working order.[1,7,24]

When a pregnant woman requires medically necessary abdominal or pelvic diagnostic x-ray examinations in which the x-ray beam directly irradiates the fetus, fetal exposure can be reduced while obtaining required diagnostic information.[7,17,25] The following techniques can reduce radiation for all modes of diagnostic radiology procedures: increasing filtration, decreasing electrical current (mAs), and increasing kVp. Additionally, for x-rays, techniques that reduce ionizing radiation include collimation of the x-ray beam to a very specific area of interest, shielding the x-ray equipment and fetus when possible, increasing kVp, removing the antiscatter grid, and taking fewer films.[1,18]

If fluoroscopy is required, it should be used sparingly and judiciously to reduce the time of fetal exposure, as fetal doses can exceed 50 mGy (5 rad), especially if fluoroscopy time exceeds seven minutes.[1,7,27] Both shorter beam time and greater distance to the patient can reduce the radiation dose.[27]

If CT of the abdomen or pelvis is absolutely necessary, consider single, low-dose CT scan.[29] Techniques that may reduce dose during CT scans in general include establishing the optimal electrical current (mAs) through the x-ray tube, scanning only the area necessary, using multiple phase scanning only if needed, and using organ shielding that is designed for CT scans.[31] Radiation reduction techniques may be used as long as they do not unduly reduce the diagnostic value of the x-ray examination.[1] Tailoring each examination and reviewing each radiograph as it is taken until a diagnosis can be achieved, then terminating the procedure, will reduce radiation exposure.[27] Examples include using low-dose CT to perform medically necessary pelvimetry. Conventional excretory urography will most likely involve lower radiation than CT urography.[29] If pulmonary embolism is suspected, a CT pulmonary angiogram exposes the fetus to less radiation than a VQ (pulmonary ventilation/quantification) scan.[30]

Lead shielding of the abdomen and pelvis will reduce radiation exposure to the fetus,[29] but only slightly, since some exposure comes from internal scatter. The American Dental Society recommends that if a pregnant woman's dental x-rays cannot be delayed until after delivery, abdominal shielding and a protective thyroid collar be applied during the procedure.[28]

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Calculation

In most cases of diagnostic radiology, fetal dose estimation is unnecessary unless the fetus is in the direct beam. If the fetus is in the direct beam or if a woman is unaware she is pregnant at the time of a high-dose x-ray procedure, a qualified expert (i.e., a medical physicist/radiation safety specialist who is experienced with dosimetry) can calculate the estimated radiation dose to the conceptus/fetus.[1,24]

The qualified expert calculates a case-specific, estimated fetal dose, rather than referring to average doses published in the clinical literature.[15] Then, this dose is compared to the date of conception or date of last menstrual period to determine fetal risks associated with the length of the gestation.[24]

Pregnancy Presumption/Determination

Until proven otherwise, amenorrhea occurring in regularly menstruating women should be considered due to pregnancy.[1,24] All women of childbearing age should be questioned about the possibility of pregnancy prior to diagnostic radiation exposure.[1,7,18]

Pregnancy testing may be necessary;[18] however, because fetal doses are usually well below the 1 mGy (0.1 rad) used in diagnostic radiology, pregnancy tests are not usually performed.[1,19] Moreover, in most diagnostic radiology situations, the "10-day rule" in women of childbearing age has been proven to be unnecessary.[16] But in high-dose procedures involving the lower abdomen and pelvic area in which the embryo-fetus is in the direct beam, it would be prudent to conduct a pregnancy test and/or restrict such radiography to the first 10 days of the woman's menstrual cycle.[16] In high-dose procedures, the absorbed fetal dose might range by a factor of 10 to 100.[1,7,15,16] Thus, the absorbed dose may be above the threshold dose for malformations, and cancer risk becomes appreciable.

When a patient is pregnant or possibly pregnant, the technician or clerk relates the information to the radiologist. The radiologist, in turn, determines whether the embryo/fetus will be in the primary x-ray beam. If not, the risk to the fetus is very low, and the best risk reduction strategy is good radiologic practice.[1]

While pregnancy testing is not necessary for low-dose, low-risk diagnostic radiation procedures, testing may be prudent prior to high-dose procedures, particularly of the abdomen and pelvis. As communicated in PA-PSRS reports, patients who have firmly denied the possibility of pregnancy have undergone high-dose diagnostic procedures during which fetuses were revealed.

Another issue identified in PA-PSRS reports is the performance of imaging procedures prior to the return of pregnancy test results. Facilities may address this issue by evaluating/improving systems and processes to improve turnaround time of pregnancy test results or implementing point-of-care testing that involves personnel who have the competencies to conduct and interpret these tests prior to conducting such diagnostic procedures.

Awareness

Increasing public awareness of the safety of low-dose diagnostic radiation may reduce anxiety and prevent test delays or termination of otherwise wanted pregnancies.[10] Heightening physician awareness about diagnostic radiation doses and effects may promote accurate estimation of diagnostic radiation risk and therefore more appropriate patient counseling.[1,13]

The medical professional who prescribes or uses radiation needs to be familiar with the effects of radiation on the conceptus. The associated risk is low with less than 100 mGy (10 rad) of radiation exposure, except during the pre-implantation stage of pregnancy (refer to Table 4). The risk of carcinogenesis related to ionizing radiation throughout pregnancy is unclear, but a study by ICRP indicates that it is discernable.[21] Risks associated with greater than 100 mGy (10 rad) include CNS abnormalities, malformations, growth restriction, and fetal death.[1]

Patient education brochures can provide information about risks associated with diagnostic ionizing radiation and pregnancy; for example, see http://www.familydoctor.org.

For a given radiographic examination, the range of entrance doses (doses measured at the body surface at the site where the x-ray beam enters the body) is very broad. At times, the lowest and highest doses measured at individual radiological installations vary by a factor of 100.[7] Therefore, facilities can establish diagnostic reference levels for each of the principal studies. These levels can be used to identify x-ray machines in need of corrective actions, thus reducing the average facility-specific radiation dose to patients.[7]

Moreover, regular preventive maintenance will help to ensure that the equipment is in proper working order and is providing an appropriate dose of radiation.

Good procedural technique can be promoted through confirming staff competencies and monitoring techniques utilized.[7]

Notice

Consider posting notices in several places within diagnostic radiology departments or wherever diagnostic x-ray equipment is used, advising patients who are pregnant or could be pregnant to inform a staff person prior to the procedure.[1] These notices could also be posted in reception/waiting areas and written in the predominant languages of the communities served by the facility. Using pictures instead of text in the notices may help to convey to individuals from different languages or cultures the need to report actual/potential pregnancies.[17]

Documentation

When ordering diagnostic radiation procedures, providing to the radiologist adequate clinical information, the suspected diagnosis, and/or reason for the examination will prevent wrong procedures, techniques, and/or useless tests.[7] When a high-dose diagnostic procedure is performed and the fetus is in

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the primary x-ray beam, documenting the following technical factors will provide information required for the medical physicist/qualified expert to calculate an accurate fetal radiation dose.

For all modes of diagnostic radiation, document the following as applicable: film projections, geometrical description, dose area product, beam filtration, x-ray generator settings (mAs and kVp); and whether a grid was used.[1,18,27] In addition, for x-rays, document the number of films and locations.[27] For fluoroscopy, additional information includes beam time.[27] For CT scans, additional information includes slice thickness, number of slices, pitch (distance between adjacent slices), and location of the uterus.[27]

The healthcare professional should document the details related to counseling and consents in the patient's medical record.[1]

Counseling/Consent

A pregnant patient has a right to know the extent and type of potential radiation effects that might result from in utero radiation exposure.[1] The extent of disclosure is determined by what a reasonable person believes is material to a mother's decision to be exposed to radiation.[1]

The scope of information provided to a pregnant patient is related to the level of risk to the fetus.[1] For low-dose procedures such as a chest x-ray, verbal assurances can be provided that the risk is extremely low and this discussion can be documented in the patient's medical record or radiology report.[30] When fetal doses are 1 mGy (0.1 rad) or greater, more detailed information is given.[1]

The clinician ordering the imaging procedure is responsible for counseling the pregnant woman and obtaining informed consent, in consultation with the radiologist.[20] Women who have had routine plain films of the head, chest (including mammograms), and extremities (not the hip), or CT of the head or chest, may be counseled that the following risks to the fetus are not increased: miscarriage, growth restriction or congenital malformation (e.g., microcephaly), or mental retardation.[34] The benefits outweigh most risks.[20] While any one diagnostic radiology procedure is below the threshold, the fetuses of women exposed to radiation exceeding a cumulative dose of more than 50 mGy (5 rad) may be at risk.[6]

Pregnant women may also be counseled that the risk of a fetus developing childhood cancer is less than 1%.[34] Fetal exposures to diagnostic radiation in doses less than 100 mGy (10 rad) are not considered a reason for termination of pregnancy.[1,24] One author has suggested that for direct fetal exposure of greater than 1 mGy (0.1 rad) a more detailed explanation can be given indicating minimal risk below 10 mGy (1 rad).[20]

In the fetal dose range of 100 mGy to 200 mGy (10 rad to 20 rad), the situation is less clear.[1] There appears to be a risk of measurable IQ loss if the fetus is exposed between 8 to 15 weeks gestation. At fetal doses greater than 500 mGy (50 rad), there can be significant fetal damage, of which the magnitude and type depend upon the dose and stage of pregnancy.[1,24] Three to 16 weeks after conception, if the absorbed fetal dose is in excess of 500 mGy, there is a substantial risk of growth retardation and CNS damage. The fetus may survive, but the parents need to be informed of the high risks involved.[1]

A qualified biomedical or health physicist should calculate the absorbed fetal dose as accurately as possible. Then the physician provides information and determines the situation/perspective of the parents. The parents will make decisions after being fully informed.[1]

Information provided may include the following:[1,16]

- Analysis of gestational age
- Estimation of fetal dose and risks of in utero radiation exposure
- Benefit of radiological examination for the mother and medical indication
- Maternal risk if the examination were postponed until after delivery
- Comparison of radiation risks with other environmental hazards in ordinary life
- Spontaneous incidence of fetal abnormalities in populations without diagnostic radiation exposure

One approach suggested is to indicate to the mother the probability of not having a child with a malformation or cancer and how that probability is affected by diagnostic radiation exposure.[1,17] Another approach is to present a graph that compares the radiation dose of various diagnostic studies and/or environmental sources with the threshold limit of 5 rad. The patient's specific study could be plotted on the graph for comparison.[6,17]

For higher dose tests (e.g., CT of the abdomen or pelvis, barium enema, IVP, lumbar spine, hip radiograph), it may be prudent to obtain written informed consent.[30] One example of such a form was developed by the University of California, San Francisco.[30] If a patient states she is or may be pregnant and the procedure involves ionizing radiation, the procedure should not be performed unless a radiologist is consulted.[30]

If the patient has limited English proficiency, obtaining consent before the procedure and counseling a pregnant woman after a procedure using ionizing radiation is considered critical communication. A certified language interpreter is required to ensure that the patient understands the information provided prior to making decisions.

