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# A Comprehensive Quality Assurance Program for Personnel and Procedures in Radiation Oncology: Value of Voluntary Error Reporting and Checklists

John A. Kalapurakal, MD,\* Aleksandar Zafirovski, MBA, RT,\* Jeffery Smith, BS,\* Paul Fisher, AS, RT,\* Vythialingam Sathiaseelan, PhD,\* Cynthia Barnard, MBA, MSJS, CPHQ,<sup>‡</sup> Alfred W. Rademaker, PhD,<sup>†</sup> Nick Rave, MS,<sup>§</sup> and Bharat B. Mittal, MD\*

Departments of \*Radiation Oncology and †Preventive Medicine, Northwestern University Feinberg School of Medicine, and Departments of †Quality Strategies and §Physicians Services, Northwestern Memorial Hospital, Chicago, Illinois

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## Summary

This report describes the value of a voluntary error reporting system and the impact of quality assurance measures including checklists and timeouts on error rates in patients receiving radiation therapy. A total of 256 errors in 139 patients were recorded, and the staff compliance rate for checklists and timeouts was 97%. These quality assurance measures significantly reduced many categories of errors and eliminated errors related to wrong patient, wrong site, and wrong dose. **Purpose:** This report describes the value of a voluntary error reporting system and the impact of a series of quality assurance (QA) measures including checklists and timeouts on reported error rates in patients receiving radiation therapy.

**Methods and Materials:** A voluntary error reporting system was instituted with the goal of recording errors, analyzing their clinical impact, and guiding the implementation of targeted QA measures. In response to errors committed in relation to treatment of the wrong patient, wrong treatment site, and wrong dose, a novel initiative involving the use of checklists and timeouts for all staff was implemented. The impact of these and other QA initiatives was analyzed.

**Results:** From 2001 to 2011, a total of 256 errors in 139 patients after 284,810 external radiation treatments (0.09% per treatment) were recorded in our voluntary error database. The incidence of errors related to patient/tumor site, treatment planning/data transfer, and patient setup/treatment delivery was 9%, 40.2%, and 50.8%, respectively. The compliance rate for the checklists and timeouts initiative was 97% (P<.001). These and other QA measures resulted in a significant reduction in many categories of errors. The introduction of checklists and timeouts has been successful in eliminating errors related to wrong patient, wrong site, and wrong dose.

**Conclusions:** A comprehensive QA program that regularly monitors staff compliance together with a robust voluntary error reporting system can reduce or eliminate errors that could result in serious patient injury. We recommend the adoption of these relatively simple QA initiatives including the use of checklists and timeouts for all staff to improve the safety of patients undergoing radiation therapy in the modern era. © 2013 Elsevier Inc.

Reprint requests to: John A. Kalapurakal, MD, FACR, Department of Radiation Oncology, Northwestern Memorial Hospital, 251 East Huron St, LC 178, Chicago, IL 60611. Tel: (312) 926-3761; E-mail: j-kalapurakal@northwestern.edu

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## Introduction

Medical errors are an important cause of patient morbidity and mortality in the United States (1). *The New York Times* published a series of reports of severe morbidity and mortality caused by errors committed during the delivery of radiation therapy (RT) in the United States. They raised considerable concerns regarding the safety of patients treated with advanced RT technologies like intensity modulated RT (IMRT), image guided RT (IGRT), and stereotactic radiosurgery (SRS) that are specifically designed to improve, not worsen, patient outcomes (2, 3).

The specialty of radiation oncology has a long track record of safe delivery of radiation to cancer patients (4). Most quality assurance (QA) procedures in use currently are directed to ensure good functioning of treatment machines and treatment planning software (5, 6). Although these are important, there is also an urgent need for greater emphasis on the quality of performance of personnel and procedures because most errors are the result of human performance failures rather than equipment failures (7-9). The Institute of Medicine has recommended the adoption of a comprehensive approach to improve patient safety because there is no single solution that would solve the problem of medical errors. They highlight the importance of analyzing errors and improving processes that would lead to the design of systems that will improve safety for all patients (8). Radiation treatment is a complex process involving many medical personnel and relies heavily on complex data transfer and handoffs between staff and systems that are all at risk for errors (Fig. 1). This report describes a comprehensive QA program for all personnel, the value of a voluntary error reporting system, and staff compliance with QA initiatives including checklists, timeouts, and their role in improving patient safety.

