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ASSESSING THE RELIABILITY OF THE RADIATION THERAPY CARE DELIVERY PROCESS USING DISCRETE EVENT SIMULATION

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ABSTRACT

This paper presents a discrete event simulation-based analysis of the Radiation Therapy (RT) care delivery process at the Radiation Oncology Center of the University of North Carolina (UNC) at Chapel Hill with the goal of assessing process reliability and patient safety. The use of quality assurance (QA) checklists in radiation oncology is a widely recognized method for detecting potential human and non-human errors before they reach the patient. In this study, data on patient safety events ("an incident that reached the patient, whether or not the patient was harmed") and near misses ("an incident that comes close to reaching the patient but is caught and corrected beforehand") were collected through a comprehensive safety program and used to estimate incident rates and the reliability score for each QA checklist.

1 INTRODUCTION

Patient safety has become one of the major concerns of healthcare providers due to the growing complexity of healthcare work systems and processes. In 1999 the Institute of Medicine published a report entitled "To Err is Human: Building a Safer Heath System" that attracted national attention. The report revealed 44,000 to 98,000 deaths from medical errors occur each year in the United States which is equivalent to a large airplane crash every day in a year (Borgstede and Zinninger 2004; Donnelly et al. 2010). A study by McGlynn et al. (2003) indicates that American patients receive only 50% of the recommended medical care processes. Scientific and technological advances and challenges associated with translating them into widespread practice, the increase in the prevalence of chronic conditions, and a poorly organized delivery system are some known contributing factors that have adversely affected the quality of care in the US (Daniels et al. 2005).

One of the most complex settings in healthcare is radiation therapy (RT) treatment (Arnold et al. 2010). During the last decade, the planning and delivery of RT has greatly changed due to the

introduction of new advanced technologies. This emergence of new technologies along with the increasing patient volume brought opportunities for new types of incidents (Huang et al. 2005). A front page New York Times article in 2010 spotlighted RT errors with the potential to harm patients and raised concerns about patient safety in the RT process (Ford and Terezakis 2010). It is estimated that each year more than 740,000 patients receive radiation in the United States (Ford and Terezakis 2010). The actual incident rate and the seriousness of patient safety issues in RT are not clear due to lack of information on incidents that have occurred. Because of legal concerns, often, only the people who were directly involved with an incident have information about it (Fraass 2008, Ford et al. 2012a). Ford and Terezakis (2010) estimated an incident rate of 1 in 600 patients while a study by Arnold et al. (2010) reported incident rates ranging from 0.06% to 4.66% depending on the incident calculation method. Although several studies have shown that serious RT incidents are occurring infrequently and the majority of incidents have little or no clinical consequence (Bissonnette and Medlam 2010), there is always room for improvement because of the nature and severity of consequences which could be death in some cases (Fraass 2008).

While humans are one component of medical error, many medical errors stem from faulty systems and processes. Therefore, it is crucial to use process-improvement methods to identify and eliminate process inefficiencies. Several researchers have discussed the benefits of developing and implementing a comprehensive quality assurance (QA) program as one of these process-improvement methods in radiation oncology for resolving safety issues (Kutcher 1994; Yeung et al. 2005; Donnelly 2010;). The studies indicate that using a QA checking program can help detect and reduce errors during the various stages of the RT process and improve safety performance as well as the safety culture (Donnelly 2010). A QA program is a "quality plan" which establishes the specific quality practices, resources, and activities associated with the service it provides. This requires a team of care providers that is committed to a policy of quality throughput for all activities it performs. "The team leader must create a 'quality system' known as a QA comprehensive program that provides the organizational structure, responsibilities, procedures, processes and resources for meeting the quality requirements of patient management" (Kutcher 1994). As a part of a QA checking program an internal system of incident reporting must be established aimed at: (1) documenting and classifying events, (2) evaluating the impact of events on patients in terms of dose errors, and (3) assessing the effectiveness of the checking procedure in a QA checking program (Yeung et al. 2005).

Discrete event simulation (DES) has been found to be an effective and flexible technique for modelling and analyzing health systems and processes (Katsaliaki and Mustafee 2011). In this paper we use DES to analyze and assess the reliability of the radiation therapy care delivery process along with the QA program that is implemented at the Radiation Oncology Center of the University of North Carolina (UNC) at Chapel Hill.

The next section reviews the relevant literature followed by the sections that describes the case study and the simulation model. The discussion on simulation results is presented and recommendations for future work are provided in the last section.

