TRACE Program: Improving Patient Safety

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EXECUTIVE SUMMARY

- The Tools for Radiation Awareness and Community Education (TRACE) program was designed as a two phase approach to radiation dose awareness and overall patient dose reduction achieved through patient and community education, physician awareness, staff training, and technological enhancements. It was made possible by the AHRA and Toshiba Putting Patients First grant program.
- Phase one of the program began by engaging radiation safety committee and management to address new radiation safety policy and procedures followed by patient and community education. Next, fluoroscopy dose reduction was addressed through physician awareness and dose notification. The final step was CT dose reduction through protocol changes.
- Phase two will contain three components: The implementation of software that will assist in recording and reporting dose; patient and referring physician notification for radiation dose >3 Gy; and CT dose reduction through technology and additional changes to protocols.

In the past few years, the topic of radiation exposure has gained increasing attention in the media, the government, the healthcare industry, and among the general public. As such, Overlake Hospital Medical Center in Bellevue, WA recently focused a quality improvement initiative on radiation safety in all aspects of radiation producing imaging. We were awarded the Toshiba Putting Patients First Grant in 2010 and began down the circuitous path of developing the Tools for Radiation Awareness and Community Education (TRACE) program.

Overlake is a Level III trauma, 337 bed, nonprofit regional medical center. The organization employs over 2500 people and has over 1000 active and courtesy physicians on staff. Overlake's medical imaging department performs over 150,000 exams annually and employs over 100 employees in various imaging modalities and locations.

Research was conducted in order for the leadership team to establish the perimeters of this program. From this research, the focus for the program was determined and was subsequently broken down into two phases. The first phase would contain the items to accomplish without additional capital and operational resources. The second phase would contain items that require an operational or capital budget.

Phase One

The first phase of the TRACE program contained items to accomplish without additional capital and operational resources. This included creating new policies and procedures, developing patient and community education, providing staff education, and implementing both fluoroscopy and CT dose reduction

New Policies and Procedures

There were several smaller policies and procedures that addressed some elements of radiation safety, such as radiation monitoring and protective apparel, but lacked a comprehensive approach to overall radiation safety. There were no established guidelines for radiation dose and no discussion of patient risk or patient and community education. In order to alter the policy, all of the research that actually went into the program had to be considered. Several meetings with the physicist were held to decide on the key elements, such as which measure of dose to use (mGy, Gy, Rad, mSv, Rem, etc), which regulatory agencies' recommendations to consider, which governing or professional organizations' recommendations to consider, and how best to roll out a comprehensive program. Also considered were elements of risk

management and that any changes to the policy had to be reviewed and signed off by the radiation safety committee.

A comprehensive policy was designed to include a summary, purpose statement, and regulations and practices governing the following:

- Community radiation safety policy
- Washington—WAC 246-221-005
- ALARA
- Community radiation exposure emergency policy
- Radiation safety officer, radiation safety committee
- Radioactive materials license
- Community education
- Employee/physician radiation safety
- Supervision
- Film badge, exposure reporting
- Annual lead apparel audit
- Patient radiation safety
- Patient education
- Reporting of patient radiation dose
- Fluoroscopy dose management
- Pre-procedure considerations
- Procedure performance
- Patient monitoring
- Appropriate documentation and follow-up
- Appendices and references

Patient and Community Education

Finding a consistent and reliable source of information is essential for education of the general public. According to the Society of Interventional Radiology (SIR) "In general, the risk of radiation is low compared to other procedural risks, and the benefits of imaging guidance are great. Image-guided procedures typically cause less morbidity and mortality than the equivalent surgical procedure. An informed patient will virtually always agree that the potential harm due to radiation is less than the potential harm due to a procedure that is cancelled, incomplete, or clinically inadequate because of concerns over radiation."[1]

To share information, we had to first understand that information, and with all of the variable ways to measure and report dose just deciding on which "language" to use was a challenge. Radiology Info.org had the easiest to understand public material, so patient and community education was modeled utilizing the examples provided on this website. The next hurdle was that existing equipment either did not express dose at all (eg, just fluoroscopy time) or it expressed it in different ways (eg, CT is expressed in dose length product [DLP]), which had to be converted.