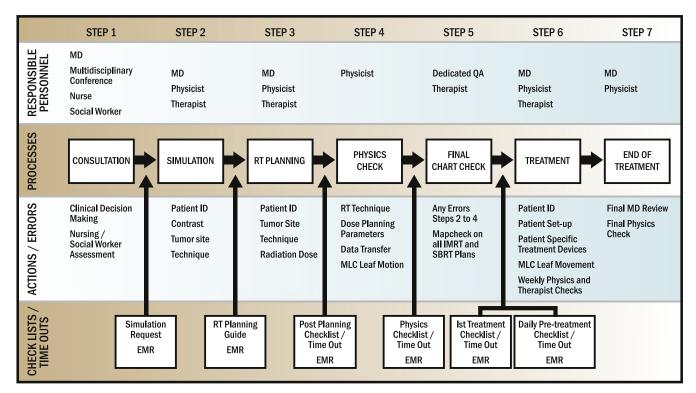
## **Methods and Materials**

The radiation oncology department at our institution has 9 physicians, 1 manager, 7 radiation physicists, 10 nurses, 1 QA resource coordinator, 1 social worker, 8 radiation oncology residents, 3 radiation physics residents, 5 radiation dosimetrists, 20 radiation therapists, and 7 RT students. The department has 5 linear accelerators, a gamma knife, and a high-dose and low-dose brachytherapy program. The radiation treatment capabilities include IMRT, IGRT, SRS, stereotactic body RT (SBRT), and total body irradiation.

The departmental QA committee consists of a physician, manager, resource coordinator, 2 physicists, 2 radiation therapists, 1 nurse, 1 dosimetrist, 1 social worker, and 1 resident. This committee meets monthly or sooner if required, and it reviews staff QA compliance, examines reported treatment errors, and provides recommendations for improving the quality of treatment.

# Voluntary error reporting

A voluntary error reporting system was instituted in 2001. This system recorded errors that were committed by any member of the staff during radiation treatment planning and delivery to patients (Fig. 1). Near-misses and minor workflow errors were not recorded. Voluntary reporting was encouraged by the leadership and was promoted as a learning tool, and no punitive actions were



**Fig. 1.** Radiation oncology departmental personnel and procedures, key functions, potential errors, and position of checklists and timeouts where handoffs occur between different teams. EMR = electronic medical records; ID = identification; MD = physician; MLC = multileaf collimator; QA = quality assurance; RT = radiation therapy.

taken against those who reported a particular incident. All errors were recorded on a standard incident reporting form that gathered all relevant details of the incident. These incidents were reviewed and discussed by the departmental and in selected cases by the hospital QA committee. The primary goal of this system was to study the causative factors of errors, analyze their clinical consequences, and develop broad consensus recommendations to reduce or prevent their occurrence. For this report all errors were stratified into 3 risk levels as defined by Macklis et al (9). Level I errors were minor dose discrepancies that resulted in <5% overall calculated change in dose to target volume with only a negligible chance of adverse medical outcome. Level II errors were minor dose discrepancies that resulted in >5% calculated change in dose to target volume with a low but not negligible chance of an adverse medical outcome. Level III errors were defined as any dose-delivery discrepancy of any kind that resulted in a significant and documented adverse clinical outcome or a substantially increased risk of long-term treatment toxicity or decreased tumor control. In this report all errors involving treatment of the wrong patient, wrong site, and wrong dose were classified as level III