2 RELATED WORK

Medical errors and their impact on patient safety has been the focus of many recent studies in RT practice. A medical 'error' is defined as a preventable adverse effect of care (Zhang, Patel, and Johnson 2002). Examples of medical errors include misdiagnosis or delayed diagnosis, administration of the wrong drug to the wrong patient or in the wrong way, giving multiple drugs that interact negatively, surgery/RT on an incorrect site, failure to remove all surgical instruments, etc.

An incident is defined as "an unwanted or unexpected change from normal system behavior which causes or has the potential to cause an adverse effect to persons or equipment" (Ford et al. 2012a). This includes both incidents that come close to reaching the patient but were caught and corrected beforehand by means of timely intervention (near misses), and the incidents that reached the patients, whether or not

the patient was harmed. Although implementation of a QA checking program can reduce the frequency of errors significantly, it is impossible to eliminate all the errors and increasing the number of checking points known as QA checklists does not necessarily enhance the effectiveness of a QA program (Yeung et al. 2005). Ford et al. (2012b) defined the error-detection effectiveness of a QA checklist as the number of incidents that each QC checklist could detect divided by the total number of incidents. They evaluated the commonly used QA measures in radiation therapy at two academic radiation oncology clinics and concluded that a small percentage of errors cannot be prevented by any of the standard formal QA checks that are in widespread use.

Some studies have argued that the current paradigm for QA programs which was originally developed for conventional three-dimensional conformal radiotherapy needs to be re-evaluated because of the emergence of new technologies such as intensity- modulated radiation therapy (IMRT) and image-guided radiation therapy (IGRT) that has influenced the practice significantly (Palta, Liu, and Li 2008). Palta, Liu, and Li (2008) suggested that each facility offering IMRT must develop its own guidelines for QA of IMRT planning and delivery systems. Fraass (2008) discussed two incidents that lead to patient deaths in IMRT practice and emphasized the need to use more effective and organized approaches to understand the RT process and analyze it failure modes. Ford et al. (2009) used failure mode and effects analysis (FMEA) as a systematic risk analysis technique to find and improve failure modes with high risk probability number (RPN) in the delivery process of external beam radiography. However, the scoring system in FMEA is somewhat subjective and relies upon human assessment. To the best of our knowledge, there are no studies in the literature that present quantitative method for analyzing the risks in the RT process.

In this paper a process map representing the essential steps and workflow path in the RT delivery care process of UNC Cancer Center is used to create the simulation model of the process including the QA components. Computer simulation has been applied to many real world problems in healthcare settings. Katsaliaki and Mustafee (2011) have conducted comprehensive literature reviews on the simulation research in healthcare and highlighted the importance of simulation in providing insights to deal with these systems. However, few researchers have used simulation to improve the RT process. The majority of simulation studies in the radiotherapy context have focused on long delays and waiting times due to inefficient scheduling and resource allocation policies. Ogulata et al. (2008) developed a "slack capacity" approach for scheduling patients in RT and conducted a simulation analysis to determine the appropriate scheduling parameters. A discrete incident simulation model by Kapamara et al. (2007) is used to analyze patient flow in the radiotherapy treatment process revealing the intricacies and potential bottlenecks of the process. Ebert et al. (2013) proposed an approach to find optimal waiting times and maximize the efficiency of radiotherapy treatment using the patient population rather than an individual. Their analysis suggests that tumor doubling time is the key factor in determining optimal waiting time.

Mont Carlo simulation was used in a study by Munro and Potter (1994) to estimate the 95% confidence intervals on projected waiting times. A Monte Carlo analysis by Thomas (2003) is used for calculating the required level for patient capacity to meet target waiting times. In a more recent study by Werker et al. (2009) used DES to model the planning section of the radiation therapy treatment process at the British Columbia Cancer Agency and recommended improvement in waiting times in the process. To the authors' knowledge this is the first study to use simulation to address the issue of patient safety in RT practice and to quantify the impact of a QA program.

3 CASE STUDY

3.1 Radiation Oncology Center of UNC at Chapel-Hill

The UNC Radiation Oncology Center is part of the North Carolina Cancer Hospital which is the state's only public cancer hospital. It was opened in September 2009 and is the clinical home of the UNC Lineberger Comprehensive Cancer Center. NC Cancer Hospital physicians treat patients from every

county in North Carolina with more than 135,000 patient visits each year. The Radiation Oncology Center offers the following radiotherapy treatment methods 1) external beam radiation therapy, 2) intensity-modulated and image-guided radiation therapy 3) Tomo-therapy 4) cyberKnife robotic radiosurgery and 5) Brachytherapy.

