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The utilisation of probabilistic risk assessment in radiation oncology

Gordon Sands[a,b], Enda F. Fallon[c], Wilhelm J. van der Putten[a,b,]*

[a]*Department of Medical Physics and Bioengineering, Galway University Hospitals, Galway, Ireland*
[b]*School of Physics, National University of Ireland, Galway, Ireland*
[c]*School of Engineering and Informatics, National University of Ireland, Galway, Ireland*

Abstract

The technology in radiation oncology has rapidly evolved over the last number of years. The increased complexity of the technology has brought with it increased risk. Systematic risk assessment techniques are now required to ensure the safe delivery of treatment with these new technologies. The risk assessment methodology proposed here combines portions of Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA) and human error probability modelling. The radiotherapy treatment process was modelled using the analysis described by Ford et al. [*Medical Physics* 39, no. 12 (2012): 7272-7290]. The output of the model is graphically represented to demonstrate the interactions and relationships between the individual tasks in the radiotherapy process. The components of each process were critically analysed to ascertain their fault potential. Prostate external beam treatment was used as a case study. The proposed methodology identified 34 error modes with the potential to affect the safe delivery of treatment. This method of risk analysis in radiotherapy is novel. It is highly beneficial in evaluating the effectiveness of the safety system currently in place in Radiotherapy. The human error probability is an estimated value which can vary under different conditions. The use of quantitative human error probability values enables the utilisation of mathematical methods to predict the effect of different interactions..

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Keywords: Radiotherapy; Probabilistic risk assessment (PRA); Human error; Risk assessment

* Corresponding author. Tel.: +00-353-91-544311; fax: +00-353-91-893320.
E-mail address: wil.vanderputten@hse.ie

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1. Introduction

Radiotherapy is common and effective treatment modality for cancer. Radiotherapy works on the radiobiological principle that by and large, cancer cells being treated are more sensitive to radiation damage than healthy, normal tissue. The treatments are fractionated to allow time for the healthy tissue to repair. The most common type of radiotherapy utilises beams of high energy xrays, created in a Linear Accelerator (Linac). The patient is placed on a bed and the machine delivers a high dose of radiation to the cancer tissue. Other types of radiotherapy exist as well such as electron therapy orthovoltage, brachytherapy etc., but this paper concentrates on Linac based radiotherapy. [1].

Since the introduction of Computed Tomography imaging in radiotherapy, the nature of treatments has evolved rapidly. These new treatment methods result in a greater accuracy and the suitability of radiotherapy for more patients. Examples of developments in radiotherapy are the introduction of the multi leaf collimator (MLC) which is used to shape the beam around the target allowing a more accurate treatment of the cancerous lesion. Dose delivery to the target improved with the introduction of Intensity Modulated Radiotherapy (IMRT). This was followed by Image Guided Radiotherapy (IGRT) which is now used to account for intra-fraction and inter-fraction organ motion. Intra-fraction organ motion refers to movement of organs between treatment fractions whereas Inter-fraction organ motion refers to the movement of organs occurring during treatment. The direct result of all these technologies is that target sizes can be reduced with a concomitant reduction of radiation dose to non target (healthy) tissue. The result of all these advancing technologies is a higher quality treatment with better outcome and less side effects. Paradoxically, the increased complexity has also lead to more room for error[2].

The risks surrounding the use of radiation have been well established. Between 1985-1987 a number of patients have been fatally injured directly arising out of their radiotherapy treatment. One of the more infamous were incidents with The Therac-25 Linac. The errors occurred due to the use of incorrect software. At least 5 people died [3].

Between August 2000 and March 2001 28 patients being treated for cervix and prostate cancer were overdosed in Panama in which 17 were lethal. In this case a new protocol for shielding blocks was introduced involving the treatment planning system. The introduction of this new protocol was not validated correctly and found later to be incorrect [4]. In February 2001 a Linac in Bialystok (Poland) malfunctioned overdosing a number of patients. No patients died from this incident however the tissue involved was seriously damaged [5]. In 2004, in France, an error involving the introduction of a new system for delivering wedge fields resulted in the overdose for a number of patients. The primary cause of this was the incorrect implementation of the wedges. Contributing factors included staffing levels, patient safety culture and incorrect planning [6]. In 2010 a patient in New York received a lethal radiation dose while being treated for tongue cancer. In this case a computer error resulted in the field size being reset. A large field was delivered to the patient instead of a series of small fields. This particular incident was highlighted in a series of New York Times articles that highlight safety in Radiotherapy [7]. This case received a lot of professional and media attention. This incident resulted in a series of initiatives to discuss and implement methods for improving safety in modern radiotherapy.