# QA initiatives and compliance monitoring

Several QA initiatives were implemented to improve patient care and foster a culture of safety (Fig. 1). Staff compliance was regularly monitored, and the data were presented to the OA committee and provided to all personnel as part of a continuing quality improvement program. The specific QA initiatives included switching to electronic medical records (EMR), use of patient identification cards, use of a photo identification system in the treatment room before treatment, requirement of an approved presimulation order before simulation, identification of high-risk patients for treatment errors (eg, patients with multiple treatment sites, multiple tattoos, craniospinal irradiation), electronic treatment data transfer, development of standardized electronic treatment setup notes, use of bar codes for automatic recognition of patient-specific accessories like treatment blocks, use of couch indexing for accurate patient positioning, limiting treatment machine computer override capability to only physicists, verification of all IMRT plans at the machine by comparing delivered and calculated fluence maps before the first treatment, requirement of at least 2 radiation therapists at the treatment machine during treatment delivery, and monthly QA education conference for all radiation oncology staff. Furthermore, our workflow protocol required that the complete patient chart be made available to a dedicated chart check therapist 24 hours before treatment for a final review.

A novel QA initiative in radiation oncology involving the use of checklists and timeouts for all personnel was implemented in September 2008 (Fig. 2). This initiative was implemented in response to specific errors committed by personnel that involved the treatment of the wrong patient, wrong treatment site, and wrong dose (Table 1). These checklists and timeouts were similar to the widely observed surgery timeouts and physics checklists and timeouts already in place (Fig. 3). These timeouts were positioned at important junctures of patient treatment delivery or where handoffs occur between different teams (Fig. 1), would take only a few minutes to complete, and were done online and recorded in the patient's chart for real-time auditing. They included the following features: (1) posttreatment planning timeout to be

completed by the physicians, dosimetrists, and physicists before approval of the treatment plan and dose prescription; (2) initial/ first treatment timeout to be completed by physicians, physicists, and therapists at the treatment machine before delivery of the first radiation treatment; and (3) daily pretreatment timeout to be completed by at least 2 therapists in the treatment room before daily treatment delivery to the patient. Each checklist was designed to permit a review of important parameters before proceeding to the next step in the treatment planning or delivery. Again, the specific errors targeted by these timeouts included treatment of the wrong patient, wrong site, and wrong dose.

# Statistical analysis

Descriptive statistics include the number of treatments, patients, total errors, and errors of different types for each year of observation. Comparisons of different time periods were done using a 2-sample test for Poisson rates. Error rates and their standard errors were analyzed using the number  $\pm$  standard error of treatments as the denominator, and were expressed as the number of errors per 10,000 treatments. Compliance with timeouts was analyzed by determining a Spearman correlation between time and the percentage complying with these criteria.

#### Results

#### Radiation treatment errors

From January 2001 to October 2011, a total of 256 errors were reported in 139 patients out of a total of 284,810 external beam radiation treatments for a voluntary error reporting rate of 0.09% per treatment, or 9.00  $\pm$  0.56 per 10,000 treatments (Table 1). All errors were classified into 3 categories: errors in patient/tumor site treated (9%), errors in treatment planning and data transfer (40.2%), and errors in patient setup and treatment delivery (50.8%). In 120 patients, only 1 error was committed, and in 19 patients, an error was committed during more than 1 treatment (range, 2-17 treatments; mean, 7 treatments). All errors pertained to external beam treatments including conformal RT, IMRT, and IGRT. No errors were reported during SRS, SBRT, or brachytherapy procedures. Human failures were the cause of 251 (98%) of errors, and 5 (2%) errors were due to machine faults or EMR errors. Level I errors were noted in the majority 104 (74.8%) of patients. Level II and III errors were noted in 12 (8.6%) and 23 (16.6%) of patients, respectively. The 4 most common tumor types with reported errors were as follows: breast, 47 patients (66 errors); brain and orbit, 22 patients (47 errors); gynecologic/pelvic tumors, 13 patients (32 errors); and gastrointestinal and liver tumors, 11 patients (19 errors).

