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CANRAD-3741; No. of Pages 7

ARTICLE IN PRESS

Cancer/Radiothérapie xxx (2017) xxx–xxx

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Original article

Implementation of failure mode and effective analysis for high dose rate brachytherapy at Tata Memorial Hospital, Mumbai, India

Mise en place de l'analyse des modes de défaillance et de leurs effets au Tata Memorial Hospital (Mumbai) pour les curiethérapies de haut débit de dose

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A R T I C L E I N F O

Article history:
Received 5 May 2018
Accepted 15 May 2018

Keywords:
Failure mode and effective analysis
High dose rate
Brachytherapy
Patient safety

A B S T R A C T

Purpose. – To report our experience of failure mode and effective analysis for high dose rate brachytherapy of gynaecological cancer carried out in our hospital.
Materials and methods. – Failure mode and effective analysis process described in AAPM TG 100 was followed: a multidisciplinary team consisting of two physicians, physicists, dosimetrists, a medical resident, a nurse, and a secretary was formed. A weekly meeting was held for four months. A process tree was created based on the overview of the entire process, with the main branches as follows: procedure in the operating room, patient imaging, contouring, treatment planning, machine quality assurance and treatment delivery. Each team member assigned the risk probability numbers based on the predefined scoring system. For a particular failure mode, if the risk probability number assigned by one member differed from the other, the highest risk probability number was taken into consideration.
Results. – The process tree consisted of 185 nodes, with risk probability numbers ranging from 1–220, with 77 possible failure modes. Four nodes were found with risk probability numbers greater than 200, which were considered for immediate process improvements. Twenty-four nodes were found to be with risk probability numbers ranging from 100 to 200. All 24 processes were considered for process improvement, out of which 12 were found effective and feasible, which includes failure nodes with high severity score at least 8. The processes with high-risk probability numbers (greater than 200) were reduced after the introduction of process improvements. For the other processes, standard procedures were modified. The common causes of failure, were found to be due to lack of attention, human error and work pressure.
Conclusions. – Failure mode and effective analysis is a useful tool that uses a systematic approach for quality management of a specific process.

Mots clés :
Analyse des modes de défaillance
Haut débit de dose
Curiethérapie
Sécurité

R É S U M É

Objectif. – Cet article a pour objectif de rapporter l'expérience d'analyse des modes de défaillance et de leurs effets mise en place dans notre hôpital lors de la curiethérapie de haut débit de dose des cancers gynécologiques.
Matériels et méthodes. – Le procédé d'analyse des modes de défaillance décrit dans le rapport de l'American Association of Physicists in Medicine TG 100 a été suivi : une équipe multidisciplinaire a été constituée, consistant en deux médecins, des physiciens, des dosimétristes, un interne de médecine, un(e) infirmièr(e) et un(e) secrétaire. Une réunion hebdomadaire s'est tenue pendant quatre mois. Un arbre de processus a été créé à partir de l'étude du procédé complet, avec les branches principales comme suit:

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https://doi.org/10.1016/j.canrad.2018.05.001
1278-3218/

Please cite this article in press as: Swamidas J, et al. Implementation of failure mode and effective analysis for high dose rate brachytherapy at Tata Memorial Hospital, Mumbai, India. Cancer Radiother (2017), https://doi.org/10.1016/j.canrad.2018.05.001

procédure dans le bloc opératoire, imagerie du patient, délinéation, planification, assurance de qualité de la machine, et réalisation du traitement. Chaque membre de l'équipe attribuait un nombre de priorité du risque, défini sur un système de score prédéfini. Pour un mode d'échec particulier, si le nombre de priorité du risque attribué par deux membres de l'équipe différait, le score le plus élevé était pris en considération.
Résultats. – L'arbre de processus a consisté en 185 nœuds, avec des nombres de priorité du risque compris entre 1 et 220 et 77 modes de défaillance possibles. Quatre modes de défaillance ont été retrouvés avec un nombre de priorité du risque supérieur à 200, lesquels étaient considérés pour un processus d'amélioration immédiate. Vingt-quatre modes de défaillance présentaient des nombres de priorité du risque compris entre 100 et 200. Ces 24 modes de défaillance ont été considérés pour des améliorations du processus, parmi lesquels 12 ont été montrés comme faisables et efficaces, incluant des modes de défaillance avec un score de sévérité d'au moins 8. Les modes de défaillance avec des nombres de priorité du risque élevés (supérieur à 200) ont été diminués après l'introduction d'un processus d'amélioration. Pour les autres modes de défaillance, les procédés standard ont été modifiés. Les causes fréquentes de défaillances étaient principalement dues à un défaut d'attention, une erreur humaine, ou une pression de travail.
Conclusions. – L'analyse des modes de défaillance est un outil utile qui repose sur une approche systématique de management de la qualité d'un processus spécifique.