The marketing department was utilized to produce a patient brochure that would be easy to read and understand. The brochure contained information on radiation dose measures, risks, and other related concerns. The brochure provided a wallet-style card to record dose and encouraged patients to discuss their concerns with their physicians (Figure 1).

In order to gain recognition of the program, posters were also created in partnership with the marketing department to be placed throughout the organization in key traffic areas. The posters were designed with the message, "Giving You Peace of Mind," to emphasize Overlake's commitment to providing a safe environment for patients. The posters invited patients to visit the website for additional information. See Figure 2.

Prior to the project, Overlake's website was designed with basic patient information regarding imaging procedures and some marketing information. During the project, it was updated with radiation safety educational material and links to radiation safety videos and FAQs. In addition, the ACR certification seals were added to the website as a symbol of the highest standards in radiation safety.

Utilizing online resources, a patient letter was created that would be given to patients before their scheduled exams. The research required for this endeavor was the most daunting, as there were multiple online tools to calculate and convert dose. The patient letter was designed to outline the expected radiation dose for a given exam. To make the task a little easier, ranges were created from the available information to cover multiple views and patient sizes. For example, a chest x-ray range is 0.1-0.3 mSv. This range covers a one view or two view chest x-ray for a small to large patient. In addition to dose, the letter provided a dose equivalency to background radiation and an explanation of risk.

The letters were created for all radiography, fluoroscopy, computed tomography (CT), and nuclear medicine exams (Box 1). The letters were vetted through

Exam Type	Average Dose	Risk
Chest X-ray	0.1-0.3 mSv	Minimal
Spine X-ray	1.5-1.8 mSv	Very low
Hand/Foot X-ray	0.001-0.002 mSv	Negligible
Head CT	2– 3 mSv	Very low
Chest CT	7-8 mSv	Low
Spine CT	5-6 mSv	Low
Abdomen Pelvis CT	13-15 mSv	Low
UGI Fluoro Exam	6-8 mSv	Low
Mammography	0.4-0.6 mSv	Very low
NM Renal Scan	2.0-2.5 mSv	Very Low
NM Bone Scan	6.0-7.0 mSv	Low

Negligible - 0-0.09mSv
Minimal - 0.1-0.9mSv
Very Low - 1.0-2.9mSv
Low - 3.0-20.0mSv
Moderate - 20-50 mSv

Dose ranges are based on the average adult.
Average Adult Dose by Exam Type.

My Radiation Exposure

Date	Exam	Dose (mSv)	Total (mSv)

Figure 1 • Wallet-style card to record dose.