One way to minimize the chance of error (and thus risk) is through a rigorous Quality Assurance (QA) program. Quality Assurance traditionally is based on the measurement of deviations of selected machine parameters against specified tolerance limits. As the treatment delivery has become more complex, QA has equally become more complex. The focus of traditional QA on individual machine parameters without taking account of an overall "system view" is increasingly being called into question. It has for instance been argued that current quality assurance measures are outdated and in fact negatively affect patient safety [8]. The argument was made that the current system concentrates resources into one particular area and fails to look at the system as a whole; recognizing that very few errors are caused by not following rigorous QA documents and that indeed few of the tests have little bearing on patient safety. The counter argument to this is that while there is a limited value to some of these tests they do not negatively affect patient safety. A paper by Huq et al. commented on the use of Failure Mode and Effect Analysis (FMEA) and Fault Tree Analysis (FTA) as tools to specify where quality assurance resources should be directed [9]. The approach on using a system wide, risk based approach has the ability to incorporate not just machine based risk factors, but also allows for the incorporation of human factors as a component of the overall risk profile in radiotherapy. Human factors have been shown to be involved in the majority of serious incidents in radiotherapy. In this paper a system wide approach is taken, incorporating human actions as an important causal factor in the creation of risk

2. Methodology

A structured approach to risk assessment was developed based on best practice from other industries. This was done using a step based approach, the individual steps of which are described below.

2.1. Graphical representation of the system

The system is graphically represented using the process steps described by Ford et al[10] (see Fig. 1). The graphical representation is used to assess the process flow, the interaction of the patient with various tasks, the interaction of staff with tasks and the interaction of software and hardware with tasks.

2.2. Task analysis

The task analysis is used to analyse the parameters. They are analysed based on the potential error modes, contribution to treatment, input to task, output from task and where the potential error will iterate.

2.3. Human error probability estimation (Application of SPAR-H)

2.3.1. Nominal values

The probability of human error (HEP) was assessed using the method SPAR-H[11]. This method was chosen due to its ease of use compared to other HEP techniques. SPAR was developed for the nuclear power generation industry. There is little evidence of the use of the SPAR-H method in healthcare. However, its potential for use in fields outside of nuclear power has been recognized [12]. SPAR-H divides human actions in two distinct categories, actions and diagnosis. An action task is a task that can be described as:

"Guidance for action has to do with carrying out one or more activities (e.g., steps or tasks) indicated by diagnosis, operating rules, or written procedures."[11]

This is taken as having a nominal error rate of 0.001. By contrast, a diagnosis task is defined as:

"Guidance for diagnosis has to do with attributing the most likely causes of the abnormal event to the level required to identify those systems or components whose status can be changed to reduce or eliminate the problem." [11]

This is taken to have a nominal error rate of 0.01.

2.3.2. Performance shaping factors

The performance shaping factors (PSF) are used to increase or decrease the probability of an error occurring. There are 8 PSFs that are discussed in the SPAR-H protocol used in this assessment. Each of the PSFs will change the error rate.

1) *Available time* describes how rushed the task is. If the task has a limited amount of time to be completed then there is a higher probability that it won't be completed correctly. If a task has more time to be completed there is a higher chance that it will be successfully completed.
2) The *stress/stressors* can be represented as being either internal or external factors. There will be times when internal factors will affect individual stress due to factors that are outside the control of the department. However there are factors associated with the general layout of the department that can create a general stressful environment. Staffing levels, workload and personal relations within a department all can have a positive or negative affect on stress levels.

3) *Complexity* will depend on the task being performed. There are some parts of the radiation oncology process that have a high level of complexity which are more susceptible to error. This can be cancelled out by the high levels of training.
4) *Experience/Training* is self-explanatory. As people are more highly trained and gain more experience, they will be more used to performing the tasks. As a consequence of this they will be less likely to make a mistake.
5) *Procedures* are an assessment of the quality of the written protocols in place. Badly written procedures can lead to confusion and thus will increase the probability of error.
6) *Ergonomics/HMI* refers to both the general ergonomics of the place of work and the HMI. The high complexity of the software in radiotherapy and the constant interface between the staff and the software would suggest that the human machine interface will play an important role in the successful completion of tasks.
7) *Fitness for duty* is a variable that will change in an individual on a day to day basis. As this variable is constantly changing it is difficult to assess it on a macroscopic level unless there is some organizational variable that is affecting it.
8) *Work processes* refers to the management and administrative processes. The design of the work flow and the patient safety climate will both influence the probability of an error occurring.

