2009 RSNA, AUR, APDR, SCARD Radiology Education Research Development Grant
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NOTE: Personal information for the applicant and other investigators has been removed from this sample application.

Title:
Using Six Sigma Techniques to Reduce Radiation Dose

Abstract:
Radiologists and technologists must work as a team in order to optimize the risk/benefit ratio of fluoroscopic procedures. In this project, a technologist with a strong quality and safety background will enroll in Six Sigma Green Belt Training. As part of that course, she will develop the project charter for capturing dose metrics from pediatric fluoroscopy procedures. Through a combination of classroom instruction, web-based training and collaborative learning with other Green Belt trainees, the applicant will learn the Design, Measure, Analyze, Improve and Control (DMAIC) steps.

The second project aim is to inspire technologists and other team members to actively seek process improvement opportunities. The applicant's experience as a technologist will provide valuable insight into technologist workflow. The applicant has already demonstrated strong leadership and educator skills through her role in the department's Quality and Safety Office. As a result, she is uniquely qualified to lead this process improvement project.

Percent of Time Dedicated to this Project:
20

Detailed Education Plan:

CATEGORY 1 – Research in Educational Settings
Research will be conducted in an established accepted educational settings, involving normal educational practices. Research will include education instructional strategies, or research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

Section III: Research Plan Mandie Street , ARRT
Principal Investigator: Street, M
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A. USING SIX SIGMA TECHNIQUES TO REDUCE RADIATION DOSE – SPECIFIC AIMS

The recent focus on ionizing radiation in diagnostic imaging has prompted a reappraisal of how to optimize the risk/benefit ratio. Based on the success of Six Sigma process improvement strategies in other fields, we contend that this approach could be applied to radiation dose reduction during pediatric fluoroscopy procedures.

The aims of this project are:

a) Enroll a radiology technologist with a strong quality/safety improvement interest in Six Sigma Green Belt training
b) Have that technologist train the pediatric radiology technologists about how Six Sigma strategies can be applied to dose reduction during fluoroscopy procedures.

B. BACKGROUND AND SIGNIFICANCE

Patients present to physicians because they seek treatments which will efficiently and effectively alleviate whatever conditions caused their presenting symptoms. They view diagnostic imaging as a means of gathering information which leads to informed treatment decisions. While they recognize that ionizing radiation carries risk, they rely on the healthcare workers to optimize the risk/benefit ratio associated with this process(1). While the risks associated with ionizing radiation are typically small, when summed across the population, those small risks aggregate. Hence, small dose reductions can have a significant impact at the population level and this is especially true when imaging children and young adults (Figure B1).

Figure B1. Benefits of small reductions in radiation dose during common procedures. Investigators from the FDA modeled the benefits that might be observed 10 years after 15% reduction in radiation dose during upper GI series (solid diamonds), diagnostic coronary angiography (red circles) and coronary angioplasty (dotted red line). The projected years of life saved was estimated using dose savings, exam frequency, excess mortality due to cancer and years of life remaining. Their figures demonstrate the vast majority of benefit would accrue in children and young adults undergoing routine upper GI exams. While the need to reduce dose during CT exams and other high dose exams has rightfully received considerable attention, this analysis suggests that dose reduction during fluoroscopy procedures that are commonly performed in children and young adults would also provide substantial benefit. This data is taken from Stern et al, Estimated Benefits of Proposed Amendments to the FDA Radiation-Safety Standard for Diagnostic X-Ray Equipment, which was presented at the 2001 FDA Science Forum and later reported in the Federal Register (2).

B.2 Dose reduction requires a team approach

A team approach is needed simply because radiologists do not control the entire process. Other physicians typically see the patient, order the relevant studies and select the appropriate treatment. They consult radiologists for advice on how to obtain and interpret diagnostic images. In turn, radiologists rely on technologists to either perform or assist with the requested study. The technologists often adjust various imaging parameters in order to optimize the risk/benefit ratio for each individual patient and as a result, technologists develop a working knowledge of how to improve image acquisition.

B.3 Six Sigma uses structured process improvement teams

Difficult problems require a systematic, data driven approach. One of the most widely used process improvement strategies, Six Sigma, advocates using a team approach to such problems(3). Projects are supervised by a team member with extensive training and experience (Six Sigma Black Belt). While the Black Belt helps define the project objectives and workflow, the day to day work of collecting and analyzing data is performed by team members drawn from the workplace who are organized by local team leader trained in Six Sigma philosophy and techniques (a Six Sigma Green Principal Investigator: Street, M

Six Sigma Techniques to Reduce Radiation Dose Page 2 Radiology Education Research Development Grant Belt). Black Belts typically oversee a variety of process improvement projects being performed throughout the organization while Green Belts focus on a single project designed to improving performance at the local level.