Communication

Even though diagnostic radiation is unlikely to cause harm to the fetus, it is not appropriate to promise parents a perfect baby because there are baseline risks associated with pregnancy even without diagnostic radiation.[6]

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Open communication with the patient about the nature of the test, potential outcomes, and risks encourages a trusting relationship both before and after a diagnostic study.[6] Such communication can alleviate patient concerns about the effects of radiation.[25]

When healthcare workers (physicians, technicians, radiologists, nurses) work closely together with the patient, they can determine the most appropriate study that will obtain the maximum amount of information while reducing exposure of the fetus to ionizing radiation.[20,25]

Key Points[1,6,7,12,17,24]

The following key points can help promote the safe use of diagnostic ionizing radiation in pregnant women:

- Prenatal doses from most properly performed diagnostic procedures present no measurable increase of fetal death, malformation, or impairment of mental development over background incidence of these complications.
- If a diagnostic radiology examination is required to guide diagnosis and treatment, the risk to the mother of not performing the procedure is usually greater than the risk of potential harm to the fetus.
- Ultrasound and MRI are considered safe alternatives to ionizing radiation and can be used throughout the pregnancy.
- There are radiation-associated risks throughout pregnancy relative to the fetal absorbed radiation dose and the stage of pregnancy. The most significant radiation risks occur during organogenesis and the early fetal period. During those periods, non-urgent x-rays can be avoided.
- Many complex factors are involved in an individual's decision to terminate a pregnancy, including fetal radiation exposure information and religious, ethical, and individual beliefs, as well as laws and regulations. However, a fetal dose below 10 rad (100 mGy) is not considered a reason for terminating a pregnancy.
- The majority of diagnostic procedures, excluding pelvic CT and barium enema, do not involve fetal exposure of greater than 50 mGy (5 rad) and are not, therefore, usually associated with known deterministic effects (malformation, mental retardation).
- The main practical issue following in utero exposure at diagnostic levels is the increased risk of cancer.
- It is important to know the patient's pregnancy status with as much certainty as possible. One should not rely on the patient's history alone.
- Pregnant women should be informed in writing of the radiation dose and date of the procedure so that cumulative effects can be appreciated.
- Patient counseling before and/or after diagnostic radiation exposure can help reduce anxiety and misunderstanding about the effects of such exposure on the conceptus.
- When healthcare workers (e.g., physicians, technicians, radiologists, nurses) work closely together with the patient, the study most appropriate for the situation can be determined so the pregnant patient obtains the maximum amount of information while reducing exposure of the fetus to ionizing radiation.

Accompanying Resources

Visit the Pennsylvania Patient Safety Authority (http://www.psa.state.pa.us) for resources that include the following:

- A pocket resource discussing radiation doses of common diagnostic procedures and effects according to stage of pregnancy
- A patient record to track cumulative radiation exposure

To view the resources, click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Next, click on "Resources Associated with Patient Safety Advisory Articles."

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Self-Assessment Questions

1. The central nervous system of the fetus is most sensitive to ionizing radiation during which of the following?
   a. Pre-implantation
   b. Organogenesis
   c. Early fetal development
   d. a and b only
   e. b and c only
2. Medically necessary x-rays of the head, chest, and arms can be performed on a pregnant woman at any time during the pregnancy.
   a. True
   b. False
3. Fetal radiation doses for a fluoroscopic procedure are as easy to calculate as for a radiograph.
   a. True
   b. False
4. During a nine-month gestation, the conceptus usually receives how much natural ionizing radiation?
   a. 1 mGy (0.1 rad)
   b. 10 mGy (1 rad)
   c. 20 mGy (2 rad)
   d. 30 mGy (3 rad)
5. Sources of natural background ionizing radiation include which of the following
   a. Heat and light
   b. Sound waves and microwaves
   c. Sun and rocks
   d. All of the above
6. Absorbed fetal radiation can be calculated accurately by referring to average doses published in the clinical literature.
   a. True
   b. False

The American College of Surgeons Recommends Sharps Safety Practices

Editor's Note:

This text was abstracted from the following: College of Surgeons Committee on Perioperative Care. Statement on sharps safety. Bull Am Coll Surg *2007 Oct;92(10):34-7.*

The American College of Surgeons (ACS) recommends that healthcare facilities adopt certain operating room (OR) work practices to avoid surgeons' and OR staff members' exposure to bloodborne infections as a result of sharps injuries and surgical glove tears. The recommended practices include using the double-glove technique, using blunt tip suture needles, using the hands-free technique (HFT) in designated neutral zones, and using engineering sharps injury prevention (ESIP) devices. Preventing exposure of surgeons and OR staff members to patients' blood reduces the need for more blood tests and venipunctures on patients.

Double Gloving

Double gloving can reduce the risk of exposure to patient blood by nearly 90% when an outer glove is punctured; however, surgeons have not universally accepted the technique. Periods of adaptation and retraining may help improve conformity.

> The ACS recommends the universal adoption of the double glove (or underglove) technique in order to reduce body fluid exposure caused by glove tears and sharps injuries by surgeons and scrub personnel. In certain delicate operations, and in situations where it may compromise the safe conduct of the operation or safety of the patient, the surgeon may decide to forgo this safety measure.

Blunt Tip Suture Needles

The efficacy of blunt tip suture needles in reducing sharps injuries is demonstrated in several studies; furthermore, use of such needles does not require surgeons to change their work practices.

> The ACS recommends the universal adoption of blunt tip suture needles for the closure of fascia and muscle in order to reduce needle-stick injuries in surgeons and OR personnel.

The Neutral Zone

Use of HFT includes the surgical team establishing a neutral zone for pickup and release of sharps to ensure no direct handoff of sharps between team members. If surgeons are required to maintain eye contact with the surgical field (e.g., during a critical portion of a surgery), use of partial HFT has been established; that is, the scrub person hands sharps directly to surgeon, but the surgeon returns sharps via the neutral zone. Data supporting the use of HFT is inconclusive.

> The ACS recommends the use of HFT as an adjunctive safety measure to reduce sharps injuries during surgery except in situations where it may compromise the safe conduct of the operation, in which case a partial HFT can be used.

ESIP Devices

ACS stated that there were no studies available demonstrating the clinical effectiveness of ESIP devices at the time of publication of the ACS statement, but added that that such devices may contribute to minimizing sharps injuries.

> The ACS recommends the use of ESIP devices as an adjunctive safety measure to reduce sharps injuries during surgery except in situations where it may compromise the safe conduct of the operation or safety of the patient.

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Medication Assessment: One Determinant of Falls Risk

ABSTRACT

Medication assessment is often absent from falls assessment and reassessment. As a result, patients who are at risk for falls may receive medications that increase falls risk. In 2006, more than 4,000 of the total 33,882 falls reported to PA-PSRS were associated with concomitant use of two or more medications. Seventy percent (23,806) of the falls did not result in any patient harm, and less than 1% (17) indicated deaths associated with falls. Medication classes contributing to fall risk that were most frequently reported to PA-PSRS include anxiolytics/hypnotics, antidepressants, neuroleptics, opioid analgesics/antagonists, and insulin/oral hypoglycemics. Risk reduction strategies include recognizing the problem and involving pharmacy staff in developing medication assessment and reassessment strategies for patients at risk for falls. (Pa Patient Saf Advis 2008 Mar;5[1]:16-8.)

> [An elderly] *patient had been assessed at 7 a.m.;* [the patient was] *in bed,* [there were] *no unusual findings, and four side rails were up as per order. At approximately 7:30 a.m., a nurses aide went into the room and found the patient on floor, unresponsive. No carotid pulse was noted. Resuscitation was initiated, but unsuccessful. . . . The patient had been prescribed benzodiazepines, anticoagulants, laxatives, diuretics, and antipsychotic medications.*

Medications may have compounding effects that increase the potential for falls or the potential for harm from falls. Although most healthcare professionals consider patients' falls risk, medications may be prescribed and dispensed without proper consideration of patient selection, contraindications, or drug-drug interactions for patients who are at high risk for falls. Some PA-PSRS reports, such as the one above, discuss patients who were taking medications that could have factored into the falls or the falls outcomes. Other reports did not indicate initial medication high-risk falls assessments, or made it clear that patients were not subject to medication re-evaluations after falling.

Over the course of one year (2006), a total of 33,882 falls events were reported to PA-PSRS. Of these, the severity of effect was reported as no injury in 70% of falls (23,806). (See Table 1.) The most common injury as a result of falls required the application of ice, dressings, and limb elevation. There were, however, reports of severe injuries that required sutures, splints, fractures, and surgery. Less than 1% (17 reports) indicated death as the result of falls.

