

# Failure mode and effects analysis of skin electronic brachytherapy using Esteya<sup>®</sup> unit

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## Abstract

**Purpose:** Esteya<sup>®</sup> (Nucletron, an Elekta company, Elekta AB, Stockholm, Sweden) is an electronic brachytherapy device used for skin cancer lesion treatment. In order to establish an adequate level of quality of treatment, a risk analysis of the Esteya treatment process has been done, following the methodology proposed by the TG-100 guidelines of the American Association of Physicists in Medicine (AAPM).

**Material and methods:** A multidisciplinary team familiar with the treatment process was formed. This team developed a process map (PM) outlining the stages, through which a patient passed when subjected to the Esteya treatment. They identified potential failure modes (FM) and each individual FM was assessed for the severity (S), frequency of occurrence (O), and lack of detection (D). A list of existing quality management tools was developed and the FMs were consensually reevaluated. Finally, the FMs were ranked according to their risk priority number (RPN) and their S.

**Results:** 146 FMs were identified, 106 of which had RPN  $\geq 50$  and 30 had S  $\geq 7$ . After introducing the quality management tools, only 21 FMs had RPN  $\geq 50$ . The importance of ensuring contact between the applicator and the surface of the patient's skin was emphasized, so the setup was reviewed by a second individual before each treatment session with periodic quality control to ensure stability of the applicator pressure. Some of the essential quality management tools already being implemented in the installation are the simple templates for reproducible positioning of skin applicators, that help marking the treatment area and positioning of X-ray tube.

**Conclusions:** New quality management tools have been established as a result of the application of the failure modes and effects analysis (FMEA) treatment. However, periodic update of the FMEA process is necessary, since clinical experience has suggested occurring of further new possible potential failure modes.

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**Key words:** electronic brachytherapy, Esteya, FMEA, QA, skin cancer, TG-100.

## Purpose

Esteya<sup>®</sup> (Nucletron, an Elekta company, Elekta AB, Stockholm, Sweden) is an electronic brachytherapy device that has been recently introduced for treatment of non-melanoma skin cancer. Clinical use and quality control of this equipment, which have been described in other research papers [1,2,3,4,5], are based on complying with the recommendations of the Task Group 40 report of the American Association of Physicists in Medicine (AAPM) [6], in which quality control of radiotherapy equipment is described. These controls consist of periodic assessment of certain parameters, whose baseline values are established during the period of acceptance and commissioning of the equipment, within certain tolerances.

In the case of brachytherapy equipment, the Task Group 56 report of the AAPM [7] describes the procedure for performing the acceptance and commissioning test of the equipment. Furthermore, the booklet published by the European Society for Radiotherapy & Oncology (ESTRO) and the Groupe Européen de Curiethérapie (GEC) [8] is useful for practical implementation of quality control of brachytherapy equipment.

Traditionally, quality control in radiotherapy has been based on the measurement of certain parameters with different periodicities, and with certain restrictions on their tolerance [6,9]. However, recent reports have revealed that many of the incidents in radiotherapy are caused by problems occurring during the various steps, through which the patient passes from the initiation to

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the conclusion of treatment rather than due to failures in a particular parameter that is detectable by traditional physical controls [10,11,12]. For this reason, a change in the methodology of quality management in radiotherapy is required, which makes it appropriate and necessary to consider the option of adapting quality control to each individual unit according to a risk analysis of the specific treatment undertaken [13,14,15].

The Task Group 100 of the AAPM (TG-100) [13] proposes to adapt the quality assurance (QA) program to the potential specific facility risk scenarios. To do this, a practical methodology for risk assessment of individual units of risk of exposure resulting from the specific treatment processes needs to be followed. Risk analysis in radiotherapy examines potential errors, their causes and consequences throughout the treatment process. In addition, it allows for the sharing of facility resources, in terms of unit and staff time, since redundant or unnecessary checks are avoided.