3.2 External Beam Radiation Therapy Process

This study focuses on the external beam radiation therapy (EBRT) which is commonly used to treat patients with cancer. The goal is to design and deliver high-energy photon beams to malignant tumors while minimizing risks to neighboring healthy tissues. The potential for errors in EBRT is high, as the planning and delivery processes include numerous handoffs between RT professionals, each interpreting and entering information through multiple electronic systems. Further, the consequences of an error can be significant. The process can be divided into seven main stages shown in Figure 1. The blue color indicates that the patient is present during the process.

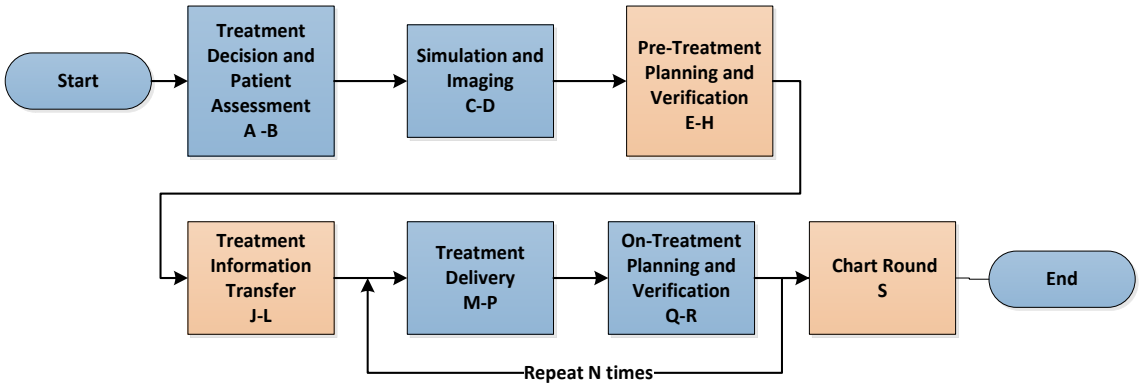

Figure 1: High level external beam RT process map.

The first step is a consultation visit with a physician to review the patient's medical history and develop a care plan for him/ her. The plan may include radiation therapy alone or in combination with surgery, chemotherapy or both. If radiotherapy is identified as an appropriate method of treatment, the patient will be scheduled for a Computer Tomography (CT) simulation session which is a procedure to map the three-dimensional shape of the tumor and normal tissues. In the Pre-treatment Planning and Verification stage, the treatment field information obtained from the Simulation and Imaging stage will be used to calculate dose and optimize dose distribution. The radiation oncology physician reviews and approves the treatment plan. Depending on the cancer type and patient characteristics, a course of treatment is usually delivered in five sessions per week for several weeks. During the treatment course, the patient's radiation chart consisting of patient identification, treatment plan, clinical assessment during treatment, treatment summary, follow-up and QA checklists must be reviewed at least once a week by different people in the department.

3.3 QA Checklists

As a part of the QA program, checklists are used throughout the process to prevent, control, or mitigate undesired safety incidents. Each QA checklist consists of a number of elements that have to be checked. Table 1 presents the description of QA checklists and the elements they check. There is a total of 35 QA elements each referring to a specific outcome of a process step. QA 7 and QA 8 consist of the same elements, however QA 7 is completed after each treatment session by a physicist while QA 8 is

completed once a week during weekly physicists chart checking. Table 2 shows the description of the top six critical QA elements used in QA checking program of our study.

Table 1: QA checklists.

QA Checklist Number	Description	QA Elements
QA 1	Dosimetrist (dose calculator) pre-planning	1-3
QA 2	Dosimetrist plan review	4-12
QA 3	Physicists pre-treatment checks	2-7, 9-20
QA 4	CT Simulation therapists: chart write-up	2, 10-20
QA 5	Radiation therapists - QA day	10, 11, 15, 21-25
QA 6	Radiation therapist daily treatment	25, 26, 27
QA 7 & 8	Physicists perform weekly chart checks	2, 4-20, 28-35

Table 2: QA elements.

QA Element Number	QA Element Description
1	Review attending MD contours
2	Confirm TxPlan (treatment plan) note is valid (approved by attending)
5	Verify total dose and fractional dose
6	Verify spatial dose distribution
8	Verify DVH (Dose Volume Histogram), hot and cold spots
10	Check that Rx (prescription) is approved by attending physician

In order to understand and analyze the complex RT process effectively, the high-level process map in Figure 1 is divided into more detailed and more granularly-defined process steps. Table 3 shows the steps in each stage labeled A through S, the number of steps and the QA checklists embedded in each group.