The Joint Commission requires organizations to implement and evaluate the effectiveness of a falls reduction program.[1] The falls reduction program should include an evaluation of falls history and medication review. A literature review revealed that many healthcare facilities include pharmacy review of medications *only* after a patient falls or is identified as at high risk for falling.[2] A review of the 2006 PA-PSRS reports of falls associated with medications indicated that there was a concomitant use of two or more medications in more than 4,000 instances. This concomitant use may have contributed to patients' falls risk (see Table 2), although most of these reports indicated that the medications prescribed for the patients did not or were not known to contribute to the patient falls. A medication review by pharmacists can assist to identify and notify prescribers of medications that require adjustment. If possible, this review is conducted during the initial falls assessment, but there should also be a stopgap measure during prescription order fulfillment in which newly ordered medications are reviewed to determine if there will

Table 1. Severity of Effects Associated with 2006 PA-PSRS Reported Falls

SEVERITY OF EFFECTS	NUMBER OF FALLS	PERCENTAGE (%)
No injury	23,806	70%
Required dressing, ice, cleaning, limb elevation, or topical medication	6,349	19%
Resulted in suturing, steri-strips, fracture or splinting	923	3%
Resulted in surgery, casting, or traction	349	1%
Patient died as a result of fall	17	<1%
Not specified	2,438	7%
Total	33,882	100%

Table 2. Concomitant Use of Two or More Medications Associated with Patient Falls

NUMBER OF MEDICATIONS LISTED	2006 PA-PSRS FALLS REPORTS	
2	2,173	(54%)
3	1,135	(28%)
4	492	(12%)
5	158	(4%)
6	41	(1%)
7	7	(<1%)
8	2	(<1%)
9	1	(<1%)
Total	4,009	(100%)

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be an increase in falls risk. Including a pharmacist is important because many falls are the result of dosage issues, drug-drug interactions, or other problems related to medications. Further, the pharmacist is an integral part of the healthcare team for patient safety. Certain drugs may have exacerbating effects that contribute to patient falls. The dosage adjustment and discontinuation of these medications can lower the potential for a patient fall.[3]

Medications Contributing to Falls Risk

Commonly prescribed medications, including antidepressants, anxiolytics/hypnotics, and insulin and oral hypoglycemics, increase the risk of falling by causing changes in cognitive and physical function, dizziness or lightheadedness, balance difficulties, confusion, and sedation.[2] Ongoing pharmacy review of patients' medications can identify potential interactions and side effects that may increase falls risk, and when possible, identify opportunities to reduce the dose of medications, discontinue medications, or select alternatives. Reducing the number and types of medications, particularly antidepressants and anxiolytics/hypnotics, can be an effective falls prevention strategy when used alone or as part of a multicomponent intervention.[2] In 2006, the medication classes associated with falls that were most frequently reported to PA-PSRS included anxiolytics/hypnotics, antidepressants, neuroleptics, opioid analgesics/antagonists, and insulin/oral hypoglycemics (see "Medication Classes Most Commonly Reported with Falls in PA-PSRS").

Routine medication assessment and reassessment as part of identifying a patient's falls risk is important when interventions are implemented to prevent patient falls, yet according to Perell et al., not all available falls assessment tools consider these measures necessary to evaluate fall risk.[4]

Of the 33,882 falls reports submitted to PA-PSRS in 2006, falls assessments identified 55% of the patients at high risk for falls, while 22% of the patients who fell had not received falls risk assessments at all. (See Table 3.)

PA-PSRS Example

The following PA-PSRS report outlines the need for routine medication assessment and reassessment in falls prevention.

> *A 66-year-old patient was found on the bathroom floor. He sustained a subdural hematoma that required surgical intervention. He had been prescribed cardiac/antihypertensive medication prior to the fall but had not been considered high risk for falls.*

Medications may be prescribed, dispensed, and administered without proper consideration of patient selection criteria, contraindications, and drug-drug interactions for patients who are identified at high risk for falls. The inclusion of pharmacy staff can provide ongoing medication assessment and reassessment

Medication Classes Most Commonly Reported with Falls in PA-PSRS

The following medication classes associated with falls were most frequently reported to PA-PSRS in 2006.

Anxiolytics/hypnotics. Benzodiazepines are the most commonly reported anxiolytic drugs. Common side effects include orthostatic hypotension, vertigo, and lethargy. Due to the onset of action of these drugs (within 30 minutes to 1 hour, with a peak action of 1 to 2 hours), unsteady gait is a significant concern, particularly with concomitant use of other medications and other disease processes.[1]

Antidepressants. While these medications elevate mood and improve mental alertness, one significant adverse effect is orthostatic hypotension, which increases the risk for falls and is a potentially serious problem, particularly in the elderly.[1]

Neuroleptics. These medications work to block dopamine and serotonin receptors and many of the newer agents are also adrenergic, cholinergic, and histamine receptor blockers. The actions of these medications cause side effects that include orthostatic hypotension, vertigo, confusion, and extrapyramidal effects.[1]

Opioid analgesics/antagonists. Adverse effects include respiratory depression and sedation. These effects, combined with population-specific conditions, difficulty with ambulation, and concomitant use of other medication, may increase the risk for falls.[1]

Insulin/oral hypoglycemics. Due to the various types of exogenous insulin and oral hypoglycemic agents, the duration of action varies from patient to patient. For exogenous insulin, the injection site and tissue condition can alter the absorption rate and peak action times. Too little or too much insulin can cause hyper- or hypoglycemic reactions, which can result in orthostatic hypotension, vertigo, and change in mental status.[1]

Note

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Table 3. Falls Risk Assessments Identified High-Risk Patients

2006 PA-PSRS REPORTS INDICATE HIGH FALLS RISK ASSESSMENT		
Yes	18,660	(55%)
No	7,484	(22%)
Information not specified or unknown	7,738	(23%)
Total	33,882	(100%)

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during the development of the falls prevention program and medication reconciliation, as well as when filling a prescription order.

Risk Reduction Strategies

Healthcare facilities may consider the following information when developing medication assessment and reassessment strategies to reduce falls risk.

Routine Assessment, Reassessment, and Reconciliation of Routine Medications

When medications are routinely assessed and reassessed in patients with falls risk, their use will be minimized whenever possible. Healthcare facilities may consider involving pharmacy staff during the development or revision of interdisciplinary falls prevention programs to address medication assessment and reassessment strategies. Pharmacist involvement assists prescribers in determining whether a lower dose of a medication or an alternate drug has less falls risk potential, considering laboratory test results (i.e., renal and hepatic function) and side effects. Further, pharmacists can assist prescribers with medication selection for patients known to be at high risk for falls. Pharmacists also review medications for increased falls risk when prescriptions orders are being filled. If providers are not knowledgeable about the contraindications for patients at high risk for falls, then the pharmacy staff may provide information to prescribers about which medications have fewer side effects.

Routine Assessment and Reassessment with Medications that Increase Fall Risk

Consider providing falls risk assessments for those patients taking certain medications that increase falls risk or harm. Involving pharmacy staff also supports prescribers and nurses in the medication reconciliation process, including assessment of medications, over-the-counter drugs, and herbal supplements. Whenever feasible, organizations could consider the use of a 24-hour pharmacy service so prescribers and nurses have access to ongoing pharmacy consultation and medication reconciliation services.[5] Hospitals may consider creating a list of high-risk medications currently in the hospital formulary and make it available to nurses, physicians, and pharmacists. These medications should be noted as high risk within computerized order entry systems.

Interdisciplinary Interventions

Reviewing all falls prevention strategies, including medications, is necessary before and after the patient falls so that realistic and appropriate changes can be made to help minimize the risk of falls. Without ongoing physician, nursing, and pharmacy involvement in the falls prevention and medication assessment and reassessment processes, failure to identify and implement necessary modifications will result in more falls because of medications. Falls prevention strategies should have a medication component associated with pharmacy review as part of a falls prevention program.[6]

Notes

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Timely Treatment of Stroke Symptoms in the Emergency Department May Improve Outcomes

ABSTRACT

PA-PSRS has received reports involving the use of thrombolytic therapy for the treatment of a suspected stroke in the emergency department. Delays in treatment occurred because staff were unaware of stroke protocols, the protocols or printed orders were missing, medication was administered in the absence of the written protocol; communication handoffs were lacking among caregivers; or staff were not knowledgeable about the limited time to treat with thrombolytic therapy. Given the narrow therapeutic windows for treatment of acute ischemic stroke, timely evaluation and diagnosis is critical to avoid significant harm and even death. This article will review the challenges in confirming the diagnosis of stroke quickly and discuss risk reduction strategies that include establishing stroke teams; using stroke scales during initial physical examination, when indicated; administering recombinant tissue plasminogen activator in a timely manner; obtaining certification as a primary or comprehensive stroke center; and educating providers and patients. (Pa Patient Saf Advis 2008 Mar;5[1]:19-23.)

There were 29 reports involving the use of thrombolytic therapy for the treatment of a suspected stroke in the emergency department (ED) reported to PA-PSRS from January 2006 through December 2007. Eleven of the reports involved the absence of, delay in implementation of, or deviation from facility stroke protocols, which impacted the administration of thrombolytics within time frames set forth by the American Heart Association.[1] The following are some deidentified examples:

> *Patient was admitted to ED with possible* CVA [cerebrovascular accident] *diagnosis. Stroke protocol was stated, but there was a delay in neurologist response. Neurologist said that he ordered* [tissue plasminogen activator (tPA)], *but there was no tPA order in chart nor a consent form signed for tPA. No tPA was given.*
>
> *Patient was ordered tPA just as the three-hour window expired. Drug was administered 3 hours and 15 minutes after onset of symptoms.*
>
> *Received report from the ED stating that patient arrived to ED at approximately 5:30 a.m. with diagnosis of possible stroke. The NIH Stroke Protocol was not initiated during the patient's stay in the ED. Per the protocol, the flowsheet needs to be started in the ED and two hours post initiation of the protocol.*
>
> *Patient* [presented] *to ED with stroke-like symptoms. Patient was a John Doe. Stroke orders entered, but due to not having a unit number, the order did not go through. Original order placed at 10 p.m. and then reordered again* [15 minutes later].
>
> *Called for head* [computed tomography (CT) scan] *but did not identify as stroke case; second call identified case as stroke case.*
>
> *For stroke protocol patient, blood work not sent until patient returned from CT.*
>
> [The patient] *presented to ED at 2:50 p.m. with right-sided vision loss that began at 2 p.m. The patient was triaged at 3:25 p.m. and sent back to the waiting room. . . . The ED primary nurse took patient to an exam room at 4:40 p.m. The patient was seen by the ED physician at 5 p.m. The ED physician identified the patient as an acute stroke and initiated the Neuro Alert protocol. A CT demonstrated a left parietal occipital infarct. The delay in triage resulted in a delay in care outside the three-hour window or tPA infusion for embolic stroke. . .*

ED delays in the treatment of a possible stroke occurred because staff were not aware of the stroke protocol; the protocols or printed orders were missing; medication was administered in the absence of the written protocol; communication handoffs were lacking among caregivers; or there was a lack of knowledge about the time sensitivity associated with administration of thrombolytic therapy.

Solutions to these delays include using tools to identify strokes immediately upon triage, establishing a stroke team to facilitate mobilization of appropriate specialists, and educating providers about the importance of delivering appropriate care as rapidly as possible.

Stroke is the third leading cause of death in American men and women.[2] Each year, approximately 700,000 people have a new or recurrent stroke. A stroke happens when the blood flow to the brain is disrupted because of either a blood clot (i.e., an ischemic stroke) or a ruptured blood vessel (i.e., a hemorrhagic stroke). The emergency care for patients experiencing stroke changed in 1995 when investigators demonstrated that the use of thrombolytic therapy within three hours after the onset of ischemic stroke symptoms significantly reduced mortality and disability.[3] In other words, the longer the delay between the onset of stroke symptoms and treatment, the lower the chance of restoring blood flow and the higher the risk for hemorrhagic complications. Therefore, thrombolytic therapy is indicated for stroke patients only if it is administered within three hours after the onset of symptoms.[1] (Refer to "Table. Stroke Chain of Survival.")