B.4 Radiology needs to train Six Sigma Black and Green Belts

Radiology departments should simultaneously conduct a series of process improvement projects aimed at optimizing the balance between the risks and benefits of ionizing radiation. This will require multiple teams trained in dose reduction and Six Sigma. While radiologists will perform supervisory roles, technologists are well suited to execute and lead projects at the local level. Although it is possible to lead a dose reduction project without Six Sigma training, Six Sigma offers a proven, data driven method of conducting process improvement projects. Participation in Six Sigma training courses will allow project leaders to network with quality professions from other radiology departments and outside healthcare. Such interactions will minimize the tendency to “reinvent the wheel” within radiology department. Also, since numerous Six Sigma training courses already exist, the resulting educational system has substantial capacity to accommodate technologists and physicians who seek Six Sigma training. Six Sigma certification exams will also provide evidence that trainees have mastered the requisite content.

C. PRELIMINARY WORK

C.1. Creating a Quality and Safety Office (QSO) within the Department of Radiology

In July 2008, the Mallinckrodt Institute of Radiology created a Quality and Safety Office. The goals and duties of this office are presented in Table C1 and this formalized a series of quality and safety activities. The need for a coordinated approach to quality and safety was recognized in 2006 and Jim Duncan MD PhD was identified to lead the effort in 2007. He had studied process improvement in other industries and found a series of parallels between the strategies used in Six Sigma and biomedical research(4-7).

Table C1: Goals and Duties of QSO

1. Facilitate process improvement within the department.
2. Coordinate the department’s ongoing quality and safety activities with those of local, regional and national quality oversight agencies including the hospitals’ Medical Staff Performance Review Committees, American Board of Radiology, Joint Commission and Centers for Medicare and Medicaid Services.
3. Establish process improvement as a research program within the department. That background work identified the need to create a formal budget for the QSO. As per Six Sigma, the QSO must justify its annual budget using a return on investment model. From the outset, the QSO budget has included funding for a QSO coordinator. The QSO coordinator’s salary has been justified by the fact that most of the daily work performed in the QSO is better suited to a research coordinator than a physician. Having a full time employee dedicated to quality and safety has also been a key factor in building up the department’s quality and safety program.

Table C2: Responsibilities of the QSO Coordinator

1. Coordinate and maintain records of the various quality/safety conferences and incident investigations for the Dept of Radiology. Prepare reports which are submitted to oversight committees.
2. Administer research activities occurring under the QSO (obtain human studies approval, manage human resources working in the QSO, enrolling participants in approved protocols, gather and analyze data from those protocols) Implement a department wide program that meets the requirements of programs such as the ABR's Practice Quality Improvement (PQI) initiative Principal Investigator: Street, M Six Sigma Techniques to Reduce Radiation Dose Page 3 Radiology Education Research Development Grant.

C.2. Developing a department wide project on radiation dose reduction

In April 2008, we learned that the American Board of Radiology (ABR) had chosen radiation dose reduction as a high priority topic. Since the ABR's Maintenance of Certification program requires every radiologist to participate in a Practice Quality Improvement (PQI) project, the QSO has been developing projects which will satisfy the PQI requirement for every radiologist in the department. In May 2008, a pilot project was initiated to assess the feasibility of recording fluoroscopy time for every interventional radiology procedure. Since June 2008, the fluoroscopy time for over 7000 procedures has been recorded in the Radiology Information System. In November 2008, the Centers for Medicare and Medicaid Services (CMS) announced that fluoroscopy time would be included in its Practice Quality Reporting Initiative (PQRI) for 2009. As a result, efforts are underway to expand this pilot project to every section within the department that utilizes fluoroscopy. The need to rapidly move from pilot testing to department wide implementation indicates the importance of providing basic quality and safety training to physicians and technologists in every portion of the department.

C.3. Lessons learned from pilot project

This pilot project has provided numerous insights into various aspects of continuous process improvement. Most of observed issues have also been described in Six Sigma texts and this supports our contention that Six Sigma training will provide substantial benefit as we begin to expand the dose reduction effort.

C.3.1. Support of leadership is crucial to project success

The Six Sigma literature cites lack of leadership support as the most common cause for project failure(3, 8). This project which focused on radiation dose reduction enjoyed excellent support from the outset because both radiologists and technologists have an interest in reducing their own doses. As a result, physician and technologist leaders supported this project and this support carried over to the entire staff. In contrast, other process improvement initiatives that have not enjoyed such support and, as a result, have had much more limited success.