2.3.3. Probability density functions

The human error probability is represented as a probability density function. The subjective nature of the assessment means that this will be represented as a constrained non-informative prior distribution as described originally by Atwood [13]. In SPAR-H this is represented in the form of a Beta distribution [11]. The information presented in the probability density function represents the probability of human error occurring, P(x). The probability density function is produced using a random number generator that is weighted to produce a Beta distribution based on the specified alpha and Beta values for the human error of the task. The method by which the alpha and Beta values are calculated are documented in the SPAR-H manual [11].

2.4. Fault tree analysis

In order to evaluate the propagation of error the mathematics used in fault tree analysis (FTA) techniques were used to assess the probability reaching various stages of the process. Individual error modes occurring in conjunction were treated as OR gates and are represented (for two inputs) as:

$$P(A\,.OR.\,B) = P(A) + P(B) - P(A)P(B) \tag{1}$$

Any safety checks in the system is then taken as an AND gate. This means that both the initial task and the checking task both have to be done incorrectly in order for an error to occur. The AND gate is represented by the following equation:

$$P(A\,.AND.B) = P(A)P(B) \tag{2}$$

The prior distribution is used as the input for the FTA analysis. The mathematical formalisms for the model were programmed in R [14]. The inputs were taken from the random number generator producing the PDFs as described in section 2.3.3.

3. Results

The full reliability model will take account of all the possible steps and tasks in the radiotherapy process. In this paper the results from a subset of the entire treatment process, treatment planning, is presented. Treatment planning is the process whereby the tumour is outlined and the radiotherapy beams are applied, following which the dose to tumour is calculated using computer algorithms. The treatment planning process was critically analysed on a task by task basis. The subtasks are identified and the potential error modes analysed.