The methodology of risk analysis described by the TG-100 [13] proposes to solve the lack of synchronization between new techniques in radiotherapy treatment and the safety (including past failures), offering a prospective approach, establishing safety principles based on possible potential failures. The common characteristics of radiotherapy equipment used in different centers require similar quality checks regarding the parameters to be measured and tolerances established in the regulations. However, the wide variability of processes carried out in different centers, highlights the need to adapt the QA program to the specific conditions of the center. In this regard, an ideal solution would be to establish an assurance program based on risk analysis at individual centers, considering their processes, resources, and quality requirements. However, these limitations of time and resources must not result in a decline in the safety of the facility. On the contrary, risk analysis is used to make the most of these resources, avoiding redundant controls, and adding new checks to improve the safety of the patient and the quality of the treatment.

In the same vein, the European Commission issued the publication 181 in the radiation protection series, on risk management in external beam radiotherapy, which was formally endorsed by ESTRO. This report [14] exposes a risk analysis methodology based on the development of matrices, which result oriented about the priority in implementing control measures at each stage of a process.

In recent years, some centers have performed risk analysis of certain techniques and procedures implemented in their facility, detecting potential failure modes that were not included in the initial setting of the QA program [15,16,17,18,19,20,21,22,23,24,25,26]. In the context of the aforementioned, a risk analysis of the process associated with the treatment of skin lesions using the Esteya electronic brachytherapy system in our institution has been done.

## Material and methods

Esteya is an electronic brachytherapy unit that has recently been introduced in the radiotherapy environment to

treat non-melanoma skin lesions. This device emits X-rays of 69.5 kVp through an applicator, which collimates the treatment area, allowing the treatment of field diameters ranging from 1 to 3 cm. In our center, the absorbed dose prescribed to treatment of skin lesions by Esteya is 42 Gy at 3 mm or 4 mm depth, depending on the lesion thickness of the lesion. Treatment is given in 6 fractions with 7 Gy per fraction. This treatment regimen demonstrated satisfactory clinical results [1,2,4]. For treatment planning, the user must enter only the prescribed dose, the number of fractions, the prescription depth, and the selected applicator. The device calculates the irradiation time required to deliver the treatment fraction, which does not allow direct alteration by the user. Esteya is a single unit in which the user can not modify directly the treatment time. The treatment set-up for Esteya is shown in Figure 1. Note that the applicator, which is located on the output surface of the articulated X-ray tube, must exert pressure on the skin surface of the patient, which ensures fixation and prolonged contact during the treatment.

The adaptation methodology program for QA to the risks of the facility proposed by the TG-100 is based on three main tools: the process map (PM), failure modes and effects analysis (FMEA), and the fault tree analysis. These three tools are used to understand the process in depth and systematically analyze the risks involved. For this purpose, a multidisciplinary team was formed consisting of radiation oncologists and medical physicists familiar with the process and involved at some stage of the treatment. In our center, the team consisted of seven people who held regular meetings to ensure an understanding and familiarity with the method of analysis.

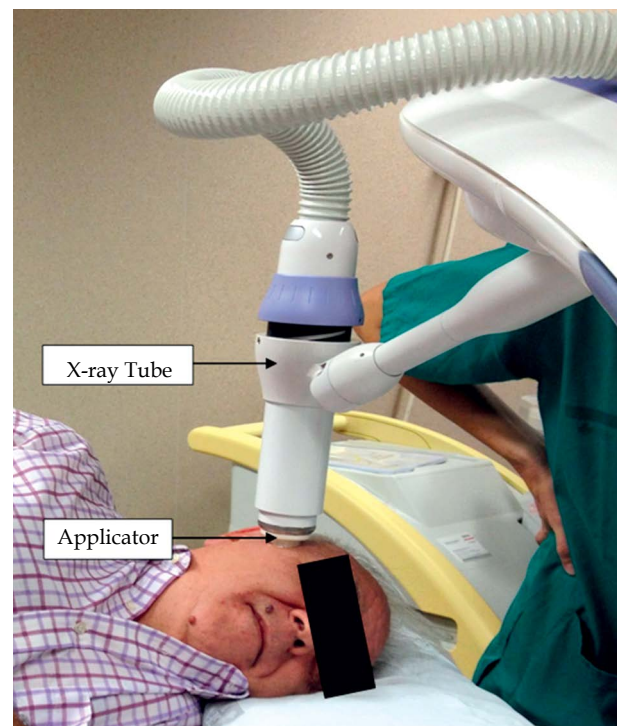


Fig. 1. Treatment set-up for skin lesions using Esteya® (Nucletron, an Elekta company, Elekta AB, Stockholm, Sweden) unit