C.3.2. Assess the success of incremental steps using small tests of change

Another key to this project has been that it required only minimal changes in daily workflow. After each procedure, technologists typed the fluoroscopy time into the Radiology Information System (RIS). Since the technologists were already entering supply codes, procedures codes and other parameters into the RIS, implementing this change added little to their overall work. While we eventually plan to capture data on dose area product and reference dose, there were four reasons for capturing only the fluoroscopy time in this pilot study. First, some of the angiography units do not report advanced dose metrics such as dose area product and reference dose. Second, our current RIS does not provide a field for these metrics. Third, asking technologists to begin recording three new parameters for every case could have been viewed as a substantial imposition on their workflow. Fourth, we had recently studied decision making during image guided procedures and developed models that provided insight into how the data might be analyzed (Beta, Parikh, Street and Duncan, Capture and analysis of data from image guided procedures, submitted for publication). It was decided that uniform capture and detailed analysis of a single low level metric was a better goal for this pilot project than piecemeal capture and superficial analysis of multiple higher order metrics. Figure C1. Control charts for monitoring compliance with fluoroscopy time capture. These two charts are updated each month and posted on bulletin boards in the Interventional Radiology areas. These charts and notes regarding specific incidents where noncompliance was observed are also sent to the Chief Technologist in Interventional Radiology on a monthly basis. Principal Investigator: Street, M
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C.3.3. Feedback leads to improved compliance

Compliance with data capture has been monitored over the last 7 months (Figure C1). While data capture started in June 2008, data was not available for systematic analysis until mid-September. The initial analysis suggested several methods of improving compliance. First there was substantial variation amongst the technologists and the chief technologist addressed this by specific feedback to each technologist. In some cases, this included fresher training about how to enter the data into the RIS. Second, since there were some types of procedures that "never" used fluoroscopy, there was confusion about the need to record fluoroscopy time after these cases. It was decided to standardize the workflow and have technologists record fluoroscopy time for every procedure performed in Interventional Radiology. With these changes, compliance has increased 75 to 95%. As per Design, Measure, Act, Improve, Control (DMAIC), the Six Sigma approach to improving an existing business process, control is the final step and emphasizes the need to continue monitoring to "sustain the gain". We expect that with continued feedback, it should be possible to maintain compliance at >95%.

D. EDUCATIONAL ACTIVITIES

D.1. Enrolling in a Six Sigma Green Belt course

The key aspect of this proposal is learning Six Sigma techniques so that they can later be applied to radiation dose reduction. Although there are numerous possible Six Sigma courses, the PI will enroll in the American Society for Quality's Six Sigma Green Belt for Healthcare course. The PI is currently a member of the American Society for Quality (ASQ) which is world's leading authority on quality. The ASQ has more than 100,000 individual and organizational members worldwide and is an organization dedicated to learning, quality improvement and knowledge exchange. The ASQ has recognized the need for quality improvement training in healthcare and has partnered with organizations like the Institute for Healthcare Improvement and American Hospital Association to enhance the use of quality improvement theories, methods and tools.

The blended format for ASQ's Six Sigma Green Belt Training for Healthcare was chosen since it combines instructor led classroom training with virtual courses and web based training. The course begins with 2.5 days of face-to-face training where the PI will be introduced to the concepts and tools of Six Sigma (Table D1). Upon returning home, the PI will work with the process improvement team in Pediatric Radiology to finalize the project charter. During this project, the PI will have the support of the ASQ Six Sigma Green Belt course instructor, classmates from the Green Belt course, and the Quality and Safety staff at St. Louis Children's Hospital and Mallinckrodt Institute of Radiology. These Quality and Safety staff have typically completed or are pursuing Six Sigma Green or Black Belt training.
The project charter will be finalized within three weeks of the initial classroom course. The PI and other Green Belt students will then convene with their instructor for an online Webinar to review the Define and Measure strategies for the project. Three weeks later, the students will again convene for a second Webinar that will focus on the Analyze, Improve and Control steps.