Challenges in Confirming Diagnosis

Given the narrow therapeutic window for treatment of acute ischemic stroke, timely evaluation and diagnosis is critical.[4] A patient with acute stroke must

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Table. Stroke Chain of Survival

DETECTION	Recognition of stroke signs and symptoms
DISPATCH	Call 9-1-1 and priority emergency medical services dispatch
DELIVERY	Prompt transport and prehospital notification to hospital
DOOR	Immediate emergency department (ED) triage
DATA	ED evaluation, prompt laboratory studies, and computed tomography imaging
DECISION	Diagnosis and decision about appropriate therapy
DRUG	Administration of appropriate drugs or other interventions

Source: The American Heart Association. The links in the chain of survival [online]. [cited 2008 Feb 20]. Available from Internet: http://www.americanheart.org/presenter.jhtml?identifier=3012016.

meet several specific criteria to be eligible to receive thrombolytic treatment. The eligibility evaluation includes

1. neurologic examination and confirmation of time of symptom onset;
2. brain imaging with CT or magnetic resonance imaging (MRI) scans to detect hemorrhage or other intracranial abnormality that would preclude treatment;
3. physical assessment including vital signs, particularly blood pressure trends, and respirations; and
4. laboratory evaluations of blood chemistry and coagulability.[5]

EDs must create efficient pathways and processes to rapidly move through these four steps. Steps 1, 2, and 3 should be performed concurrently.[6]

Before any decision can be made as to whether thrombolytic therapy is appropriate treatment for the patient's presenting symptoms, quick and careful assessment must be done to answer the following two basic questions:

1. What type of stroke is the patient having—ischemic or hemorrhagic?
2. How long has it been since the onset of symptoms?

What Type of Stroke is It?

Approximately 80% of all strokes are of the ischemic type, caused by the blockage of a large or small blood vessel to the brain. The remaining 20% of strokes are hemorrhagic, caused by the rupture of a blood vessel in the brain.[2,4] Upon their arrival, patients must be carefully and quickly evaluated before the initiation of treatment. This diagnostic process includes a CT scan. A CT scan of the brain is essential to definitively establish that the mechanism of the stroke is ischemic. Thrombolytics are contraindicated in hemorrhagic stroke. The noncontrast brain CT must be completed to rule out hemorrhage as the primary cause of a patient's presenting illness. This study accurately identifies intracranial hemorrhage approximately 90% of the time.[4] Within the first 24 hours after stroke onset, ischemia is not generally visible on CT scan; therefore, this study simply rules out intracerebral hemorrhage and does not confirm clinical suspicion for cerebral ischemia.[4] The ideal time goals for all hospitals that treat patients with acute stroke include 25 minutes from arrival to CT scan and 60 minutes from arrival to treatment.[7] Ideally, patients would have to arrive in the ED less than 2 hours after symptom onset to be assessed and treated with thrombolytic therapy.

How Long has it Been Since the Onset of Symptoms?

The time from the onset of stroke symptoms to the patients' arrival in the ED is often referred to as patient delay and can vary widely across studies; however, most researchers report median delays from three to six hours.[8] Notably, an estimated 19% to 60% of stroke patients present within 3 hours of stroke, and 14% to 32% of those arrive within 2 hours of symptom onset.[4] If the patient arrives to the ED in sufficient time, systems must be in place to move them quickly through to diagnosis and treatment. In one study, Kothari et al. evaluated the ability of an ED to comply with consensus panel recommendations.[5,9] They determined that workup and treatment of acute stroke was faster if the patient activated the 9-1-1 system. But even for patients using 9-1-1, only 37% saw a physician within 10 minutes after arrival to the ED, and only 17% proceeded to CT scan within the 25-minute recommended time window.[9]

Risk Reduction Strategies

Establishment of Stroke Teams

Despite successes in delivering effective new therapies, significant obstacles remain in ensuring that scientific advances are consistently translated into clinical practice. In many instances, these obstacles can be related to a fragmentation of stroke-related care caused by inadequate integration of the various facilities, agencies, and professionals that should closely collaborate in providing stroke care.[10] One critical element of the multidisciplinary stroke system is the hospital-based acute stroke team. This is the component of the stroke system that is prepared to handle the hyperacute phase of diagnosis and treatment of acute stroke events. The availability of providers capable of diagnosing and treating all aspects of acute stroke remains critical. The composition and responsibilities of the team will vary as appropriate for specific facilities.[10] The use of acute stroke teams improves stroke care and increases the appropriate use of stroke therapies through established protocols. Acute stroke teams facilitate the rapid evaluation and treatment of acute stroke patients that result in improved patient outcomes. The lack of acute stroke teams is associated with less frequent use of known effective stroke therapies and may compromise stroke care.[11] Acute

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stroke teams help to coordinate stroke care from the moment the patient arrives at the ED or after notification from prehospital personnel. Rapid identification of acute stroke patients enables the early administration of effective and appropriate stroke therapies. Providers who triage potential stroke patients can be trained to identify acute stroke symptoms. Providers might be physicians, nurses, or physician assistants, if appropriate training and treatment protocols have been implemented.[10]

Use of Stroke Scales during Initial Physical Examination

There are several acute stroke assessment scales that are currently in use in many EDs.[12] Prehospital stroke assessment scales, those used by emergency response teams in the field, most commonly include either the Cincinnati Stroke Scale or the Los Angeles Prehospital Stroke Screen. The National Institutes of Health Stroke Scale (available online at http://www.ninds.nih.gov/doctors/NIH_Stroke_Scale.pdf) is the most commonly used scale for rapidly evaluating and quantifying stroke severity. This scale assigns numeric scores to each portion of the neurologic examination. Scores can range from 0, representing a normal neurological examination, to 42, which indicates profound disability. The goal of the neurologic examination is to confirm the clinical suspicion of stroke and localize the ischemic territory involved. Treatments are then targeted toward the clinical findings.[4]

Timely Infusion of rt-PA, if Indicated

Once all risks and benefits have been assessed and recombinant tissue plasminogen activator (rt-PA) is recommended, the dose for intravenous (IV) rt-PA is calculated based on weight (0.9 mg/kg with a maximum dose of 90 mg). The first 10% of the total dose is given as a bolus over one minute followed immediately by the remainder of the dose, administered via IV infusion for one hour. Proton pump inhibitors or H_2 blockers should be administered simultaneously with the thrombolytic agent for gastrointestinal protection. Blood pressure and neurologic examination should be closely monitored during the infusion.[5]

The American Academy of Neurology and the Stroke Council of the American Heart Association recommend that patients treated with rt-PA for stroke receive neurological assessments and blood pressure monitoring for the first 24 hours in the following intervals: every 15 minutes for 2 hours, every 30 minutes for 6 hours, and every 60 minutes after starting treatment.[1,13] Pathophysiological considerations and observational studies indicate that hypotension and cardiac arrhythmias in the acute phase of ischemic stroke may aggravate brain damage and worsen outcomes.[14] Any change in neurologic status prompts discontinuation of the medication, followed immediately by CT scan to rule out treatment-related hemorrhage.

Certification as a Primary or Comprehensive Stroke Center

Recognition as a primary or comprehensive stroke center indicates that the facility makes exceptional efforts to foster better outcomes for stroke care. Achieving certification signifies that the services provided to patients have the critical elements to achieve long-term success in improving outcomes and demonstrates compliance with national standards and performance measurement expectations in stroke care. The Joint Commission's Primary Stroke Center Certification program[15] was developed in collaboration with the American Stroke Association. The consensus statements conclude that there are a number of key elements supported by evidence-based medicine that are important for a primary stroke center and its ability to deliver the wide variety of specialized care needed by patients with serious cerebrovascular disease. These elements include: (1) healthcare personnel with specific expertise in a number of disciplines, including neurosurgery and vascular neurology; (2) advanced neuroimaging capabilities such as MRI and various types of cerebral angiography; (3) neurosurgical techniques, including clipping and coiling of intracranial aneurysms, carotid endarterectomy, and intra-arterial thrombolytic therapy; and (4) other specific infrastructure and programmatic elements such as an intensive care unit and a stroke registry. Integration of these elements into a coordinated hospital-based program or system is likely to improve outcomes of patients with strokes and complex cerebrovascular disease who require the services of a comprehensive stroke center.[16]

Improve Education about Acute Stroke

Education about stroke can be managed on two levels. Patient education is vital for quick identification of symptoms that prompt patients to go to the ED, and provider education is critical for rapid identification and treatment of the stroke once the patient arrives.

Despite numerous efforts to increase awareness, overall knowledge among the public remains poor with regard to stroke risk factors, the signs and symptoms of stroke, and the availability of a time-sensitive therapy, especially among groups at the highest risk for stroke.[17] Improving the public's knowledge of the risk factors, signs, and symptoms of stroke is critical to improving the quality of stroke care. Without organized, coordinated, and comprehensive approaches to educate the public, the full potential of proven therapies for prevention or acute intervention will not be realized. Increased awareness of the risk factors and common warning signs of stroke may increase the appropriate use of emergency response numbers such as 9-1-1, resulting in timely presentation to the ED.[18]

Ensuring that all members of the ED staff are familiar with the standards and guidelines for treating a patient that presents with stroke symptoms is a lofty objective for many facilities, especially in light of staffing shortages and overcrowded EDs. Many institutions have

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undertaken provider education by using the American Heart Association/American Stroke Association's "Get with the Guidelines" (GWTG) program aimed at educating staff about the treatment options for acute stroke. Using the GWTG program empowers healthcare provider teams to consistently treat stroke patients according to the most up-to-date guidelines. The implementation steps within the GWTG program include many risk reduction strategies discussed here, including developing a primary stroke center, identifying a champion(s) and building a team, assessing facility treatment rates, and evaluating baseline data to identify areas for improvement.[19]

Conclusion

Analysis of PA-PSRS reports found that delays in the treatment of a possible stroke occurred due to a lack of awareness of protocols in place to manage acute stroke symptoms quickly and efficiently in the ED. Given the narrow therapeutic windows for treatment of acute ischemic stroke, timely evaluation and diagnosis of ischemic stroke is critical. The answers to two basic questions are required before deciding on treatment: (1) what type of stroke is the patient having, and (2) how long has it been since the onset of symptoms?