## Staff compliance with QA initiatives

Out of 6963 new treatment plans performed, 4329 were audited for postplanning physician (MD) timeout compliance (Fig. 4). The compliance rate was 96% (Spearman correlation, r=0.87; P<.0001). A total of 5387 new patients required an initial radiation treatment MD timeout, and all were audited. The compliance rate was 97% (Spearman correlation, r=0.83; P<.0001). Auditing the performance of daily treatment timeouts by radiation therapists was more challenging because it required monitoring of the

Post-Planning Checklist / Timeout	YN
EMR Prescription, Target Volumes, Pathology, Imaging Correct Patient in all systems?	
Is the Diagnosis in EMR correct?	
Is the Treatment Site correct?	
Simulation Note Approved? Treatment Note Approved?	
Staff Present (initials)	
First Treatment Checklist / Timeout	YN
Correct Patient on Treatment Table	
Treatment Consent present and complete Digitally Reconstructed Radiographs (DRRs) match Portal Images	
Staff Present (initials)	
Daily Radiation Treatment Checklist / Timeout	Y N
Identify Patient	
Name\Date of birth\Photo	
Treatment Side\Site	
Action to the control of the control	
Treatment Devices	
Action to the control of the control	

Components of the postplanning, initial treatment, and daily radiation treatment checklists and timeout. EMR = electronic medical records.

timeout process without drawing the attention of the treatment team. Thus, only a sample of approximately 1% of the total treatments (880 out of 92, 605 treatments) was audited. The compliance rate was 96.6% (Spearman correlation, r=0.80; P < .0001. The other QA initiatives with increasing compliance over time included completed CT simulation requests by MDs (r=0.64, P=.0002), preventing radiation therapist's treatment machine computer overrides (r=0.69, P=.0001) and nurse's charting of patients' pain assessment (r=0.60, P=.0007). However, the compliance was not as good for other QA measures such as timely completion of tumor volumes by physicians (r=0.12, P=.55) and patient chart approval 24 hours before the start of treatment (r=0.08, P=.67).

# Impact of QA initiatives on voluntarily reported error rates

Analysis of targeted error rates after the implementation of specific QA measures showed a significant reduction in many categories of errors. Although the error rates are described before and after implementation of a specific measure, it is acknowledged that more than 1 initiative could have resulted in the reduction of

specific categories of errors because of the overlapping beneficial effects of multiple QA initiatives that were implemented. The treatment block-related errors reduced from 13 errors in 13 patients to 1 error in 1 patient (1.09  $\pm$  0.3 to 0.06  $\pm$  0.06 per 10,000 treatments) (P < .0001), after the introduction of automated recognition of patient-specific treatment blocks by bar coding (2006-2011). However, this calculation did not consider the reduced use of blocks in recent years because of the increased use of patient-specific multileaf collimators for radiation field shaping. Errors related to treatment planning and data transfer, including monitor units and dose calculations, reduced from 101 in 23 patients to 2 errors in 2 patients (8.47  $\pm$  0.84 to 0.12  $\pm$  0.09 per 10,000 treatments) (P<.0001) after the introduction of electronic data transfer as opposed to manual entry of treatment data into the record and verify system (2006-2011). Errors related to radiation therapists' activities reduced from 79 errors in 75 patients to 51 errors in 25 patients (6.63  $\pm$  0.75 to 3.08  $\pm$  0.43 per 10,000 treatments) (P<.0001) after implementation of the policy of having at least 2 radiation therapists in each treatment machine (2006-2011). The introduction of checklists and timeouts resulted in the reduction of the total number of errors from 221 errors in 126 patients to 35 errors in 13 patients (11.2  $\pm$  0.75 to 4.00  $\pm$  0.68 per 10,000 treatments) (P < .0001). The most serious errors such as