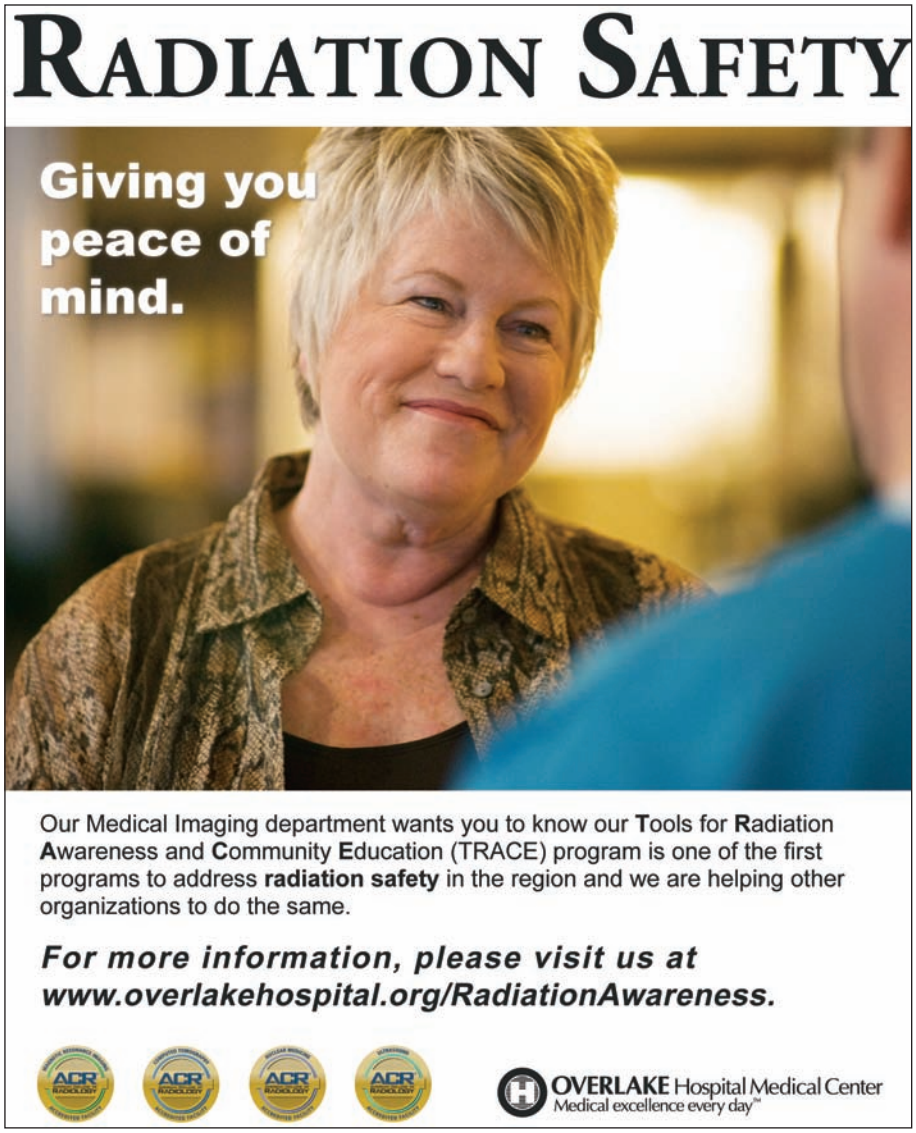

Figure 2 • Poster to help increase recognition of the program.

executive leadership, marketing, and risk before they were approved for dissemination. The calculations were garnered through the RadiologyInfo.org website and correlated to Overlake's equipment through the physicist. According to RadiologyInfo.org: "A chest radiograph is 0.1 mSv, which equals 10 days of background radiation and is minimal risk."[2] To calculate other dose equivalencies for background radiation the formula 0.1 mSv/10 = 0.01 mSv per day of background of radiation was used. Overlake's physicist confirmed this calculation would be accurate while extrapolating the data. When explaining the risk associated with the exam, Table 1 was used.

Staff Education

The imaging department is staffed with approximately 100 employees, made up of technologists, administrators, nurses, and support staff. While technologists are expected to have knowledge of radiation principles, such as ALARA, there is an entire subset of employees with very little knowledge of radiation principles at all. In order for the program to be successful, all employees would have to be given a greater depth of knowledge and it had to be determined which employees would be referenced for various types of information. For instance, would front desk staff be expected to field questions about background radiation equivalencies?

Deciding on the method of communication and providing the time and opportunity for staff to learn is often a challenge. At Overlake, all imaging employees are expected to access their emails daily. Oftentimes, long emails are ignored and become one-way communication. As a result, email was used as a heads-up notification before education was rolled out or it was used as a summary of the items that were already discussed.

It was decided the most effective method for educating staff would be single modality staff meetings and one-on-one conversations with staff and leads/supervisors. This was followed by an email summary and handouts of posters and brochures, as well as links to websites that provided additional information. Additional resources were created, such as an FAQ for the staff to use in anticipation of questions that might be asked by physicians and patients upon receiving radiation dose information. It was decided early in the process to direct all detailed questions directly to the technologists, and in the event of any unanswerable question, to direct them to management.