Table 3: Process steps and QA checklists in each step.

Stage	Group	Number of Steps	QA Checklists
Treatment Decision and Patient Assessment	A	6	0
	B	12	0
Simulation and Imaging	C	2	0
	D	12	0
Pre- treatment Planning and Verification	E	4	0
	F	2	0
	G	14	QA 1- QA2
	H	3	0
	J	8	QA3
	K	1	QA 4
	L	3	0
Treatment Delivery	M	12	QA5
	N	1	0
	P	12	QA 6
On- Treatment Planning and Verification	Q	1	QA7- QA8
	R	1	0
Chart Checking	S	6	0

3.4 Good Catch Program

Incidents that occur throughout the process may cross the QA checklists and not be discovered until later in the process. QA checklists are not 100% reliable and may not detect all errors. To improve quality and patient safety in the UNC Radiation Oncology Center, the Good Catch Program was implemented as part of a comprehensive QA program to provide a system of reporting, analyzing and managing incidents that have a negative impact on patient safety and the care delivery process. The phrase "Good Catch" is used to provide a positive connotation and disseminate a "no blame" environment for reporting incidents and system issues to the staff. GC refers to all incidents that happen throughout the RT care delivery process including the incidents that reached the patient regardless of causing or not causing harm or the incidents that came close to reaching the patient but were caught and corrected beforehand.

For each Good Catch (GC), a systematic root-cause analysis is performed to identify: a) where a GC started/was caught in the process; b) the number of QA checklists it crossed; c) the root-cause(s) and d) the action(s) needed to be taken for preventing future occurrence and improve the overall process. Employees are encouraged to actively report good catches and a summary of all GCs are reported in monthly QA meeting to make the staff aware of the continuous improvement efforts.

Incidents can lead to rework and unsafe conditions in the process. Depending on the incident type and its severity, the magnitude of rework varies. For incidents that reach the patient usually re-planning and re-treatment is required. The rework not only affects the patient directly involved in the incident and increase his/her treatment duration but it also increases the treatment waiting time for other patients which can cause tumor progression (Chen et al. 2008).

4 SIMULATION MODEL

4.1 Input Data

The input data used to create the simulation model comes from historical data and data obtained during several meetings with care provider and department staff. We used Arena input analyzer to analyze the collected data. The distribution of patients and treatment times by cancer types are shown in Table 4.

Table 4: Patient Mix.

Type of Cancer	Percentage	Treatment time (Number of Sessions)
A	10.2%	16
B	18.1%	22
C	6.3%	14
D	12.5%	24
E	19%	30
F	8.1%	19
G	8.2%	17
H	17.6%	16

Table 5 shows the sample mean, standard deviation and the fitted distribution to the throughput and Good Catches data based on a sample observations for 150 days.

Table 5: Throughput and good catches data.

	Number Scheduled	Number Treated	Number of Good Catches per Day
Sample Mean	109	99.4	1.23
Sample Standard Deviation	11.4	12	1.27
Distribution	Weibull	Weibull	Weibull
Expression	81.5 + WEIB(1.92, 1.43)	62.5 + WEIB(1.92, 1.43)	-0.5 + WEIB(1.92, 1.43)

4.2 Model Assumptions

4.2.1 New Patients' Arrival Schedule

Historical data indicates that 17% percent of the total numbers of patients that are scheduled each day are new patients (average of 19 new patients). The arrival rate for new patients is assumed to be that 3 patients arrive every hour from 7:00 to 11:00, 2 patients arrive every hour from 11:00 to 14:00, and 1 patient arrives from 14:00-15:00.

4.2.2 Lead Times and Processing Times

The key assumptions regarding the lead times and processing times are as follows:

- It is assumed that for all patients the Treatment Decision and Patient Assessment are completed on their first visit to the Radiation Oncology Center and the Simulation and imaging appointment will be scheduled for between 4-8 days later (The time interval is assumed to follow a uniform distribution (4,8)).
- The patient comes for the first treatment session 5-9 days later (the treatment waiting time is assumed to follow uniform distribution(5,9)).
- The patient goes through N sessions to complete one course of treatment depending on the cancer type (refer to Table 4). Treatment sessions runs on consecutive days, i.e. a patient complete five sessions in a week.
- If an incident begins in a pre-treatment planning step and is detected later sometime after the patient starts his simulation (which means the incident reached the patient), depending on the incident, some of the treatment planning steps must be repeated and a new treatment plan has to be developed for future treatment sessions. In this case, the waiting time until the next treatment session is assumed to be 1-2 days (uniform distribution(1,2)).
- All processing times are assumed to follow uniform distributions with parameters that are estimated based on several interviews with department staff.