The reversal or reduction of stroke disability depends on timely triage, assessment, and treatment beginning before the patient arrives, continuing in the ED, and during the acute care phase of treatment. Rarely will patients be admitted to an ED with sufficient time remaining in the treatment window. And even if time is not an immediate factor, any added delay of treatment could increase the likelihood of disability. To meet the need for timely care, stroke team members can begin their assessment immediately, even while the patient is en route to the ED if possible.

Risk reduction strategies for improving acute stroke care in the ED and patient outcomes include using a stroke assessment scale during initial physical examination; establishing stroke teams; administering rt-PA in a timely manner; achieving accreditation as a primary or comprehensive stroke center; and educating patients and providers about the symptoms of acute stroke.

Providing rapid acute stroke care to the patient with an acute ischemic stroke can be a challenge to many healthcare systems. Provision of the latest, cutting edge management strategies requires a multidisciplinary and cohesive approach. Knowledge of available therapies and management techniques allows care to be individualized for each patient. Rapid response to this devastating emergency can make the critical difference between independence and disability for the patient.[4]

Notes

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. A computed tomography scan is the most common diagnostic test used to rule out the presence of a hemorrhagic stroke.
   a. True
   b. False
2. Before a decision can be made as to whether thrombolytic therapy is appropriate treatment, there are two questions that need to be answered. The first question that needs to be answered is what type of stroke the patient is having. The other question that needs to be answered is
   a. how long has it been since the onset of symptoms.
   b. when did the patient last eat.
   c. does the patient have a family member with them.
   d. is the patient aphasic.
3. Recombinant tissue plasminogen activator (rtPA) should be administered within how many hours of the onset of symptoms?
   a. Within 6 hours
   b. Within 4 hours
   c. Within 3 hours
   d. Within 12 hours
4. The four risk reduction strategies that can be employed in the emergency department to manage acute stroke include all EXCEPT which of the following?
   a. Obtaining certification as a primary stroke center
   b. Establishing stroke teams
   c. Using a standardized stroke scale during initial physical examination
   d. Having access to a rehabilitation center specializing in strokes for patient discharge
   e. Improving education among providers and patients about acute stroke

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Preventing the Retention of Foreign Objects during Interventional Radiology Procedures

ABSTRACT

PA-PSRS has received several reports describing injuries to patients from retained foreign objects related to interventional radiology (IR) procedures performed outside of the operating room (OR) setting. IR utilizes imaging guidance to perform diagnostic and therapeutic procedures in a minimally invasive manner. However, despite the smaller incision size typical during minimally invasive procedures, the risk for the retention of foreign objects remains. This article focuses on the use of sponge, sharp, and instrument counts—a process routinely used in the OR setting—during invasive IR procedures. Risk reduction strategies are presented, including practices and technologic solutions, which are applicable to the prevention of the retention of foreign objects in IR practice. (Pa Patient Saf Advis 2008 Mar;5[1]:24-7.)

PA-PSRS previously published a report from the Patient Safety Officer of a facility who wished to share the lessons learned in the facility's main operating room (OR) suite (see the June 2006 *Patient Safety Advisory*). During a procedure in the OR, the interventional radiology (IR) team entered the OR to perform their part of the procedure. An OR nurse noted that the IR team had added a VERSALON™ (nonradiopaque) sponge to the surgical field. A count was performed, and a sponge was missing and could not be accounted for because it was nonradiopaque. One of the lessons shared with PA-PSRS was that the radiology team now uses only radiopaque sponges for IR procedures.[1]

Since that article appeared, PA-PSRS has received several reports describing injuries to patients from retained foreign objects related to IR procedures performed outside of the OR setting. These reports indicate that it is important to use radiopaque sponges during any IR procedure in order to prevent the retention of foreign objects following IR procedures. Despite the minimally invasive nature of IR procedures, foreign objects may still be retained. This article focuses on the use of sponge, sharp, and instrument counts—a process routinely used in the OR setting—during invasive IR procedures. Discussion centers on the nature of IR procedures, risk factors associated with the retention of foreign objects applicable to the IR setting, and risk reduction strategies.

Evolving Scope and Complexity of Interventional Radiology

IR utilizes imaging guidance—primarily fluoroscopy, computed tomography, and ultrasound—to perform diagnostic and therapeutic procedures in a minimally invasive manner.[2] IR is a rapidly expanding area of medicine that has evolved to accommodate increasingly complex equipment and procedures.[3] IR has evolved from a predominantly diagnostic specialty into a specialty where therapeutic procedures are also performed.[4] The growth in the field has been made possible by technological advances in catheters, instrument and imaging system design and manufacture, and radiological expertise, all leading to a significant increase in minimally invasive techniques.[5] Examples of current interventional procedures include arterial stent grafts, percutaneous tumor ablation, embolization of fibroids, tumor chemoembolization, insertion of central venous catheters, and percutaneous biopsy and drainage procedures.[5]

The progressive move towards "minimally invasive" IR techniques has been associated with less physiological disruption, smaller "entry points," reduced intra- and postoperative complications, and earlier discharge.[6] However, the potential for patient safety risks during IR practice remains, despite the smaller incision size typical during minimally invasive procedures. A case study described by the Association of periOperative Nurses (AORN) illustrates one of these risks: the retention of a foreign object.[7] An open surgical technique was used to place a small radiopaque gauze sponge into the incision site to control bleeding during an endoscopic saphenous vein harvesting. The sponge was retained after the leg incision was closed. AORN notes that "despite the minimally invasive technique and small incision size, multiple occurrences have been associated with this practice."[7] AORN's case study analysis further notes that the hazards related to minimally invasive procedures can be overlooked. "Perioperative clinicians should remain aware of the placement of surgical sponges when incisions are large enough to engulf a sponge."[7]

Reports to PA-PSRS

Several reports submitted to PA-PSRS describe the retention of foreign objects related to IR procedures.

> *A patient had a venous port placed in interventional radiology. The chest port was removed approximately two weeks later, and a 4x4 gauze was removed from the port pocket.*

> *A patient was admitted following a port placement two weeks prior. The patient underwent port removal for suspected infection, and a piece of gauze was discovered in the port pocket.*

> *A patient underwent right lower extremity angiography by a vascular surgeon in the cardiac catheterization lab. A subsequent chest x-ray revealed that a guide wire had been retained in the patient's aorta.*

In one case, the facility's investigation revealed that an instrument count was not performed. The third case illustrates that IR procedures may be performed in a

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setting other than a dedicated IR suite, underscoring the need for uniform policies and procedures to prevent the retention of foreign objects no matter where the IR procedure occurs. While retained foreign objects during IR procedures are reported to PA-PSRS less frequently than in surgical procedures, they represent the potential for significant patient harm. Patient complications associated with retained foreign objects may include sepsis, infection, return to the OR, increased length of hospital stay, readmission, fistula formation, bowel obstruction, visceral perforation, and death.[8] As indicated by the PA-PSRS reports, despite minimally invasive technique and small incision size, foreign objects may still be retained during IR procedures and present risk. Accordingly, there is a need for adequate IR policies and procedures for the prevention of retained foreign objects. In the cases above, the retained sponges may have been prevented by the completion of a sharp, sponge, and instrument count. This procedure is routinely performed in the OR, but it is not yet widely used during invasive IR procedures outside of the OR setting.

Professional Societies

A search of the literature found no studies that addressed the risk of retained foreign objects in IR practice. It is unknown at this time whether this is due to the rapidly evolving nature of IR practice, the underreporting of these events. However, there is recognition among professional societies of patient safety risks inherent in IR practice, even though there are not as of yet any guidelines regarding perioperative counts in the IR setting. The American College of Radiology's (ACR) task force on patient safety has identified a list of preventable errors, most of which the task force notes as relevant to IR; however, the retention of foreign objects is not specifically listed.[9] The Society of Interventional Radiology (SIR) has recently formed a safety and health committee and publishes the *IR Safety Rounds* series to publicize lessons learned that are relevant to IR practice.[10] Both ACR and SIR publish procedure-specific guidelines relevant to the practice of IR; as of yet, none address the potential for retention of foreign objects during IR procedures.[9,10]

The American College of Surgeons (ACS) offers guidelines for the prevention of retained foreign objects after surgery, which it notes can be adapted to areas other than the traditional OR, including "other areas where operative and invasive procedures are performed."[9] Similarly, AORN recommends best practices for the prevention of retained foreign objects, which include that "sponges should be counted on all procedures in which the possibility exists that a sponge could be retained."[7] ACS and AORN suggest that sponge, sharp, and instrument counts should be utilized during any invasive IR procedure, due to the invasive nature of the procedure and the possibility that a sponge, sharp, or instrument may be retained.[7,9]

Risk Factors for Retained Foreign Objects Related to IR

Risk factors unique to IR have been identified in the context of the implementation of Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™.[3] These factors may be useful to consider in the effort to prevent the retention of foreign objects during IR procedures. Interventional imaging procedure rooms, where both diagnostic and therapeutic procedures have historically been performed, are now being used for minimally invasive surgery and image-guided procedures. These rooms may not provide the structured surgical environment required to control the flow of materials, supplies, and personnel needed for these invasive procedures.[3,11] If IR procedures are performed within the OR, traditionally designed OR suites may not be able to accommodate the wide variety of imaging equipment and number of specialists required. The large amount of equipment and personnel that may be involved can result in a crowded, potentially noisy room. In addition, equipment and supplies may need to be moved among different areas, and multiple procedures may also be performed.[3] The potential variation in location, equipment, and personnel is an important consideration in crafting policies and procedures to prevent the retention of foreign objects during IR procedures.

Safe Practices/Risk Reduction Strategies

In July 2006, AORN, with the support of ACS, published the following best practices for preventing the retention of a foreign object:[7,9]

- Consistently performing surgical counts according to national standards and facility policy
- Promoting an environment that is focused on, and attentive to, the patient's perioperative care
- Using only x-ray detectable sponges, towels, miscellaneous items, and instruments in the surgical wound
- Conducting a methodical wound exploration before wound closure and whenever a count discrepancy is noted
- Employing radiographic or other technology as needed to ensure that all potential foreign objects have been removed from the surgical site
- Documenting the outcomes of the surgical count, items intentionally used for packing, and actions taken to rectify a count discrepancy
- Providing resources to support safe practices to prevent retention of foreign objects
- Developing and reviewing count policies and procedures though a collaborative process to promote consistency in practice across disciplines
- Making count policies and procedures readily available in the practice setting

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AORN's recommended practices for sponge, sharp, and instrument counts may be adapted to various practice settings, including IR.[12]

For further consideration, refer to "Additional Measures," which discusses elements from a Pennsylvania healthcare facility's surgical count policy.