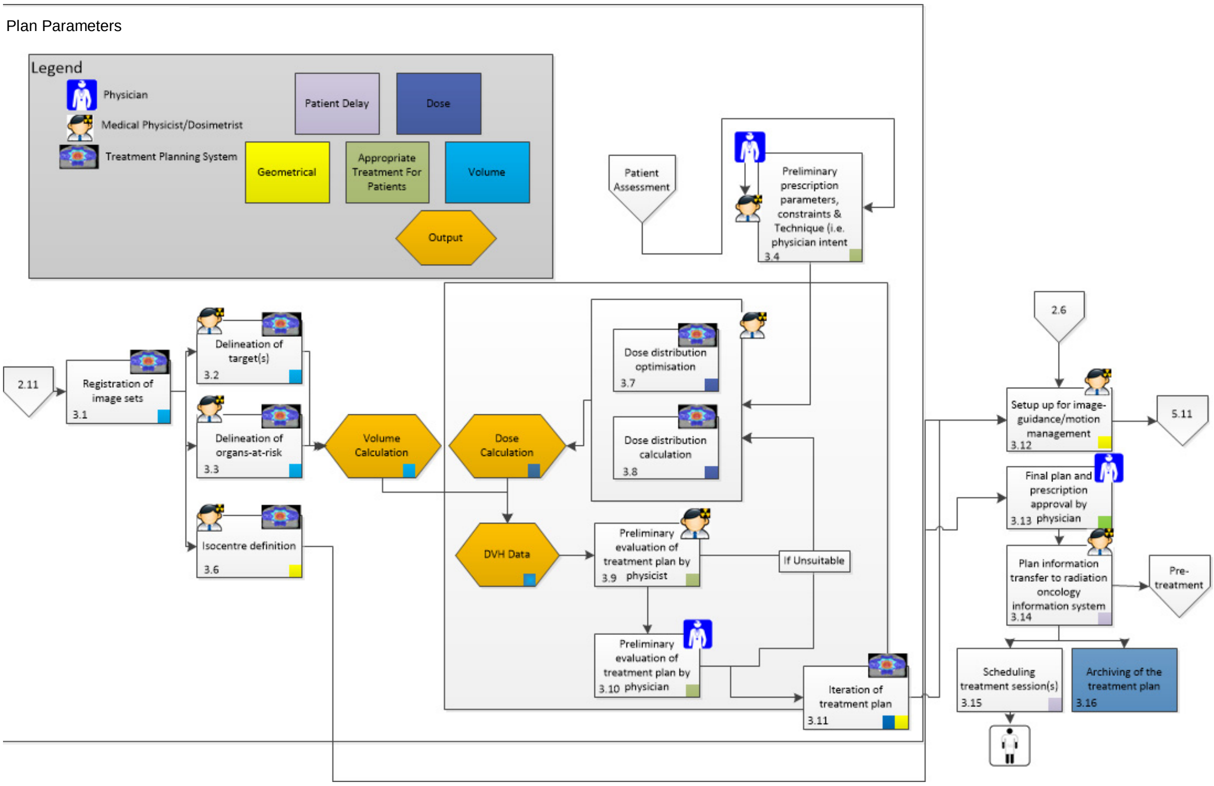

Fig. 1. Graphical Representation of Treatment Planning Process.

3.1. Graphical representation

The tasks were assessed as either a diagnostic task or as an action task. The performance shaping factors were analysed in conjunction with an experienced manager of the treatment planning section. A proportion of the PSF variables will fluctuate depending on the person completing the task. For example a senior member of staff will be more trained than a junior member. The complexity of the task will be dependent on the particular treatment plan required. For the example presented here, a 3D conformal radiotherapy plan for a radiotherapy treatment of the prostate is shown.

The process flow diagram for the planning task is shown in Fig. 1. The tasks are represented in the rectangles. The pictures attached to the boxes represent the involvement of staff and software involved in the treatment. The small square colours represent the type of error that can potentially occur as a result of unsuccessful completion of the task.

3.2. Task analysis

The diagram above allows for a generic task analysis for external beam planning based on the tasks described in [10]. The majority of these tasks will apply to all external beam treatments, although for some treatments there maybe changes. For the purposes of this example the prostate treatment is used as an example. A summary of the task analysis can be seen in Figure 2. The tasks were not all applicable to the department being evaluated. Figure 2 is colour coded based on the task. The colour code is summarised next to the figure. A quality event refers to a task that could have an effect on the quality of the plan but may not always be considered an incident.

Task			Purpose of Task	Error Mode	Probabiliy	Alpha	Beta	Input	Output	Required for treatment	Where the potential error
3 Treatment planning											
	3.7	Dose distribution optimization		Correct grid size	0.00025	0.5	1999.157	Images	DVH	Yes	Treatment
				Suitable leaf setup	0.00013	0.5	3999.157				
				Suitable normalisation point	0.02	0.493	24.16309858				
				Right Prescription Entered in Beam Calculation	0.00025	0.5	1999.157				
				Missed hotspots	0.004	0.499	124.1584				
				Coverage	0.004	0.499	124.1584				
				DVH Interpratation of Rectum v50	0.005	0.498	99.15871				
	3.8	Dose distribution calculation	Produce a suitable plan	DVH Interpratation of Rectum v60	0.005	0.498	99.15871				
				DVH Interpratation of Rectum v70	0.005	0.498	99.15871				
				DVH Interpratation of Rectum v75	0.005	0.498	99.15871				
				DVH Interpration of Left Femoral Head	0.005	0.498	99.15871				
				DVH Interpratation of Right Femoral Head	0.005	0.498	99.15871				
				DVH Interpratation of Sigmoid	0.005	0.498	99.15871				

Fig. 2. Summary of Task Analysis. Probability, alpha and beta coefficients from SPAR-H [11].

Following the task analysis the potential error modes were identified. Any error modes that result in an interlock of the system are not included, ie. if the error has no potential of affecting patient treatment but rather will prevent future tasks from being completed, it won't affect the patient but rather it will stop the process from being completed. The potential error modes for each task were identified and the effects of them on the full process. Across the 16 tasks identified based on the Ford paper a total of 34 potential error modes were identified. This includes the human error probability of a check not working correctly. The highest HEP value was 0.02, or 2 in 100 patients. This does not mean that this many patients will be mistreated. The value presented here is what happens prior to the pretreatment safety checks. These safety checks should reduce the amount of patients affected by the patient error.

3.3. Human error probability

The probability density functions were developed as described in the previous section. An example of one of them can be seen in Fig. 3. The example shown is that of an error of choosing a wrong normalization point in the treatment plan. The mean value for this human error probability was calculated to be 0.02 (represented by the blue line in Fig. 3). This was calculated from a Beta distribution for the 34 error modes identified. The mean value, alpha value and Beta value are all shown in Figure 2. This was compared to the number of such events which occurred over a 12 month period (collected as part of a Quality Assurance database). An analysis of the actual error rates revealed an error rate of 0.017 for this task (represented by the green line in Fig. 3).