First, an initial process map was proposed, which involved visual representation containing different stages in chronological order experienced by a patient from the beginning of treatment by the radiotherapy department until the conclusion. The PM is composed of a series of sequential "stages", which are formed from the different "steps". The PM was developed iteratively by some members of the group, and once an understanding in terms of the level of detail was reached, the information was shared and modified by mutual agreement. In turn, this helped the general understanding of the process by those members who were unfamiliar with some aspects of the PM. In addition, it was emphasized that the PM was an eminently practical tool, given its usefulness as a structure for understanding and support. Thus, it should be continuously assessed throughout the analysis, allowing the removal/additions of some branches if necessary. But always submitting these modifications for discussion by the group.

After securing the understanding of the stages and steps referred to in the PM, a brainstorming was performed regarding possible failures, called failure modes (FM), that could occur in each of the proposed steps. FMs are all ways in which a step may fail, defining "failure" as any unwanted event having an adverse impact at the end of the process. The causes and consequences of each of these FMs were evaluated, with a restricted number of causes and consequences described in Table 1, which is based on the causes and consequences suggested by the TG-100, with some slight modifications. The reason for

limiting the number of causes and consequences is intended not only to avoid naming similar causes with a different nomenclature, but mainly, since it allows for the subsequent objective evaluation of FMs, avoiding bias by the different evaluators.

Initially, these FMs were subject to an individual assessment by each of the members who scored by severity (S), probability of occurrence (O), and probability of non-detection (D) for each of the FMs, based on a table published in the TG-100, similar to Table 2. The first evaluation was done with the process not subjected to any quality control checks except those inherent to the computer software, which had no deactivation option. The product of S, O, and D gives a risk priority number (RPN), which each evaluator is assigned to a FM. Finally, the average values of S, O, D, and RPN were assigned to different FMs. In addition, the standard deviation of the values S, O, D assigned by evaluators for each FM were analyzed. FMs, in which the standard deviation was equal or higher than one, were discussed by the multidisciplinary team in order to establish an agreed value. After this evaluation, a list of quality management tools that were used in the facility was completed, and the values of O and D were reevaluated by consensus, quantifying the protection that these tools offer.

The FMs were sequenced according to their final RPN. As on other analyses published [15,16,17,18,19,20,21,22,23,24,25,26], a threshold value of RPN and S was chosen, above which the number of FMs was manageable to analyze these failures more thoroughly. FMs with  $RPN \geq 50$  were prioritized and new tools for quality management were proposed to avoid a recurrence. Similarly, the FMs with  $S \geq 7$ , even with a relatively low RPN value, were also given priority because it was deemed necessary to implement the corrective action.

**Table 1.** Causes and effects used in failure modes and effects analysis (FMEA) adapted from TG-100

Causes
Inadequate training
Lack of written procedures
Inattention
Heavy patient workload
Equipment or software malfunction
Uncomfortable patient position
No sufficient attachment elements
Applicator ID deteriorated
Effect
Wrong dose distribution
Wrong absolute dose
Suboptimal plan
Legal issues
Inconvenience – patient
Wrong treatment delivery
Skin infection
Inconvenience – staff