Errors	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
Patient ID, treatment	0	3 (3) 0.01%	2 (2) 0.008%	1 (1) 0.004%	2 (3) 0.008%	1 (1) 0.004%	3 (3) 0.01%	11 (1) 0.04%	0	0	0	23 (14) 9%
site errors Treatment planning and data transfer	21 (4) 0.09%	49 (8) 0.2%	8 (3) 0.03%	4 (4) 0.02%	19 (4) 0.07%	2 (2) 0.008%	0	0	0	0	0	103 (25) 40.2%
errors Patient setup and treatment delivery errors	10 (9) 0.04%	15 (14) 0.07%	21 (19) 0.08%	13 (13) 0.06%	20 (20) 0.08%	8 (4) 0.03%	4 (4) 0.02%	4 (4) 0.02%	5 (4) 0.02%	12 (4) 0.04%	18 (5) 0.06%	130 (100) 50.8%
Total number of treatments	22,706	23,030	24,802	22,942	25,750	25,787	25,608	26,688	26,869	29,827	30,801	284,810
Total number of errors Total number of level I-II-III errors	31 (13) 0.14% 9-4-18	67 (25) 0.29% 37-1-29	31 (24) 0.13% 17-6-8	18 (18) 0.08% 15-1-2	41 (27) 0.16% 19-3-19	11 (7) 0.04% 10-0-1	7 (7) 0.03% 4-0-3	15 (5) 0.06% 4-0-11	5 (4) 0.02% 5-0-0	12 (4) 0.04% 2-1-9	18 (5) 0.06% 18-0-0	256 (139) 0.09% 140-16-100

Abbreviation: ID = identification.

Each error represents an event that occurred to a patient during a radiation treatment session. The number of patients in each category is indicated in parentheses.

treatment of the wrong patient, wrong site, and wrong dose reduced from 23 errors in 14 patients to none during the past 3 years (P = .001). After the introduction of checklists and timeouts, the incidence of level I, II, and III errors significantly reduced from 115, 16, and 90, respectively, in 126 patients to 25 (P=.001), 1 (P=.026), and 9 (P<.0001), respectively, in 13 patients. It is also noteworthy that the use of checklists and timeouts did not make an impact on the incidence of source-toskin distance (SSD)/isocenter errors (1.82  $\pm$  0.3 vs 1.49  $\pm$  0.41 per 10,000 treatments, P.52). After the introduction of checklists and timeouts, approximately 43% (15/35) of errors were related to activities pertaining to new technologies that were not included in existing QA measures, such as the use of the wrong tissue window for cone-beam computed tomographic fusion during IGRT and multileaf collimator leaf motion errors during IMRT. Specific initiatives have since been implemented to reduce these errors.

## **Discussion**

Health care is decades behind other industries such as aviation in creating safer systems. The reasons for the safety of modern air travel include the early adoption of human engineering techniques, allocation of resources for research, confidential incident reporting, database analyses, and the adoption of a comprehensive approach to quality improvement (4, 8). The 2007 symposium on QA in RT recommended that current programs should evolve from a device-centered to a more process-centered program with broad participation in the department. They emphasized that although every attempt should be made to avoid all errors, more effort should be focused on preventing those errors that can result in serious injury to patients (7).

Many technologic advances in radiation oncology such as IMRT, SRS, and SBRT have considerably increased the complexity of treatment planning and delivery. The daily radiation doses delivered with SRS and SBRT are significantly higher (10-

20 Gy) compared with standard treatments (1.8-3 Gy). Thus, the likelihood of errors and their potential impact, especially for those related to wrong patient, wrong site, and wrong dose, has significantly increased in recent times (2, 3, 10-12). This highlights the clinical significance of many of the QA measures described here.

The use of voluntary error reporting has been encouraged by many organizations like the World Health Organization and others (8, 9, 13-18). This report and others have demonstrated that such an error reporting system can be a useful tool to record and analyze errors, study their clinical impact, guide the implementation of targeted QA measures, and provide feedback regarding the effectiveness of these initiatives. Not only has this system helped introduce targeted initiatives such as checklists and timeouts, but also it has permitted the QA process to adapt to the changing pattern of errors (eg, verification of all IMRT plans at the treatment machine before delivery) that we have noticed with the use of newer technologies like IMRT and IGRT. There is an urgent need for a national approach to voluntary error reporting in the United States.