4.3 Calculating Incident Probability

At the beginning of a day, the total number of incidents is drawn from the following Weibull distribution : -0.5 + WEIB(1.92, 1.43). Based on the GC data and incident distribution, we estimate how many times in a day an incident may happen during a particular step (incident frequency). At each step the incident probability for each type of patient per day is calculated as shown in Table 6:

Table 6: Calculating incident probability.

New Patients	Imaging/ Simulation patients	Treatment patients
$\frac{event\ frequency}{19}$	$\frac{event\ frequency}{15}$	$\frac{event\ frequency}{75}$

The denominators indicate the average number of each type of patients in a day.

4.4 Calculating Reliability Score of QA

We define the reliability score of a QA checklist as its ability to detect a incident. Analysis of GC, indicates how many QA checklists was crossed before the GC was caught. If a QA consists of N elements and each element on average goes "wrong" M times a day, we can conclude the QA must detect an average of $N * M$ incidents each day. If according to the analysis of GC, the QA was crossed T times in 6 months (which would be $\frac{T}{120}$ times a day) the reliability score is computed as follows:

Reliability Score = $1 - \frac{\frac{T}{120}}{N*M}$

4.5 Patient Flow Modeling

There is a total of 80 steps in the patient care delivery path. For the sake of simplicity, some of the non-QA steps are combined together and ultimately 40 steps are used in the simulation model. The patient flow between two consecutive non-QA steps (A & B) with a QA step between them, is shown in Figure 2. New patients arrive at the center based on the arrival rates shown in Section 4.2 and are assigned a cancer type based on the probabilities shown in Table 4. A dynamic incident probability is assigned to the step as shown in Table 6. Each patient is assigned a binary state variable that is a vector of size 40 and keeps track of the source of the incidents that may happen at each step throughout the process. When the patient passes through a QA step, the QA first checks whether there is any incident associated with the patient or not. If so, the second decide module checks if the QA checklist includes the QA element associated with the incident (i.e. the QA has the right element to detect the incident). Finally, based on the reliability score of the QA checklist, the last decide module determines whether the QA checklist detects the incident or not and then updates the patient state variable that keep tracks of incidents. If the incident was not detected patient proceeds to the next process step.

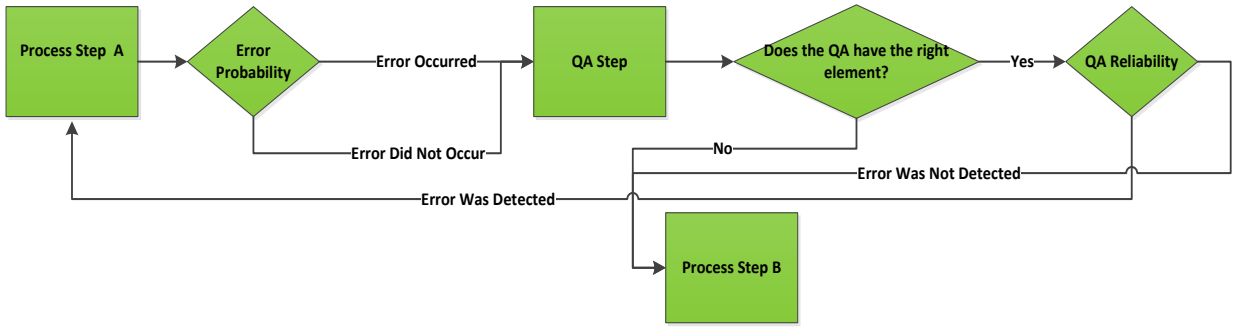

Figure 2: Patient flow between QA and non-QA steps.

4.6 Model Validation

The primary technique that we used to validate the model's accuracy in representing the actual RT process is Historical Data Validation technique (Sargent 2010). We compared the simulation results to the part of the historical data that was not used in the model, in order to verify its performance. As an example, the results for a simulation run length of 6 months shows that during each day, on average of 16 patients complete their consultation visit, 74 patients complete a treatment session and the rest visit the center for simulation and imaging. The total of 103 patients is close to 99 from historical throughput data.