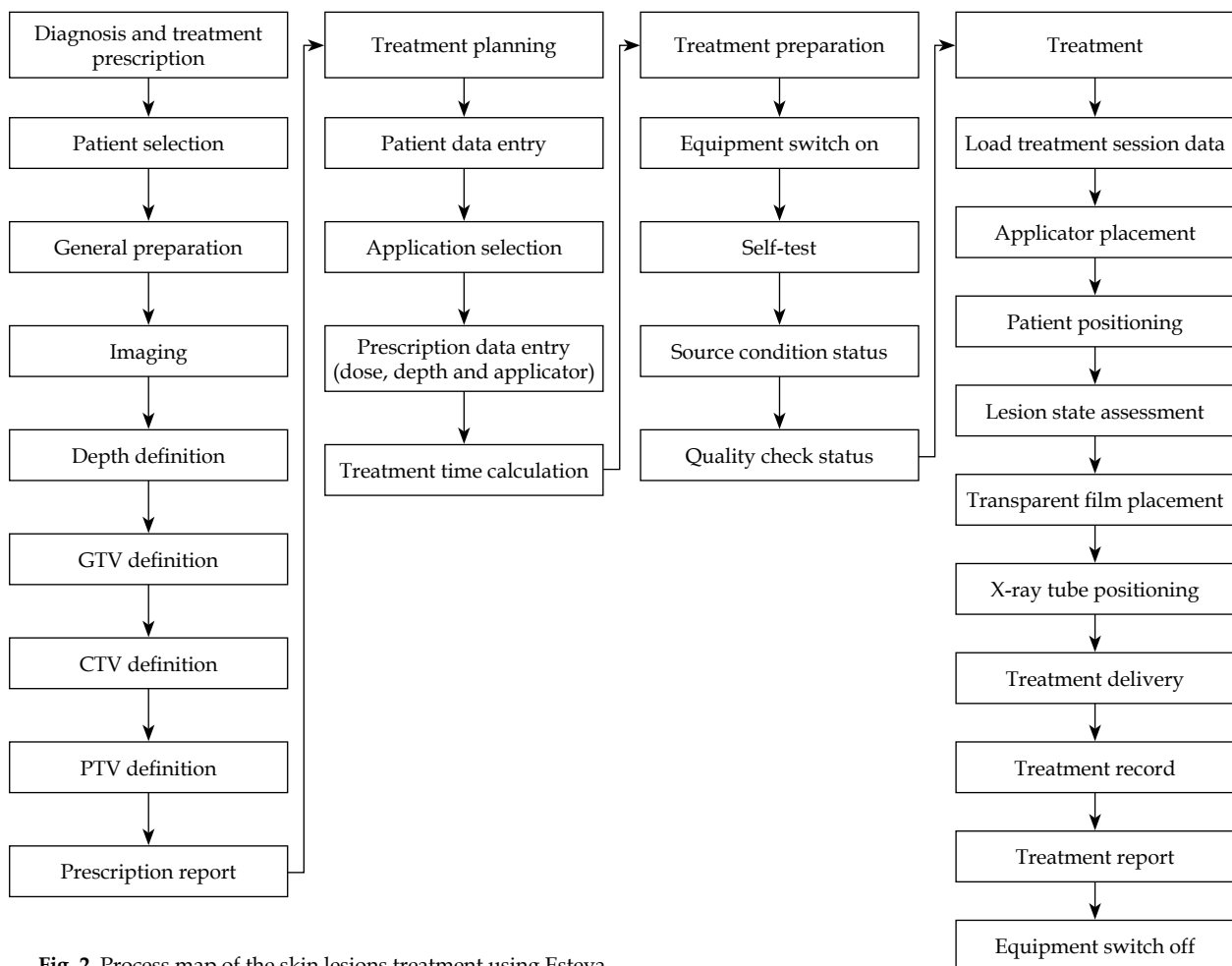
## Results

The PM showing the different stages through which the patient passes (capital letters) and the different steps experienced (lowercase letters) are presented in Figure 2. The first two stages ("diagnosis and treatment prescription" and "treatment planning") are performed only once throughout the entire process of treatment, while the third stage ("treatment preparation") is conducted once a day for all stages of the different treatments that take place that day. The last column ("treatment") stands for treatment performed at each stage.

146 FMs were identified, taking into consideration that each FM with different causes or consequences is classed as a different FM. Supplementary Table 3 online shows the different FMs in chronological order with the average values of the factors O, S, D, and the RPN. Values in parentheses are mean values prior to the application of the quality management tools, while the values obtained after the reassessment are expressed outside the parentheses. These quality management tools are shown in Table 4. Before introducing the tools of quality management, the average RPN values ranged between 13 and 178. Of the 146 evaluated types of failure, 43 had a  $RPN \geq 100$  and 106 had a  $RPN \geq 50$ .