1. Introduction

Cervical cancer is the most common cancer among women in India and Tata Memorial Hospital treats a large number of patients of cervical cancer with high dose rate brachytherapy [1]. Although the procedure is well established, the recent transition from 2D to 3D, CT/MR image based dosimetry, introduction of new applicators, new planning systems/algorithms, multiple planners, and growing patient numbers suggested for a more systematic approach for quality control/management.

Ford et al. estimated that there is approximately 0.2% rate of misadministration in the United States in radiation oncology [2]. That works out to about 1 in every 600 patients. However, when compared that to a US commercial airline, which works out to approximately 1 in 10 million. While a misadministration does not directly correlate to patient injury or death in the medical field, this statistics alone should demonstrate the need for formal, prospective methodologies to anticipate and mitigate accidents in radiation oncology; there are a variety of patient safety improvement strategies that have been suggested for implementation in medicine, and more specifically, radiation oncology. Recommendations from the American Association of Physicists in Medicine (AAPM) in their Task Group 100 report describes risk analysis such as failure mode and effective analysis (FMEA) and fault tree analysis [3]. Meanwhile, in publication 112 from the International Commission on Radiological Protection (ICRP), failure mode and effective analysis along with probabilistic safety assessment and risk matrices are recommended [4].

Failure mode and effective analysis is a risk analysis tool used in many industries, including medical device manufacturing, airline travel, nuclear power, etc [4]. Failure mode and effective analysis was first developed by the United States military and an early adopter of this formalism was the US National Aeronautics and Space Administration (NASA) for a large number of its programs. It was then used by the civil airline industry and adopted by the Society for Automotive Engineers (SAE). Since then, failure mode and effective analysis has seen widespread adoption by a variety of industries such as healthcare, aerospace, motor vehicles, semiconductors and agriculture. At the time of this writing, a quick Google scholar search for "FMEA Radiation Therapy" results in over 100 000 different "hits". Failure mode and effective analysis has been applied to tomotherapy, proton therapy, image guided radiotherapy, dynamic multileaf collimator tracking, stereotactic radiosurgery, intraoperative electron therapy and finally, sparsely in brachytherapy [5–13]; essentially it may be used for analysis of any radiation delivery technique.

It is also very important to realize that there is no "standard" clinic, resources and workflow can differ considerably at each institution, leading to large variability in rankings of risks, or different failure modes altogether. Therefore, it is crucial that each institution perform a prospective risk analysis using currently allocated resources and current workflow to assist in identifying potential areas of risk or hazard [14].

One of the largest issues with implementation of such a program can be institutional culture. Creating and developing an effective safety culture can be the key component in setting up a program. It is much easier to find errors or potential errors if the staff feels empowered to report unsafe circumstances, so there needs to be a safe and easy mechanism to report information in a non-punitive environment. However, this takes cooperation and buy-in from administration leaders at the top levels and effective communication of the program through all ranks. Recently, we have started an incident reporting program in our department, which allows the staff members to report in a non punitive environment. However, the current analysis was carried out few years ago, when there was not much awareness in the department about the safety culture. Hence, we consider that it was an important task, to carry out this analysis for high dose rate brachytherapy for cervical cancer, a potential site for errors since large number of patients are being treated with multiple numbers of planners on rotation.

2. Materials and methods

Failure mode and effective analysis is a prospective risk management tool that helps users to identify key failure modes, their cause(s), and the risk or hazard associated with them; with the risk assessed quantitatively based on three parameters: frequency, detectability, and severity. Frequency is how likely the particular failure mode is likely to occur, detectability is how likely the failure mode would be detected with current procedures in place, and the severity is the severity of the outcome such as no effect or death of patient or staff, in the case of healthcare.

A brief overview of the process of failure mode and effective analysis is described as follows.

2.1. Process tree

The first step in failure mode and effective analysis analysis is to generate a process tree. A process tree is an overview of the entire process under analysis. The process tree also referred as process map [3]. It can be generated by considering the entire workflow