Emerging Technology

A recent study evaluated the use of x-ray-detectable, numbered gauze sponges to determine ease of use and effect on the flow of a procedure. The sponges have a number sewn in the corner with suture material approved by the U.S. Food and Drug Administration. The numbered radiopaque sponges were found to be easy to use, and did not lengthen or affect the flow of the procedure.[13]

In addition, studies have evaluated the use of radio-frequency systems and bar-code technology.[13-15]

Additional Measures

To prevent the occurrence of the retention of a sponge in a pocket following interventional radiology (IR) procedures, one Pennsylvania healthcare facility developed a policy and procedure for surgical counts specific to the IR department. Elements of the policy include the following:[1]

- A count of surgical sponges, sharps, and other miscellaneous items will be done on all IR cases when the possibility exists that an item could be retained. This includes all procedures that involve a surgical pocket.
- X-ray detectable gauze will be used in all cases that involve a surgical pocket.
- Items to be counted during IR procedures involving a surgical pocket will be counted
  - prior to incision to determine baseline,
  - at the time of permanent relief of scrub or circulator, and
  - at the closure of pocket/incision closure.
- Any item added to the surgical field will be counted. Sponges will be separated to allow viewing by each participant of the sponge and the x-ray detectable strip.
- The performing operator will be notified to inspect the surgical pocket and confirm the absence of a retained foreign object with x-ray in the event of a count discrepancy.

In addition to formulating the policy and procedure, the facility conducted a mandatory training program for all staff involved with IR procedures. The facility also performs a quarterly audit of 10 cases to ensure that the policy is followed.

Note

1. Interventional Radiology Department. Policy & procedure: surgical counts. 2007 Apr. (Pennsylvania healthcare facility name withheld at facility's request.)

Bar-coding systems involve tagging surgical items and scanning each item with a handheld wand as the item enters the body, thereby identifying every item used during the procedure.[13,14] Radio-frequency systems items utilize a radio-frequency identification chip embedded in surgical items that can be detected through tissue with a handheld wand.[13,15] Incorrect use of the wand and failure to scan the entire surgical surface, thereby missing a sponge, have been identified as potential problems with these technologies.[13,15]

Conclusion

Sponge, sharp, and instrument counts are routinely used in the OR to prevent the retention of foreign objects. The consistent use of counts during invasive IR procedures could promote a similar outcome. Facilities' policies and procedures need to include the use of sponge, sharp, and instrument counts in IR to prevent the risk of serious patient harm related to the retention of foreign objects in this setting.

Notes

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. Factors that contribute to the risk of the retention of foreign objects during interventional radiology (IR) procedures include all EXCEPT which of the following?
   a. Using nonradiopaque sponges
   b. Failing to mark the operative site
   c. Performing multiple procedures during a case
   d. Failing to perform sponge, sharp, and instrument counts
2. During an IR procedure, a sponge, sharp, and instrument count should be performed at which of the following times?
   I. Prior to incision to determine baseline
   II. At the time of permanent relief of scrub or circulating nurse
   III. At the closure of pocket/incision closure
   IV. Whenever a count discrepancy is noted

   a. I,III
   b. I,III,IV
   c. I,II,III
   d. I,II,III,IV
3. A sponge, sharp, and instrument count should be performed during an IR procedure ONLY if the procedure involves a surgical pocket.
   a. True
   b. False
4. Risk reduction strategies for the prevention of the retention of foreign objects during IR procedures include all EXCEPT which of the following?
   a. X-ray detectable gauze will be used in all cases that involve a surgical pocket.
   b. Any item added to the surgical field will be counted.
   c. Documentation of the outcome of the surgical count will occur only if there is a count discrepancy.
   d. A count of sponges, sharps, and other miscellaneous items will be done on all IR cases when the possibility exists that an item could be retained.
   e. The performing operator will be notified to inspect the surgical pocket and confirm the absence of a retained foreign object with x-ray in the event of a discrepancy.

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Pneumatic Tubes: A Possible Patient Safety Vacuum?

ABSTRACT

With more than 600 reports submitted to PA-PSRS, the subject of pneumatic tubes used as material transport in hospitals has proven to be a patient safety concern. While mechanical breakdowns of the pneumatic tube systems are responsible for some transport issues, staff misuse and breaks in communication are factors in material transport as well. Many reports relate to specimen delivery, where samples were damaged, lost or delayed in transit. Additionally, cases mention having to redraw or recollect the specimen. Guidelines for proper use of pneumatic tube systems are available from several sources. Further considerations for improvement include setting up process control strategies, posting lists of authorized materials and schedules for labs, and checking the stations for tubes. (Pa Patient Saf Advis 2008 Mar;5[1]:28-30.)

While a great deal of patient information is becoming computerized, the need to rapidly collect and transport physical materials for examination and diagnosis still exists. Examples of these materials include specimens obtained for laboratory testing.[1] An efficient, rapid, and secure means of transporting various items such as blood and tissue samples, drugs, radiographs, and documents throughout the facility can be life saving.[2] Pneumatic tube systems (PTS) allow fast and reliable transport of medical material.[3] There are numerous advantages in using a PTS, perhaps the most important among them being improved turnaround time for transported items.[4] Others include the reduced risk of contamination, loss, or error by eliminating some human factors,[4] assuming that the specimens are prepared accordingly and transported in the correct containers.

However, as can happen with even a well-maintained electromechanical system, the human element may be the most important cause of system failure.[5] The following report submitted to PA-PSRS is an example of what can happen when staff fail to follow established PTS procedures:

> *Stool sample for C. diff sent to lab via tube system. Stool specimens must be hand delivered in lab due to possible exposure of contamination to tube system and lab personnel. In addition, container is screw-top and not vacuum closed. Only vacuum-closed containers (like blood tubes) can be sent via the pneumatic tube system . . .*

To date, more than 600 PTS reports have been submitted to PA-PSRS. Approximately 80% of PTS reports involve transport of specimens; the rest mainly comprise delivery of medications from pharmacy, with approximately 1% related to the transmission of paperwork (e.g., orders, charts). None were reported as Serious Events in of themselves. A little more than 5% of the reports fault a mechanical breakdown of the PTS as the cause of these Incidents.

Specimens Lost or Delayed

Three out of four reports submitted to PA-PSRS addressed specimen transfers through PTSs in which the samples were lost or delayed in transit. Approximately one-third of these specimens required a redraw or recollection of the sample. Not all the specimen transport errors were explained, but some reports submitted to PA-PSRS offered information concerning root causes for the loss or delay of these samples:

- Specimens were discovered to have never been sent or left unretrieved at the destination.

  Specimens found in the tube system the following morning. Blood for IgM, IgA, and gastrin level unable to be run.

- Specimens were not sent in a timely fashion; that is, the specimens were either sent too late to be processed in the laboratory or delayed long enough as to be considered compromised.

  Last carrier of day at 5 p.m. on Thursday (outpatient phlebotomy draw lab–first floor) did not get sent through pneumatic tube system until 7 a.m. on Friday. Some specimens too old for testing; patient [specimens] *will have to be recollected.*

- Specimens were routed to the wrong department, either due to system malfunction or human error.

  At 3 p.m., HIV, hepatitis A, B, C, macrophage inflammatory protein specimens collected and sent to lab; results not in computer at 6:15 p.m. According to the computer, labs were ordered but not in process yet. Telephoned lab and was told they never received said specimens. Asked lab to please check carefully, and if not found, to send new labels. Lab tech stated that perhaps the specimens were "lost" in the tube system. Needed to restick patient and resend blood to lab.

- Communication was inconsistent between departments, such as between nursing and the laboratory staff, or even intra-departmentally.

  Patient in postop at 8:30 p.m. Unasyn due at 10 p.m. I called the pharmacy at 11 p.m. and asked if they had the Unasyn ready yet. (Medication not in patient's cassette or on the counter despite a runner.) Pharmacy tech said she sent the Unasyn up a while ago in the lab tubes. I let pharmacy know that when they send us meds via the lab tube, they need to call because the tube system does not beep, and we have no idea that there are meds out there in an area where staff is seldom present.

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- Specimens were sent to laboratory unlabeled or mislabeled.

  A bag of tubes arrived via the pneumatic system. None of the tubes had a patient label affixed, although there were patient labels in the bag. Recollect needed.

Inappropriate Use Leads to Breakage, Loss, and Possible Contamination

About one-fifth of reports submitted on specimens transported through the PTS mention either a breakage and/or a leakage of specimens. Inappropriate use of the PTS includes transporting specimens outside of the facility's approved material list or using an improper transport method or carrier. Breakage and leaks not only compromise the integrity of the sample, which could delay treatment, but may cause a biohazard risk that could endanger staff and require a shutdown and decontamination of the PTS. Hospitals vary on the types of material considered suitable for transport, so facilities may consider posting reminders at PTS stations. Here are three examples of such reports submitted to PA-PSRS:

Red top for cryoglobulin sent through tube system. Notified unit clerk to recollect and walk down in warm bath or hot towel.

Stool sample sent to lab via pneumatic tube system. Lid for sample was not securely fastened and biohazard bag was not closed. Sample leaked into tube. Sample was C. difficile and could have posed serious health risks to laboratory staff. Lab: specimen container cleaned and lid securely fastened. Tube was decontaminated. Specimen taken to microbiology to be processed. Lab protocol states that all stool specimens must be hand-delivered to laboratory and specimen lids must be securely fastened. Infection control issue. Emergency room to investigate and finalize. Emergency room: discussion with the involved staff regarding proper utilization of tube system. Specimen was recollected and sent.

Specimen sent down in the paper tube instead of the blood tube system. Specimens should never be sent down via the paper tube.

Another inappropriate use of the PTS relates to sending certain medications. To reiterate, policies differ from facility to facility, but many hospitals bar controlled drugs and unstable medications from transport through the PTS,[5,6] as evident in the following reports to PA-PSRS.

Prescription returned to pharmacy via pneumatic tube–should not have been sent this way. Called nurse to reinforce this policy and asked her to write "vaccines" on their "do-not-tube" list.

Controlled medication sent by tube system.

Fentanyl drip, a Schedule II narcotic, was sent back from intensive care unit to pharmacy via tube system instead of being hand delivered.