**Table 2.** Descriptions of the occurrence (O), severity (S) and detectability (D) values used in TG-100 failure modes and effects analysis (FMEA) [13]

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Category	
1	Failure unlikely	0.01	No effect	Inconvenience	0.01
2		0.02			0.2
3		0.05			0.5
4	Relatively few failures	0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		< 0.2	Limited toxicity or tumor underdose		2.0
6	Occasional failures	< 0.5	Potentially serious toxicity or tumor underdose	Wrong dose, dose distribution location or volume	5.0
7		< 1			10
8		< 2			15
9	Repeated failures	< 5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20
10		> 5			Catastrophic



**Fig. 2.** Process map of the skin lesions treatment using Esteya

**Table 4.** Quality management implemented tools

1	Adequate training
2	Recheck treatment indication
3	Previous first treatment fraction to check patient's agreement
4	Adequate protocols and supervision to claim for the required attention
5	Checklist of each procedure
6	Standard communication paper between doctor and medical physicist
7	Check the plan with an independent evaluation
8	Periodic quality audits
9	Periodic refresh training
10	Templates clearly labeled and with rulers in main axis
11	Independent treatment time calculation with spreadsheet
12	Second revision of the calculated treatment time by another medical physicist
13	Threshold prescription depth (3 mm selected for depth smaller than 3 mm)
14	Zoom TV of treatment area
15	Second TV controlling the patient position
16	Picture of patient face
17	Lesion identification picture
18	Set-up picture
19	Identification by voice of patient: first and family name
20	Quality assurance graphic: the number of fractions, planning of treatment, and accumulated dose are reviewed for each patient
21	Flatness and symmetry of the applicator of 3 cm
22	Periodic output and percentage depth dose curves
23	Automatic detection of the applicator placed on the head software

Considering the quality management tools implemented in the facility, the values of O and D were reevaluated, thus changing the average value of the RPN for each FM, now ranging from 2 to 126. Of the 146 evaluated FMs, 3 had a RPN  $\geq 100$  and 21 had a RPN  $\geq 50$ . These 21 FMs, shown in grey in supplementary Table 3 online, were examined more thoroughly to propose additional solutions that would minimize the risk of the process.

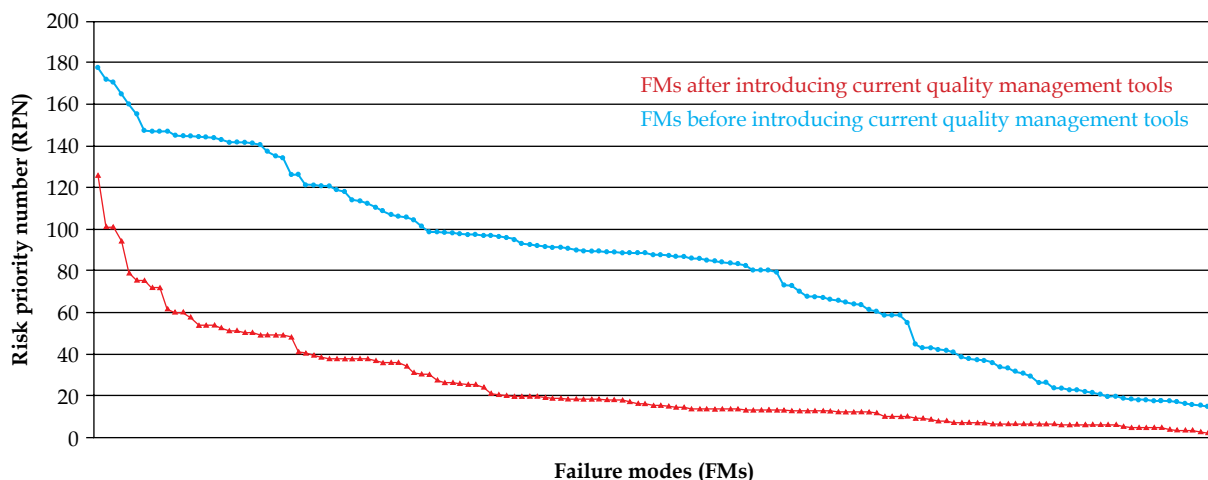
The mean values of the RPN in the different FMs evaluated individually prior to the introduction of the management tools (Figure 3 in blue), show a linear decrease with a gentle downward slope without sudden drops. However, after the introduction of the quality management tools, the slope between the FMs (which were evaluated collectively) with a higher average value of the RPN becomes steeper (Figure 3 in red).