Fluoroscopy Dose Reduction

Physicians who do not have a background in radiology may often be uninformed about radiation dose or appropriate imaging protocols. There were two areas of concern in Overlake's environment: multiple or incorrect CT exams ordered on patients and high fluoroscopy patient dose specific to particular procedures (ie, some endoscopic retrograde cholangiopancreatography's [ERCPs], some vascular, some catheterizations, and thrombectomies, etc) – basically, any procedure that was complicated or had the potential to be lengthy. Raising awareness of a particular issue through discussion or measurement of goals can often change behaviors and

BOX 1. Sample Patient Letter

OVERLAKE Hospital Medical Center
Medical excellence every day™

MEDICAL IMAGING

Radiation Safety Awareness

Welcome to Overlake Hospital's Medical Imaging Department where you can expect medical excellence every day. As a part of our commitment to your safety, you are being provided this letter on Radiation Awareness.

Accreditation

Overlake is accredited by the American College of Radiology in computed tomography (CT), magnetic resonance imaging (MRI), nuclear medicine, and ultrasound. Accreditation is earned by organizations that undergo a rigorous onsite inspection and evaluation of equipment and facilities meet quality and safety guidelines and ensure personnel are educated and certified in medical imaging.

Today's Exam

You are scheduled for a chest x-ray today. You can expect to receive 0.1-0.3mSv of radiation for this exam. This dose is equivalent to 10 days of natural environmental radiation that you are exposed to every day. This risk is considered minimal.

Radiation Dose

There are many ways to measure radiation dose. For patients, the most important way to measure radiation dose is termed "effective dose," which measures risk by assessing the long-term effects of radiation on body organs and tissue. Although there are many ways to express the quantity of radiation received, effective dose is most often expressed in milliSieverts (mSv).

Ionizing radiation is used daily in hospitals and clinics as part of x-ray, nuclear medicine, and computed tomography (CT) diagnostic imaging procedures. *These imaging procedures provide important information to your doctor about your health and help ensure that you receive appropriate care.* Physicians and technologists performing these procedures are trained to use the minimal amount of radiation necessary.

Radiation Risk

Risk level means the approximate lifetime risk of fatal cancer for an adult as the result of radiation exposure. Risk level is further defined as follows:

Negligible:	< 1 in 1,000,000
Minimal:	1 in 1,000,000 to 1 in 100,000
Very Low:	1 in 100,000 to 1 in 10,000
Low:	1 in 10,000 to 1 in 1,000
Moderate:	1 in 1,000 to 1 in 500

If your condition has resulted in the need for frequent radiologic studies, you may wish to speak with your primary care physician about radiation dose. It is important that all of your treating physicians have your complete imaging history.

Additional Information

For more information on radiation risk and dose, please see our Radiation Safety brochure available in the waiting area, or our website at www.overlakehospital.org/radiationawareness.

TABLE 1. Explanation of Risk with Exam

Risk Level	Approximate additional risk of fatal cancer for an adult from examination:
Negligible:	less than 1 in 1,000,000
Minimal:	1 in 1,000,000 to 1 in 100,000
Very Low:	1 in 100,000 to 1 in 10,000
Low:	1 in 10,000 to 1 in 1000
Moderate:	1 in 1000 to 1 in 500

**Note:* These risk levels represent very small additions to the one in five chance we all have of dying from cancer.

Source: RadiologyInfo.org. Available at: http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray. Accessed May 19, 2011.

outcomes. The leadership team felt that by bringing the radiation dose to the attention of the fluoroscopist, it would raise awareness and have the potential to lower the overall radiation dose.

There were no set guidelines in Overlake's policies and procedures to help determine how much radiation was too much given the type of procedure being performed. As a result, extensive research was conducted online, in journals, through colleagues, and through professional resources, such as the Advisory Board. Overlake's physicist provided professional opinions and helped make sense of what was found in the literature. It was concluded there was not a consensus among professional organizations, regulatory agencies, or physicists. Various organizations, such as the FDA, ACR, and SIR supported varying levels for initial notification, and it was decided to follow the strictest standard and begin verbal notification at 1000 mGy, followed by 2000 mGy, and final notification at 3000 mGy to the flouroscopist.