Communication Issues

One of the inherent problems in using a PTS is a lack of communication between departments[7] due to the lack of human interaction. These breaks in communication, such as those listed below, often cause delays that may mitigate the advantages of tube systems.

Ancef ordered from pharmacy; delay in dispensing. Medication found removed from tube system. Nurse was not notified that the medication was in the unit, resulting in a delayed administration.

Blood specimens received in the main lab from the emergency department. Lab returned the specimen through the pneumatic tube, where it sat for almost three hours. Computer tech did not relay the information that the emergency department lab was closed.

Rapid strep test obtained by doctor and sent via tube system at 8:20 p.m. By 8:55 p.m.–no results. Called lab, they still had not found it. Called central receiving, who stated that they do not log in when specimens are received. Lab called emergency room at 9:30 p.m. and stated that they just received specimen. Doctor aware.

Order for Zosyn faxed to pharmacy at approximately 5:20 a.m. Called pharmacy at 6:30 a.m. after rechecking tube system. Pharmacy stated patient "not in computer and assumed it was taken care of." Confirmed with admissions that patient in computer and manually admitted in Accudose.

A unit of packed red blood cells was sent to the unit at 9 a.m. and called to nurse at 10 a.m. Nurse called looking for blood and found it in pneumatic tube station. Unit returned to blood bank and discarded.

Strategies for Safer Tube Use

A PTS can promote rapid sample and medication delivery to remote parts of the hospital. Education of all users is essential to ensure that the tube system does not suffer downtime due to carelessness or lack of understanding.[5] Hospital-wide and individual department policies and procedures may help to set expectations, but consider whether visual reminders at the tubing stations or forcing functions could promote better adherence to procedures.[5] One comprehensive set of guidelines developed by the Massachusetts General Hospital with their rules for using the PTS may provide a useful example (see http://mghlabtest.partners.org/pts.htm).[8] Also, Vanderbilt University Medical Center published a concise explanation of the policy and procedures for their pharmacy PTS, including a competency checklist (see http://vumcpolicies.mc.vanderbilt.edu/E-Manual/Hpolicy.nsf/AllDocs/536D894BF9EC341C86256FBE0051E2A3).[9]

Consider these additional strategies on improving the PTS:

- Set up a process control that provides a means of ensuring that the time requirement for material delivery is satisfied every time.[10] When used

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properly, the PTS can be a valuable strategic device in providing timely and appropriate patient care.

- Johns Hopkins University asks their pharmacy services staff to assure patient identification is correct for material being transported.[11] Consider including all labels and paperwork with any tubed material, as well as a routing slip in the case of a misrouted delivery.
- Make clear how often staff are expected to check the station to help ensure timely removal of material in tubes.[7]
- Post a list of banned materials that are unsuitable for transport at tube stations.[5] Avoid use of the PTS for anything but its designed intention. Inappropriate use of the PTS compromises the integrity of the system and restricts the hospital's ability to ensure good patient care.
- Post a schedule of when approved items can be sent to specific locations.[8]

The first PA-PSRS report cited in this article goes on to demonstrate the PTS policy of that facility. The following is the narrative of the report pertaining to the facility's policy:

> *. . . Only vacuum-closed containers (like blood tubes) can be sent via pneumatic tube system. Refer to procedure on hospital intranet, department, laboratory test directory, procedures, and pneumatic tube system. Refer to graph in procedure for quick reference. Specimen sent to microbiology for testing.*

Notes

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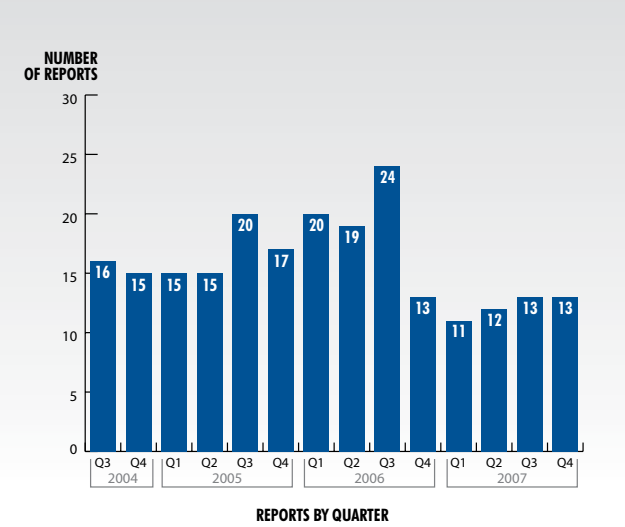
Quarterly Update on the Preventing Wrong-Site Surgery Project

The published PA-PSRS data on wrong-site surgery events has been revised as a result of discovering events that were neither classified as wrong-site events, even though they were, nor classified as having occurred in an operating room or ambulatory surgical facility, even though they did. These data supersede all previous PA-PSRS data on wrong-site surgery events. A revised graph of the cumulative number of reports of wrong-site surgery events has been extended through the fourth quarter of 2007 and replaces the previously published graph on the Pennsylvania Patient Safety Authority's Web site.* A graph of the number of reports by quarter, also based on the revised data (see Figure), has been added. Please note that the current definition of wrong-site surgery follows the National Quality Forum definition and includes punctures of the skin for the injection of local or regional anesthesia preparatory to the scheduled procedure.[1] An improved search strategy will be used for all future searches for wrong-site surgery reports. Although there has been a slight drop in the number of reports of wrong-site surgery events, PA-PSRS clinical analysts are not impressed that there has been an improvement in wrong-site surgery incidence in Pennsylvania.

Detailed wrong-site surgery reports are being submitted by cooperating facilities in follow-up to reports of near-miss and actual wrong-site events. By comparing the processes that were and were not significantly associated with trapping the error before harm occurred, the clinical analysts can better understand which processes are associated with successfully catching these rare events. As of February 25, 2008, the analysts have received the results of 34 in-depth queries about near-miss events and 14 about actual wrong-site surgery events from 33 cooperating facilities. The compliance rate with requests for detailed information within 30 days of the event has been more than 63%. Currently, six elements of a prevention program for wrong-site surgery are more commonly present when errors were trapped than when the errors advanced to wrong-site surgery (see Table). The most persistent element, having also been the most apparent in the first quarterly review that published in the December 2007 *Advisory*,* is the response of the surgeon to concerns that were raised by others. Surgeons participating in preoperative verification and reconciliation processes also support the concept that involvement of the surgeons in any program to prevent wrong-site surgery is crucial.

Figure. PA-PSRS Wrong-Site Surgery Reports by Quarter



Note that other elements that appeared to be associated with error trapping in the initial preliminary assessment of detailed wrong-site surgery reports (see the December 2007 *Advisory*) are not currently associated in this analysis of the expanded data set. The inverse association with scheduling errors disappeared, as did direct associations with the use of checklists and the use of time outs after repositioning the patient.

In a separate inquiry, analysts examined the subsequent experiences of facilities that indicated in a 2007 survey** that changes were initiated as a result of the June 2007 *Advisory* article "Doing the 'Right' Things to Correct Wrong-Site Surgery." Of 180 facilities that returned survey responses, 62 indicated that changes were implemented as a result of this particular article. During the six months before the article published, this group of facilities had reported six wrong-site surgery events, in contrast to two wrong-site surgery reports among the 118 facilities that did not indicate a change as a result of this article. During the six months after the article, the numbers were exactly the same: six more wrong-site surgery reports among the facilities that had made a change and two more wrong-site surgery reports among those that had not. However, no facility in either response group reported a wrong-site surgery error in 2007 both before and after the article. The new reports that were submitted after the article was published were all from different facilities than the reports preceding the article.

The Health Care Improvement Foundation (HCIF) Partnership for Patient Care is implementing a

* The Pennsylvania Patient Safety Authority has posted an online toolkit of articles, educational resources, and data snapshots pertaining to wrong-site surgery. This toolkit, "Preventing Wrong-Site Surgery," is available at http://www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=448010.

** This survey refers to the annual online user survey conducted among Patient Safety Officers in Pennsylvania.

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Table. Current Preliminary Associations between Elements of a Prevention Program for Wrong-Site Surgery and Success in Trapping Wrong-Site Errors before Harm Occurred

ELEMENT	NEAR MISSES	WRONG-SITE SURGERIES	SIGNIFICANCE (P LESS THAN)
Identification involved wristband and chart	27/27	11/13	0.05
Mark visible during time out	23/25	7/11	0.05
Surgeon did a preoperative verification	24/25	9/13	0.05
Surgeon reconciled discrepancies in documents	19/20	5/9	0.01
Someone raised a concern	24/26	5/12	0.001
Surgeon responded to the concern raised	19/20	3/11	0.001

Wrong-site Surgery Prevention Program for surgical facilities in the greater Philadelphia area. Part of the program is to correlate elements on the Pennsylvania Patient Safety Authority's "Self-Assessment Checklist for Program Elements Associated with Preventing Wrong-Site Surgery" with reports of wrong-site surgery events. A more user-friendly version of the checklist is now available on the Pennsylvania Patient Safety Authority's Web site in the toolkit "Preventing Wrong-Site Surgery."* By comparing facilities that do and do not have each element on the checklist with existing reports of wrong-site surgery events, the analysts may gain some insight into which suggested elements are actually associated with fewer events.

All Pennsylvania facilities that conduct surgical procedures have been invited to join this voluntary endeavor. The Authority also invites any other state collecting wrong-site surgery events to use the same checklist to replicate the study. Requests for further information can be obtained by contacting the Authority (patientsafetyauthority@state.pa.us; please address requests to John Clarke, MD, Clinical Director, Pennsylvania Patient Safety Authority).

PA-PSRS analysts will continue to track and analyze all reports of wrong-site surgery events and near misses. In the meantime, hospitals and ambulatory surgical facilities are encouraged to assess their program for preventing wrong-site surgery using the checklist on the Authority's Web site. Please consider sharing these assessments and the success or failure of any efforts to improve wrong site surgery programs. Facilities outside Pennsylvania are also welcome to share this information.

Note

1. National Quality Forum. Serious reportable events in healthcare—2006 update. Washington DC: National Quality Forum; 2007.