To eliminate the effect of the "warming period" on results , based on the analysis shown in Figure 3, only the data after day 14 is used to compute the average number of patients in a day that complete their treatment.

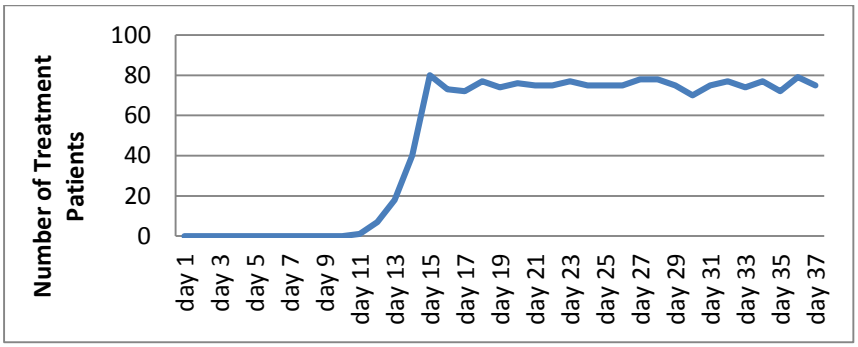

Figure 3: The number of patients that complete treatment in a day.

5 RESULTS AND DISCUSSION

5.1 Base Case

In the base case scenario, our goal is to identify the steps that generate the most rework. Only one type of patient (Type B in Table 4) is considered to remove the effect of cancer type on treatment length. The analysis reveals that if the incidents that happen during the steps: 1) delineation of organs at risk (E2) and 2) dose calculation (G6) are not detected until after the start of the treatment sessions, these steps will cause the maximum rework and consequently the maximum treatment duration. Table 8 summarizes the results and Table 9 shows the QA checklists that are able to detect the incidents occurring at these steps.

Table 8: Maximum rework (days) for patient type B.

Incident	Maximum Rework - Average	Maximum Rework - Minimum	Maximum Rework - Maximum	Half Width (days)
sub-optimal dose calculation	3.11	2.93	3.35	0.045
sub-optimal delineation of organs at risk	2.97	2.52	3.41	0.062

Table 9: The incidents that generate the most rework and the associated QA checklists.

Incident	Associated QA Checklist
sub-optimal dose calculation	QA 2 & QA 3 (element 5)
sub-optimal delineation of organs at risk	QA 1 (element 1)

5.2 Sensitivity Analysis

In this section we conduct a sensitivity analysis on the reliability of QA 1 checklist based on the "worst case" scenario. We define the "worst case" as the case when an incident starts during the consulting stage or pre-treatment planning stage, crosses all the QA checklists and reaches the patient during the treatment delivery stage. Table 10 shows the time interval between "worst case" incidents for different QA 1 reliability scores. The results clearly indicate that increasing the reliability score of QA 1, increases the time interval between the occurrence of "worst case" incidents.

Table 10: Time interval between "worst case" incidents.

QA 1 Reliability	Time Interval - Average (Days)	Time Interval - Minimum (Days)	Time Interval - Maximum (Days)	Half Width (Days)
0.85	20.36	7.64	37.60	4.84
0.90	28.42	7.64	109.66	10.32
0.93	38.70	10.42	185.32	19.23
0.95 *(base case)*	57.41	10.42	194.29	24.48
0.97	69.47	10.42	194.29	25.80

6 CONCLUSION AND RECOMMENDATIONS FOR FUTURE WORK

In this paper we presented a discrete event simulation-based analysis to assess the effect of the reliability of QA checklists on the RT care delivery process. QA checklists are recognized methods in radiation oncology for detecting incidents before they reach the patient. To estimate the incident rates and the reliability score for the QA checklists in the case study, we used data from the Good Catch program (a comprehensive safety program at UNC).

The simulation results show those incidents that start early in the process, specifically during the delineation of organs at risk and dose calculation steps, generate the most rework. The results also indicate that increasing the reliability of the QA 1 checklist reduces the number of "worst case" incidents, i.e., increasing the time between "worst case" incidents.

There are some limitations associated with this study: (i) we only considered one type of patient to identify the steps that cause the most rework, these results may be affected by the type of patient; and (ii), in order to assess the effect of different reliability scores on the time between "worst case" incidents, we only considered the QA 1 checklists and did not explore the effect of the reliability scores of other QA checklists on performance. Future work should address these limitations and explore the effect of changing the design of the process. It is important for incident prevention and detection to be designed into the process through an effective combination of QA checklists to reduce the chance that an incident reaches the patient.

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