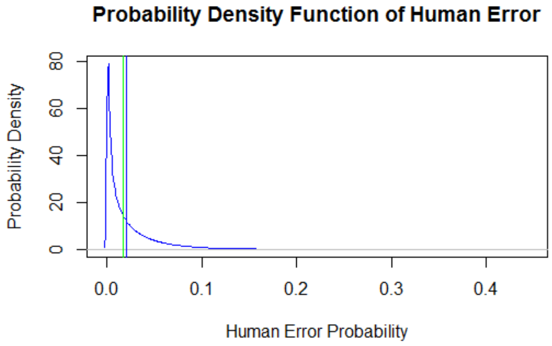

Fig. 3. Probability density function of the Human Error Probability of one particular task (an unsuitable normalisation point being used).

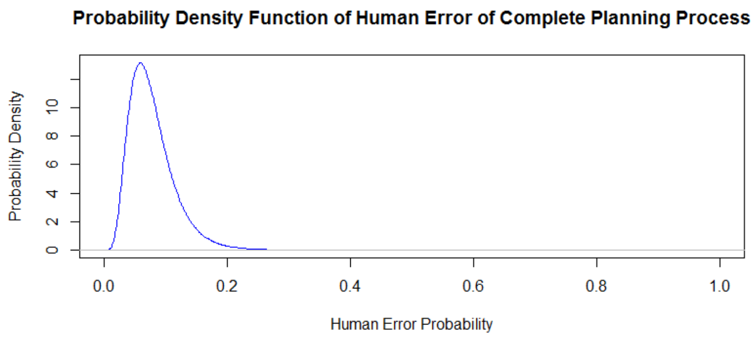

Fig. 4. Probability density function of the Human Error Probability of the overall treatment planning process.

3.4. Fault tree analysis

The PDF for all the error modes and safety checks were analysed for the task being investigated. Potential error modes were treated as OR gates while safety checks on any given error mode were taken as AND gates. The PDFs for the various tasks were then mathematically analysed producing a single PDF for the overall error probability of the treatment planning process. The overall PDF of an error occurring at the treatment planning process can be seen in Fig. 4.

The result of the calculated error probability show that typically 8% of treatment plans contain an error in any of the 34 identified error modes of the process. This is of course unacceptable and explains the necessity of independent error checking in the treatment planning process. It should not come as a surprise that such independent checking is common place in most radiotherapy departments.

4. Discussion

The model can be used to critically analyse the safety of a system. It is loosely based on tools from the nuclear industry such as SPAR-H and tools such as fault tree analysis (FTA) and Failure Mode and Effects Analysis (FMEA). Applying human error probability adds a quantitative approach. The inclusion of extra safety barriers and the effect of them on the probability of an incident occurring can be modelled using this method. This can be used to concentrate resources in areas where risk is higher. The model presented in this paper is a small sample of a larger risk model that evaluates the complete external beam radiation therapy process. There are a number of advantages to modeling error modes and error propagation;

- It allows for a quantitative approach to probability of incidents
- Error propagation and the interaction between tasks is clearer
- The baseline model produced can be easily adapted to other departments and or changed circumstances

As a possible disadvantage it can be argued that any model of Human Error Probability has a high level of uncertainty. Nevertheless, preliminary comparison of calculated error rates, with those actually found in this study show good agreement, leading us to have some confidence in the model. The model presented in this paper offers a solution to the on-going debate of addressing human error probability in healthcare/radiotherapy. The model takes performance shaping factors into consideration. It has been well established from the nuclear industry that taking large numbers of Performance Shaping Factors creates unrealistically small values for human error probabilities. In order to address this, other human error assessment methods limit the number of PSFs that can be included in the overall analysis. This will be the subject of further work.

5. Conclusions

This research demonstrates a systematic technique for process modelling with an emphasis on task analysis and safety. It evaluates the full treatment process thus ensuring patient safety. Calculating the effects of error propagation ensures that the system is assessed as a whole rather than as a series of isolated (sub-) systems. This model, although developed for radiotherapy, can be adapted to other well defined clinical processes. It offers a unique method to performing a full safety system analysis that can be used to ensure all clinical developments are safe prior to use.

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