Examining Overlake's equipment, 15 pieces of fluoroscopy producing equipment were identified: five surgical c-arms, two surgical vascular labs, two electrophysiology labs, three cardiac catheterization labs, two standard fluoroscopy suites, and one angiography suite, all of various ages and manufacturers. When looking at standardizing notification to the 1000–3000 mGy, it was found that the equipment recorded differently (eg, gray, microgray, milligray, centigray) including one piece of equipment that only recorded fluoro time. So how can a standard notification process be created when the equipment isn't standard? In order to keep the notification standard at 1000 mGy, 2000 mGy, and 3000 mGy, the correlated dose would have to be computed for each piece of equipment and posted on the equipment for the technologist. This would preclude the technologist from having to calculate or guess at the equivalencies.

Finding the best way to illustrate and educate the medical staff to this policy and procedural change was a challenge. The plans were vetted with the medical staff office, the physician champion, and other key stakeholders. Another key to communicating the notification of dose to the fluoroscopist was to delineate the difference between notification and decision making. Technologists are informing the fluoroscopist that they have reached a specific dose and not deciding for them when to stop applying fluoroscopy. The decision to proceed or cease is the fluoroscopist's/physician's.

Once notification guidelines were established, the changes were set into policy and procedure. We worked with the physician champion to be certain the policy changes were in line with radiologist expectations. In conjunction, marketing helped to create educational posters to display in surgery, special procedures unit, cardiac catheterization lab, main hallways, and the physician's lounge. The posters were designed to be simple, easy to read, and informative about the change to fluoroscopist notification during procedures (Figure 3). In addition to the posters, the medical staff office was utilized to send email notifications to the medical staff involved in fluoroscopy.

When the staff education and physician education was in place, the dose equivalencies were placed in laminated form onto the fluoro producing equipment and the process of having the technologist notify the physician performing fluoroscopy when they reached 1000 mGy, 2000 mGy, and 3000 mGy was begun.

CT Dose Reduction

Overlake has two CT scanners: one 64-slice situated in the emergency department and one 16-slice in the main imaging department. Sixty percent of overall CT volume is emergency department driven. CT dose reduction was looked at in a three phase approach: dissect protocols, dissect practice, and look to technology. An added challenge was a staffing shortage and loss of the lead CT technologist just as the program was starting to take shape. With three of the eight staff members leaving, temporary staff had to be utilized for the first time in over four years.

Existing CT protocols were in excellent shape and, because of this, it was decided to pause on making additional changes to protocols until technology could be added which would direct the changes being made. After attending a regional seminar on CT radiation dose reduction, the CT technologists were able to apply simple practice changes, such as achieving more precise centering, being conscious of the patient breathing, and avoiding Z-axis creep. They also learned about shielding,

