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Failure modes and effects analysis applied to high-dose-rate brachytherapy treatment planning

D. Allan Wilkinson*, Matthew D. Kolar

Department of Radiation Oncology, Cleveland Clinic, Cleveland, OH

ABSTRACT

PURPOSE: To apply failure modes and effects analysis to high-dose-rate treatment planning to identify the most likely and significant sources of error in the process.

METHODS: We have made a list of 25 failure modes grouped into six categories (imaging, catheter reconstruction, dwell position activity, dose points/normalization, optimization/dose, and evaluation). Each mode was rated on a one to five scale for severity, likelihood of occurrence, and probability of escaping detection. An overall ranking was formed from the product of the three scores. The authors assigned scores independently and the resulting rankings were averaged. We also analyzed 44 reported medical events related to high-dose-rate treatment planning listed on the Nuclear Regulatory Commission Web site and compared them with our own rankings.

RESULTS: Failure modes associated with image sets, catheter reconstruction, indexer length, and incorrect dose points had the highest ranking in our analysis (scores higher than 20). The most often cited failure modes in the Nuclear Regulatory Commission reports examined were indexer length (20/44) and incorrect dose points (6/44). Several of our high-ranking modes are not associated with reported events.

CONCLUSION: It is a useful exercise to identify failure modes locally and analyze the efficacy of the local quality assurance program. Comparison with nationally reported failures can help direct the local analysis, but the absence or small number of reports for failure modes with a high score may be owing to low detectability. Such modes obviously cannot be ignored.

Keywords: Failure modes; High-dose-rate brachytherapy; Treatment planning

Introduction

High-dose-rate (HDR) brachytherapy often consists of simulation, treatment planning, and dose/time calculation, followed by treatment all in a short period of time. This situation added to regimens with high doses in few fractions implies considerable risk and makes it imperative that quality assurance (QA) practices are adequate to prevent harm to the patient.

Recommendations for QA of HDR treatment planning systems (TPSs) have been included in Task Group (TG) reports of the American Association of Physicists in Medicine, for example TG-56 (1) and TG-59 (2), as part of a code of practice for brachytherapy. A broad range of good practices and tests with suggested time intervals is provided to assist in establishing an HDR program and ensuring the continued safe use of the equipment. However, it is now being recognized that such a prescriptive mode of quality management may not be sufficient to prevent serious errors and may also be an inefficient use of physics time and resources. The application of various forms of risk analysis is currently under study by another American Association of Physicists in Medicine task group, namely TG-100.

Failure modes and effects analysis (FMEA) has long been a powerful tool for design engineers during all phases of product development and an important part of a comprehensive quality management program. However, its use in radiation therapy has been relatively recent. The application of FMEA to radiotherapy programs in general has been discussed in several publications (3–5) and specifically for intraoperative radiation therapy (6), stereotactic body radiotherapy (7), and intracavitary HDR brachytherapy (8). These last authors identified 20 processes that they felt were in need of immediate improvement, including

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* Corresponding author. Department of Radiation Oncology, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195. Tel.: +1-216-445-8289; fax +1-216-444-8934.

E-mail address: wilkina@ccf.org (D.A. Wilkinson).

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source strength measurement, machine and applicator QA, and aspects of treatment planning. We have focused on the treatment planning part of HDR brachytherapy because it presents the challenges of short time constraints combined with the need for accuracy, whereas machine QA and source calibration can usually be accomplished without the pressure of having patients waiting to be treated with applicators already in place.

A process such as FMEA that is under consideration in this work has several steps (9, 10). According to Rath (10), a system-level top−down approach consists of flow charting the major steps in the process, performing an FMEA on these steps to identify those with the highest probability of injury or failure and then use FMEA on the detailed processes within those identified major steps identified. In this work, we are examining one major step (treatment planning) in the HDR brachytherapy process. The detailed processes within treatment planning are subjected to FMEA in this study. These processes are reviewed and presented in the form of a flow chart. Ways in which a process can fail are called failure modes. Once a list of potential failure modes is made, the relative risk of a failure with its effects is determined by three factors, namely consequence of failure (severity), probability of failure (occurrence), and likelihood of detecting the failure before it occurs (detectability). Each factor is assigned a ranking score and then a risk priority number (RPN) is calculated as the product of the ranking numbers. Finally, a plan is developed to eliminate or reduce high-risk modes (9).

After we had used FMEA on our HDR treatment planning and evaluated our in-house QA procedures, we examined medical events related to HDR treatment planning in the Nuclear Regulatory Commission (NRC), United States online registry for comparison with our findings.

Methods and materials

The input data for the FMEA were generated by the two authors who together have more than 20 years of HDR planning and treatment experience, involving several hundred patients. This experience was obtained using both the Plato and Oncentra TPSs (Nucletron, an Elekta company [Elekta AB, Stockholm, Sweden]), and consequently the details in this article pertain to those two TPSs. Nevertheless, the basic steps of image acquisition, contouring, source dwell positioning, and prescription apply to other systems as well. Each author drew up a list of potential failure modes. The lists were discussed, edited, and combined, and then each failure mode on the list was evaluated independently by each author for severity, occurrence, and detectability likelihood. The scoring system we used is found in Table 1. We based the severity scoring on the most recent National Cancer Institute Common Terminology Criteria for Adverse Effects handbook (11). The scoring was done with the assistance of Radiation Oncologists in our department. The occurrence scoring is based on an estimate of the fraction of treatment plans affected and is in line with previous suggestions (3, 4). The lists were combined and where necessary, items missing on one list were then also scored by the other physicist. Both authors identified the same failure modes as having high risks. Scores were then averaged. It should be noted that with our scoring system of one to five (based on the severity list), the maximum RPN is 125 rather than the 1000 that comes from the more commonly used 1−10 system. Although this results in a reduction in apparent sensitivity, it should be emphasized that scoring is somewhat subjective and increased sensitivity may not be warranted. For example, Ford *et al.* (4) used a 1−10 scoring but had only four detectability categories.

Table 1
Description of the scoring system used in this study

Score	Description
Severity	
5	Grade 5: Death related to adverse event
4	Grade 4: Life threatening; urgent intervention indicated
3	Grade 3: Severe or medically significant but not immediately life threatening; hospitalization required
2	Grade 2: Moderate; minimal, local, or noninvasive intervention
1	Grade 1: Mild, asymptomatic or mild symptoms; intervention not required
Occurrence	
5	Very likely (>5%)
4	Likely (2−5%)
3	Somewhat likely (1−2%)
2	Somewhat unlikely (<1%)
1	Unlikely ($<10^{-4}$)
Detection	
5	Highly unlikely (<10%)
4	Unlikely (10−20%)
3	Somewhat likely (20−60%)
2	Likely (60−90%)
1	Very likely: Software/hardware interlocks (>90%)

After we had completed our FMEA, we examined medical event reports on the NRC Web site (12) for HDR-related events for the years 1999 to the present. Those in which treatment planning errors were cited were selected and assigned to the relevant failure mode. Because some reports were lacking in sufficient detail, there is some ambiguity in the assignments.

Results

Figure 1 shows our usual treatment planning (forward planning) in the form of a chart that reflects the workflow of the Oncentra planning system. Table 2 is a list of 25 failure modes arranged according to the steps of the planning process. They were scored for severity, occurrence, and detectability, and RPN calculated. The results are displayed in Table 2 and Fig. 2. Differences greater than one between the authors in detectability scores were recorded for failure modes 1, 4, 8, and 20. The highest RPNs were