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Assessing Transport Stability May Yield Rewards

Assessing patients before, during, and after transport within the healthcare facility is an important strategy for mitigating potential harm to patients.[1] PA-PSRS has received several reports that discussed problems during patient transport, including the following:

> *Patient arrived to physical therapy without* [oxygen (O_2)]. *Noted in chart that patient had been on O_2 at 4L NC with O_2 saturation of 94%. Patient's O_2 saturation on arrival to physical therapy department was 80% on room air. Heart rate was 134.*

> *Unsupervised transport of patient with medication that required supervision of* [registered nurse (RN)] *and monitoring of amiodarone infusion.*

> *Procedure for transport of patient that required monitoring was not followed. Physician was advised.*

Barnes-Jewish Hospital, St. Louis, Missouri, experienced a sentinel event associated with a patient's intrahospital transport; analysis of the event showed that policy for transporting patients with the appropriate levels of staff was somewhat unknown and inconsistently followed.[2] Elsewhere, in 2005, the intensive care unit (ICU) of Calgary Health Region, Canada, experienced two similar critical events during patient transport for computed tomography (CT) scans. In both cases, the patients were not intubated for transport despite compromised respiratory status. Both patients arrested during their respective CT scans.[1]

A standard assessment tool to determine whether patients are stable for transport within the facility may have improved the outcomes in the PA-PSRS reports and other events discussed above. Barnes-Jewish Hospital and Calgary Health Region offer two unique tools to help healthcare facilities with patient transport.

In response to the sentinel event during transport, a multidisciplinary team at Barnes-Jewish Hospital developed a transport stability scale based on a color-coded chart to help identify and communicate a patient's level of stability (green, yellow, red). (This chart and more information can be found at http://www.aacn.org/pdfLibra.NSF/Files/2004CSMWard/$file/2004CSMWard.pdf.) Nurses can use the chart to identify whether a physician or additional healthcare workers should accompany the patient based on the patient's level of stability during transport (i.e., according to assessment of indicators including respiratory or cardiovascular status). Green identifies those patients who may be accompanied by a patient transporter; yellow identifies patients who need a higher level of care and accompaniment by a RN or physician; and red identifies unstable patients who require a RN and physician during transport. The RN caring for the patient uses a color-coded sticker (green, yellow, red) to identify the level of care needed, based on the patient's most recent assessment. The appropriate sticker is placed on the front cover of the patient's medical record, which communicates to the receiving department the patient's stability status. The sticker communicates information such as mode of patient travel, presence of intravenous lines, the need for oxygen during transport, isolation precautions, and the need for restraints, if necessary.[2]

At Calgary, a multidisciplinary team used the Barnes-Jewish transport stability scale to develop their own tool, an ICU patient transport decision scorecard. The team determined 29 steps involved with transporting a patient. The team involved a novice staff member during development to ensure, for example, that conditions were not overlooked because of inexperience. After initial testing, the team simplified their scorecard to only use the colors of green and red (see the revised scorecard and other information at www.longwoods.com/view.php?aid=18376&cat=452). Level of transport is identified according to system criteria (e.g., central nervous system, cardiovascular system). Green identifies patients to be accompanied by a RN. Red identifies patients to be reassessed by the physician and a registered respiratory therapist (RRT) and accompanied by a RN and RRT. Also, transport of patients meeting criteria in the red column "may include" another physician and RN. Nurses, RRTs, and physicians all have a role in the completion of the scorecard prior to every patient transport.[1]

PA-PSRS reports have shown in several cases that healthcare facilities are encountering problems with experienced staff not present during patient transfers. Tools from Barnes-Jewish Hospital and Calgary Health Region offer possible solutions for a potential adverse outcome. PA-PSRS has addressed other matters of transport; for additional information, refer to the articles "Continuity of Oxygen Therapy During Intrahospital Transport" and "Is CT a High-Risk Area for Patient Transport?" in the September 2005 issue of the *Patient Safety Advisory*.

Notes

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PA-PSRS Data Snapshot: Anoxic Encephalopathy

Table. PA-PSRS Reports of Anoxic Encephalopathy, June 2004 to June 2007

PA-PSRS staff identified 31 reports submitted from June 2004 to June 2007 that indicated an outcome of anoxic encephalopathy. A brief synopsis of each report can be found in the table. We saw no unusual patterns and gained no insights beyond what is already known about the importance of expertly managing the airway and monitoring patients, especially sedated patients. Not all anoxic brain injuries resulted from hypoxia; some resulted from hypoperfusion secondary to uncontrolled bleeding. According to the reports, more than half of the patients died (17 of 31).

DESCRIPTION OF PROBLEM	DIED	NEONATE	CHILD	DELIVERY	EMERGENCY DEPARTMENT (ED)	INTENSIVE CARE UNIT (ICU)	MEDICAL-SURGICAL UNIT	OPERATING ROOM (OR)	RADIOLOGY	TRANSFER	RESPIRATORY SUPPORT	AIRWAY MANAGEMENT	TRACHEOSTOMY	ESOPHAGEAL INTUBATION	OR INTUBATION	OR EXTUBATION	FOLLOWING PROCEDURE	IMMEDIATELY AFTER DISCHARGE	SEDATION	PROPOFOL SYNDROME	BLEEDING	STATUS EPILEPTICUS	UNWITNESSED
Bipap came off							1				1												
Esophageal intubation of a neonate		1		1		1						1		1									
Arrest following sedation on floor	1						1												1				
Exsanguinating hemorrhage	1																				1		
Arrest at end of operation								1								1							
Arrest following sedation in MRI	1								1										1				
Arrest while going home immediately after AICD implantation	1																1	1					
Difficult reintubation						1						1											
Arrest (respiratory) on floor following transfer from PACU	1						1			1							1						
On ventilator											1												
Status epilepticus following ECT	1																					1	
Postoperative hemorrhagic shock with anemia requiring resuscitation	1	1				1															1		
Propofol syndrome	1					1														1			
Unwitnessed arrest from pulmonary embolus	1						1																1
Arrest following sedation on floor	1						1												1				
Birth trauma		1		1																			
Unwitnessed arrest during monitoring malfunction	1					1																	1

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Table. PA-PSRS Reports of Anoxic Encephalopathy, June 2004 to June 2007 (continued)

DESCRIPTION OF PROBLEM	DIED	NEONATE	CHILD	DELIVERY	EMERGENCY DEPARTMENT (ED)	INTENSIVE CARE UNIT (ICU)	MEDICAL-SURGICAL UNIT	OPERATING ROOM (OR)	RADIOLOGY	TRANSFER	RESPIRATORY SUPPORT	AIRWAY MANAGEMENT	TRACHEOSTOMY	ESOPHAGEAL INTUBATION	OR INTUBATION	OR EXTUBATION	FOLLOWING PROCEDURE	IMMEDIATELY AFTER DISCHARGE	SEDATION	PROPOFOL SYNDROME	BLEEDING	STATUS EPILEPTICUS	UNWITNESSED
Hemorrhage intraoperatively; arrest on emergence from anesthesia			1					1								1					1		
Airway problem during bedside tracheostomy	1					1						1	1										
Arrest during intubation for respiratory distress						1						1											
Pre-existing unresponsiveness from overdose, plus aspiration on intubation												1											
Unwitnessed arrest on floor following transfer from ED for respiratory infection	1				1		1			1													1
Arrest in transport to ICU for respiratory problems	1									1													
Unwitnessed arrest on medical-surgical unit							1																1
Unwitnessed arrest in ED	1				1																		1
Became unresponsive						1																	
Arrest during OR intubation								1				1			1								
Arrest on induction of anesthesia	1		1					1				1			1								
Arrest at home immediately post PTCA	1																1	1					
Distress at birth		1		1																			
Difficult reintubation												1											
TOTALS	17	4	2	3	2	8	7	4	1	3	2	8	1	1	2	2	3	2	3	1	3	1	5

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Editorial

What is an Advisory?

You will notice a new format for the *Pennsylvania Patient Safety Advisory*. Let me tell you why.

The Pennsylvania Patient Safety Reporting System (PA-PSRS) collects information about all medical errors in Pennsylvania, whether or not they harm patients. More importantly, its analysts try to identify lessons to be learned that will prevent others from repeating those errors. Sometimes, providers themselves identify and convey the lessons learned through the reports. Other times, the lessons only become apparent to analysts with large-scale aggregation of rare events. Always, the primary focus of the state's patient safety reporting system is to share valid insights into the reliable delivery of appropriate, safe healthcare.

The primary vehicle for disseminating this information has been the *PA-PSRS Patient Safety Advisory*, colloquially know as the "Pennsylvania" *Patient Safety Advisory*. It is published quarterly with supplements when appropriate. The *Advisory* began, before full-scale reporting, with a four-page newsletter coinciding with Patient Safety Week in March 2004. Reporting brought information about how errors occurred and could be prevented and identified priorities for the errors that needed to be addressed. The result has been more than 140 original articles over the first four years. We have received about 500 reports of system changes per year from Pennsylvania facilities in response to these articles, including most notably, information about the wide variety of colors to convey information on wristbands, which led to standardization by a group of Pennsylvania Patient Safety Officers and ultimately an international convergence on colors for color-coded wristbands.

When conveying information to healthcare providers about improving ways to deliver healthcare, the analysts' primary concern is that the information is unbiased, rational, and supported by the scientific evidence. Most of the information is based either on original analysis of the reports in the state patient safety database, currently containing nearly 700,000 reports, or on a comprehensive review of the literature. All articles conveying insights into improving the safe delivery of quality healthcare are reviewed by outside reviewers as part of the editing process. The editorial staff is grateful for the valuable contributions the reviewers provide.

The *Advisory* is disseminated electronically to all acute care facilities covered by Pennsylvania's patient safety reporting requirement. It is also available to anyone through a free electronic subscription. The *Advisory* is currently received by more than 1,300 additional subscribers in 46 states and territories of the United States and 20 other countries, and it is indexed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL).

With the first issue of 2008, you will see a new format. In addition to matching our official name to our commonly used name, we have reserved the cover for the Table of Contents. To help you, we have added a one-line description of each scientific article. Each scientific article will also begin with an abstract to summarize the article for the benefit of you, the reader.

We are also pleased to have added an editorial advisory board to assist us in obtaining outside reviews of our scientific articles and to provide broader oversight for the quality of the *Advisory* (beyond our current surveys of Patient Safety Officers in Pennsylvania). We are indebted to them for their willingness to contribute.

We plan to continue our invited articles on leadership, our interest in publishing letters to the editor when we receive them, and our self-assessment questions to measure retention.

As always, we welcome input and feedback. Mechanisms for communicating information to the editor can be found on the expanded masthead between the cover and the lead article. We hope you find the new format an improvement in the delivery of information about safe healthcare practices.

—John R. Clarke, MD, Editor
Pennsylvania Patient Safety Advisory

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PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's Web site at www.psa.state.pa.us.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.