Many of the QA measures in this report have been widely used by others and have been shown to reduce but never completely eliminate the incidence of errors (9, 10, 13-18). In this report, many of the QA initiatives were targeted measures implemented in response to specific errors recorded in our database. Checklists are simple forms with a list of items that need to be verified during a timeout before the actual procedure is carried out. Checklists break down complex processes into simple steps, and their use has improved performance and reduced error rates in the airline industry and medicine (8, 19, 20). Checklists are most commonly used during timeouts before surgery to verify the patient's identity, type of procedure, and site of operation. Their use has gained wide acceptance and has been shown to reduce the incidence of errors and postoperative complications and to improve the perception of patient safety and teamwork among staff (19, 20). This report has for the first time, as far as we are aware, demonstrated the value of checklists in radiation oncology. We have shown that it is possible

Fig. 3. Components of the physics checklist and timeout. MLC = multileaf collimator; MOSAIQ = radiation oncology information system.

to obtain a high compliance rate for this initiative in a busy academic environment. Their acceptance among staff resulted largely from the education of personnel, prioritization by the

leadership, and their uniform requirement by all staff without exceptions. Their use has aided in reducing several categories of errors and has eliminated errors related to wrong patient, wrong

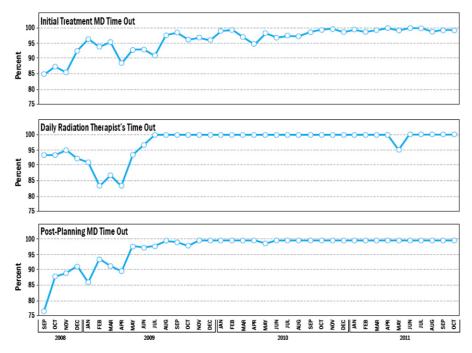


Fig. 4. Staff compliance with the initial treatment, daily therapists', and postplanning physician (MD) timeouts.

site, and wrong dose. Their use has also reinforced the importance of patient safety at all levels, and it has promoted teamwork among staff to fulfill their obligation to deliver safe and accurate treatments that patients are rightfully entitled to receive. We now use checklists and timeouts before all radiation procedures including radiosurgery, SBRT, and brachytherapy.

A limitation of this report is the voluntary nature of error reporting, which can be considered inaccurate. However, there are few alternative methods of detecting such personnel errors, and it is widely acknowledged that treatment errors are underreported. We believe that the promotion of voluntary reporting as a learning tool, the nonpunitive nature of this system, and the presence of more personnel (at least 2 radiation therapists) at the point of treatment delivery would only have encouraged this practice. Furthermore, the error rate presented here is similar to those in other reports (13-17). The conclusions drawn from a small number of events may also be questioned. However, the trend of error rates after the implementation of specific corrective measures and the recent increase in new categories of errors linked to novel technologies not targeted by QA initiatives would lend support to the findings in this report. It should also be noted that the introduction of checklists did not make an impact on the incidence of SSD/ isocenter errors during patient setup by therapists. Furthermore, the compliance rate for QA initiatives such as timely completion of tumor volumes by physicians and patient chart approval 24 hours before the start of treatment still needed improvement. These findings highlight the importance of our continuous quality improvement program, which not only monitors compliance with these QA initiatives but also strives to improve its conscientious implementation at all times by all staff.

### **Conclusions**

A comprehensive QA program focused on personnel and procedures will reduce but never eliminate the incidence of

errors. A vigilant QA program that implements targeted measures in response to a robust voluntary error reporting system can reduce or eliminate errors that could result in serious patient injury. Assessment of personnel compliance with QA initiatives and providing staff feedback on their compliance is a critical component of a continuous quality improvement program. We recommend the adoption of these relatively simple QA initiatives, including the use of checklists and timeouts for all staff, to improve the safety of patients undergoing RT in the modern era.

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