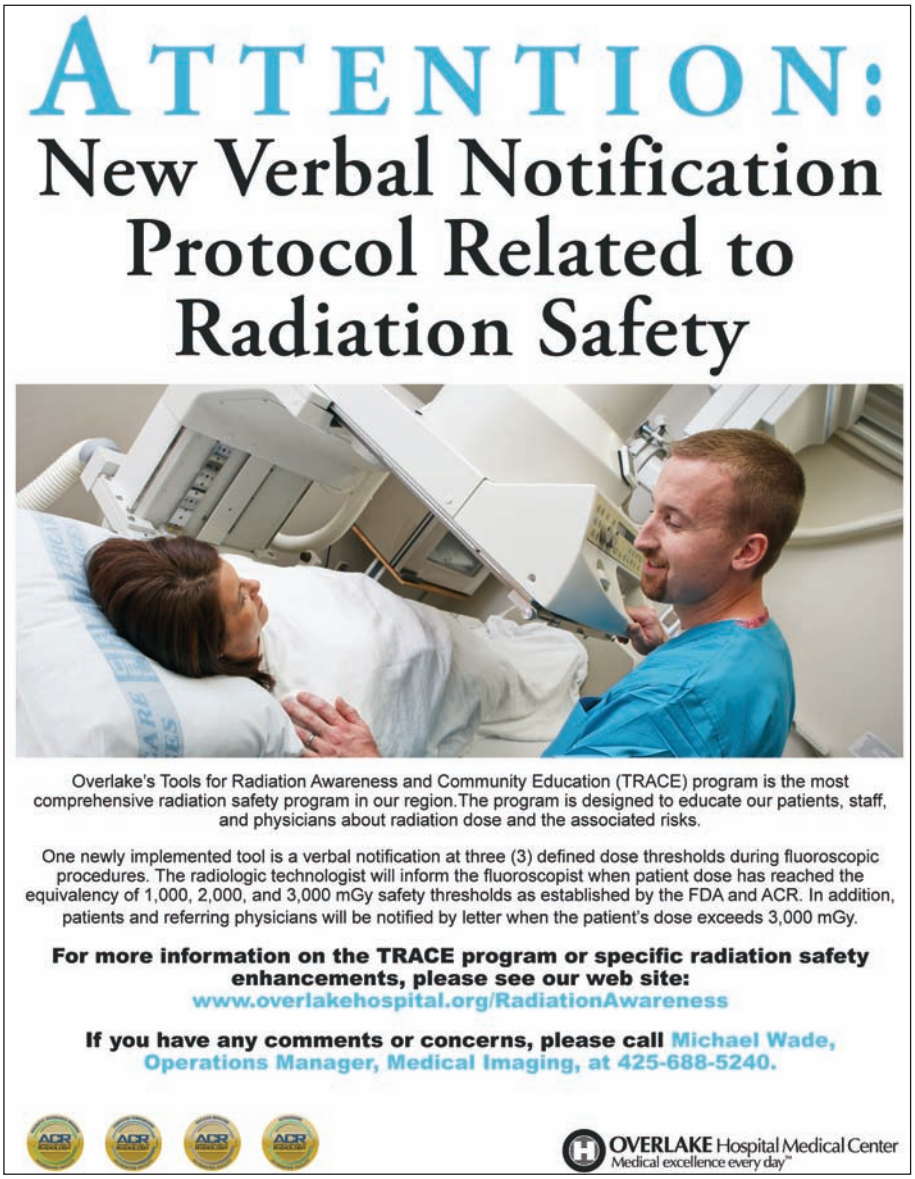

Figure 3 • Poster about the change to fluoroscopist notification during procedures.

which was once thought to be useless in CT, and bismuth shielding for breast and thyroid protection was purchased.

Phase Two

The second phase of the TRACE program contains items that require an operational or capital budget, such as acquiring CT dose reduction technology, utilization of tools for recording and reporting dose, and providing notification for excessive radiation dose.

CT Dose Reduction Technology

Research was conducted on the technology available for Overlake's scanners to reduce radiation dose. Upgrading the 64-slice scanner with the appropriate technology would require administrative approval and budgeted capital funding. It was agreed to prioritize the request for fiscal year 2012, and it is expected to move forward with the implementation of this technology at that time. Protocols will be revisited and we will work with our radiologists to determine the amount of noise in the images that they determine to be acceptable while maintaining diagnostic quality. The changes made to the protocols will be patient weight based and built on other contingent factors. As a result, it is anticipated other changes in practice during this implementation will be introduced.

Recording and Reporting Dose

Until recently, fluoroscopy time was the only recorded element of radiation dose, and fluoroscopy time requires a physicist's calculation to determine dose. CT dose, recorded as DLP, is available on our scanners, but is not recorded in the DICOM header or on the patient's images.

In order to get the dose dictated into the report, methods for each modality would have to be developed to record dose in mSv, the universal patient "language" we decided to use. We could not issue patient letters estimating dose for a given examination in mSv, and then report the actual dose in another "language," such as mGy. In addition, an independent full functioning radiology information system (RIS) or other software component that would assist in tracking the reported dose or storing it in the medical record automatically was not being used. Such systems have the ability to strip DICOM headers for each modality and obtain the dose information contained there. However, most of Overlake's equipment did not store dose data in the DICOM header.