Table D1: ASQ Six Sigma Green Belt Training – Healthcare Topics for Instructor Led Sessions

Session One: Measure and Analyze	**Session Two: Improve and Control**
1.1 Six Sigma Overview	2.1 Correlation and Regression
1.2 Rolled Throughput Yield	2.2 Analysis of Variance
1.3 Process Mapping	2.3 Introduction to Design of Experiments
1.4 Failure Mode and Effects Analysis	2.4 Randomized Blocks
1.5 Introduction to Statistics	2.5 Full Factorial Experiments
1.6 Confidence Intervals	2.6 Statistical Process Control
1.7 Basic Tools	2.7 Control Planning and Application
1.8 Measurement System Analysis	2.8 Mistake Proofing
1.9 Hypothesis Testing	2.9 Project Planning

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REFERENCES

1. Amis ES, Jr., Butler PF, Applegate KE, et al. American College of Radiology white paper on radiation dose in medicine. J Am Coll Radiol 2007; 4:272-84.
2. 21 CFR Part 1020 Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components. Federal Register 2005; 70:33997-4042.
3. Pyzdek T. The Six Sigma Handbook. New York: McGraw-Hill; 2003.
4. Bucholz EI, Duncan JR. Assessing system performance. J Vasc Interv Radiol 2008; 19:987-94.
5. Duncan JR. Strategies for improving safety and quality in interventional radiology. J Vasc Interv Radiol 2008; 19:3-7.
6. Jacobs B, Duncan JR. Improving Quality and Patient Safety by Minimizing Unnecessary Variation. J Vasc Interv Radiol, article in press and available online Dec 28, 2008.
7. Sridhar S, Duncan JR. Strategies for choosing process improvement projects. J Vasc Interv

<u>Budget</u>:
Personnel: = $4,526
* Mandie Street, RT, Principal Investigator, 20% effort, 6.5% with salary
* James R. Duncan, MD PhD, Mentor/Sponsor 0% effort

Other Expenses = $3,500
Travel = $1,000
Supplies = $974
Personnel: $4,526
Mandie Street, RT, Principal Investigator, 20% effort, 6.5% with salary

The RSNA/AUR/APDR/SCARD Education Research Development Grant is an ideal mechanism for Ms. Street because of her commitment to reducing radiation dose during diagnostic and therapeutic procedures. This funding mechanism will provide her an opportunity to continue learning process improvement techniques such as Lean Six Sigma. By learning how to collect information from existing systems, analyze that data and identify areas for improvement, she will be better able to continually apply these techniques throughout our institution and also prepare herself to train others how data driven process improvement might be used to reduce radiation dose at other institutions. She will devote 20% effort to this program by participating in the Lean Six Sigma Green Belt course sponsored by the American Society for Quality (ASQ). This will advance her learning, quality improvement, and knowledge exchange to improve patient safety. She will be committed to applying these techniques, concepts, analytical tools, and critical thinking to practical scenarios which occur daily in nearly every radiology department. Because the course design has a heavy practice orientation, the majority of her time will be spent working on problems taken from the radiology department. The development of new educational programs and the improvement of existing programs are of great need with respect to radiation dose reduction. This will help in expanding knowledge of how to help other radiology technologists can help decrease patient dose. There will be cost-sharing of 13.5%provided for by the Department of Radiology. James R. Duncan, MD PhD, Mentor/Sponsor 0% effort Dr. Duncan is an Associate Professor of Radiology and Chief Quality and Safety Officer at the Mallinckrodt Institute of Radiology. He is an Interventional Radiologist dedicated to process improvement. Dr. Duncan is committed to mentoring Ms. Street on this project and will provide instruction and guidance as needed.

Other Expenses $3,500
Tuition Expenses to attend Six Sigma Courses sponsored by ASQ are projected to be $3,500. Courses will focus on “Lean Six Sigma Green Belt Certification”. The web-based learning program will help to thoroughly prepare for ASQ’s Certified Six Sigma Green Belt exam and review the concepts a Six Sigma Green Belt should know to rapidly implement Six Sigma in our institution. The tools learned in this program are necessary to effect change and improvements in our institution. Section IV: Budget Mandie Street , ARRT

Travel $1,000
Travel expenses will be required for attendance at American Society for Quality sponsored training. Courses will provide the training and education on the sophisticated management and analytical skills required to implement the principles, practices and technologies into the radiology education program.
Travel expenses to attend the 3-day, 2-night stay are estimated to cost $1,000. (Hotel = $150 x 2 nights = $300, Airfare = $500, Meals @$50/day x 3 days = 150, and Ground transportation = $50)
Supplies $974 Software/Computer Supplies for ASQ training is projected to cost $974. This expense will assist in dissemination of advanced training and resources necessary for the Six Sigma green Belt Certification. Supplies for storage, archive, experiment analysis, and teaching will also be required.