The CT scanners reported dose in DLP, and converting DLP to mSv is dependent upon the body part being scanned (eg, an abdomen-pelvis CT will have a different multiplier than a brain CT). For this reason, a chart was created that provided the conversion for the technologist. Since the end result of mSv is a calculation, it would be recorded as an estimate based on the DLP. For fluoroscopy, the conversion is much simpler but still requires a formula because all of the machines record dose differently. A conversion chart could be provided for the technologists. Nuclear medicine dose is radiopharmaceutical dependant and was

recorded in the patient letter as a dose range based on the examination. The actual dose for the patient was recorded electronically when the patient received the dose. This information would be the simplest to provide in the technologist's notes in PACS because no calculation or conversion would be necessary.

Due to the complexity of this problem, the best way to perform and record the dose calculations is still being explored. Possible software solutions for long term storage and retrieval of the data are being researched, as well as tools to assist the radiologists in dictating this information, such as auto-populating templates.

Notification for Excessive Radiation Dose

According to SIR, "If the cumulative air kerma at the reference point exceeds 3 gray, provisions should be made for follow-up of those areas for determination of radiation effects… In such circumstances there should be documentation in the medical record that the patient was advised of the potential for radiation injury to the skin and was given instructions for proper follow-up."[1] Until the TRACE program began, Overlake did not have the ability to record this information. In recording it, we recognized that some exams, by the nature of their length and complexity, would fall into the range in excess of 3 gray.

Vetting this particular change with the Quality Improvement Committee will be the first step in introducing it to the medical staff. Further education of the medical staff will be necessary to field the potential patient questions associated with this type of notification. Risk management would need to assess the letters and consult with other resources to determine potential issues.

Conclusion

The next step in the TRACE program will be to purchase a dose area product (DAP) monitor (about $16,000) for the fluoroscopic room in the main department. Currently, this machine only records fluoroscopy time. Pending administrative approval, the software will be purchased for the 64-slice CT scanner to reduce radiation dose. The request for excessive dose notification letters will be submitted to the Quality Improvement Committee and the change will be vetted through the risk management department. In addition, we will continue to look at software applications and EMR technologies that offer access to dose index registries and permanent storage of cumulative radiation dose information, as well as software that provides the ability to set up notifications to alert ordering physicians to potential radiation dose issues due to multiple radiation producing imaging procedures. EMR applications will also be analyzed for physician order entry that check appropriateness criteria for CT and other radiation producing exams.

Recently, a member of the leadership team provided an excellent example of why we chose to embark on this journey. One of the radiologic technologists and student coordinator was operating the c-arm for a surgery case. The surgeon began asking questions about the alerts that they were told they would be receiving at 1000 mGy, 2000 mGy, and 3000 mGy, but the questions did not stop there. The surgeon wanted to know what the total dose for his patient was and how many chest x-rays the fluoro dose was equivalent to. He went on to ask how much radiation he was receiving as the operator, which provided the perfect opportunity to remind him to wear his dosimetry badge to record this dose. Education and awareness were two of the desired outcomes of the TRACE program and this example illustrates Overlake is well on its way to achieving results.

According to our physician champion, Mark Pfleger, MD, vascular interventional and neuroradiologist and president of Overlake Imaging Associates: "Medical imaging is an ever expanding important tool in diagnosis. Radiography, fluoroscopy, and CT … require ionizing radiation in order to generate images. We are committed to providing these services in an environment that is as safe as possible. The TRACE program allows the patients to be active participants in their own care. Patients can keep track of radiation exposure for an individual test and cumulative dose over time, as well as reference this to standard background radiation levels. This knowledge is also used by physicians and technologists to keep exposure to a minimum whenever an imaging test is required" [personal communication].

So why now? Why not wait until the technology is in place in order to streamline some of the processes? If we waited on resources or technology that were just around the corner or just out of reach, the opportunity would be missed to address growing problems and making great strides to change practices. It would mean a missed opportunity to help any patients that could be helped today.

References

[1]Guidelines for Patient Radiation Dose Management. Society of Interventional Radiology (SIR) Safety and Health Committee. *Journal of Vascular Interventional Radiology*. July 2009.

[2]RadiologyInfo.org. Patient Safety Radiology and CT, Naturally-Occurring "Background" Radiation Exposure. Radiological Society of North America, Inc. (RSNA). http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray. Updated November 15, 2010. Accessed May 19, 2011.

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