The number of FMs, which were examined in detail were  $S \geq 7$  30. The quality management tools did not diminish the S of the FMs, therefore these should be compensated with lower values of O and D.

## Discussion

Producing a PM was found to be very useful to examine the process from the patient's perspective as recommended by the TG-100 [13], analyzing chronologically the different stages involved [2]. To ensure an understanding of each of the steps and the unanimity of the component activities, the development of an attached document is recommended detailing the specifics of the process reached by consensus. This document should always accompany the diagram, which should not lose its schematic purpose [13].

The values of the RPN after the initial application of the control tools, shown in red in Figure 3, exhibit a "plateau" in the low value area because the RPN values of most FMs decrease when control tools are implemented and so more failures are grouped in the lower areas. This contrasts with the values of the RPN prior to the introduction of the management tools (Figure 3 in blue), which



**Fig. 3.** Graphical representation of the risk priority number (RPN) average values, before the introduction of the quality management tools (blue circles) and after its implementation (red triangles). This graph shows the overall decline in the value of RPN of the modes of failure, that after the initial application of the quality management tools, are accumulated in low RPN values

decreases with a gentle downward slope because they are not concentrated in areas of low RPN value.

It should be noted that some of the essential quality management tools implemented in the procedure have been the simple templates for reproducible positioning of skin applicators (quality management tool number 10 in Table 4). These templates are transparent acrylic sheets, with two concentric circles. The inner circle must contain the entire lesion, since it delimits the useful area of the selected beam applicator, while the outer circle delimits the position of the applicator on the patient and allows the replication of the same position of the X-ray tube in all treatment fractions [27]. The FMEA shows that these templates can significantly reduce the risk of the process because their use considerably reduces the RPN of the FM "inadequate applicator" of the "applicator selection" step, and the FM "offset X-ray tube" of the "X-ray tube positioning" step. In the latter FM, the decrease of the RPN value is more remarkable, moreover it is one of the FMs that initially had a greater risk priority number.

A detailed analysis of the 21 FMs with a higher than RPN value ( $RPN \geq 50$ ) after application of the quality management tools, showed that the most common cause of these FMs was "heavy patient workload", since this occurred in 18 of the 21 FMs analyzed. The difference between "heavy patient workload" and "inattention", and the probability that a FM is undetected is very subtle, but it exists. The "heavy patient workload" may cause a general lack of attention on the part of staff, while the "lack of attention" has been found to affect only an individual patient. Therefore, when a double-review is assumed during the stages of the process, the review would be more effective if the fault is "inattention" as opposed to "heavy patient workload".

This analysis also corroborated that most of the FMs with a high average value of RPN are produced by human causes, which had already been shown in other similar risk analyses [13,16]. Following the analysis of these 21 FMs, new tools for quality management were proposed. Among these were: 1. Ask the patient if the treatment position is comfortable. With a photo of the patient position taken, the same degree of comfort at all sessions should be expected although it may not be easy to obtain exactly the same position. A solution is proposed, therefore, to consult the patient regarding the level of comfort before each treatment session; 2. Properly immobilize the patient area to be treated; 3. Examination of the template mark on the patient's skin around the lesion by a second physician before the first treatment session; 4. Set-up revision before each session by another staff member. The patient's position is reproducible from the photo taken but it is appropriate that this should be verified with the lesion, mainly in patients with multiple lesions. In addition, the X-ray tube pressure should be verified, since the lack of head pressure generates an air gap between the head and the lesion, and a lack of uniformity on the input surface of the lesion leads to an inadequate dose distribution; 5. Periodic monitoring of X-ray tube pressure. A quality control should be implemented to verify that the X-ray tube pressure is constant throughout treatment.

This analysis supports the need to pay particular attention to the potential FMs in the early stages of

treatment [17]. The 21 FMs with a higher than RPN value ( $RPN \geq 50$ ) that refer to the stages of "diagnosis and treatment prescription" and "treatment planning" are extremely serious and their occurrence affects the rest of the treatment. Therefore, it is advisable to pay special attention during these treatment steps. A solution to attempt to reduce the RPN of these FMs would be to include in the protocol a note in red, drawing the attention of staff to the problem and emphasizing the importance of this particular stage.

In this study, we initially opted for the individual assessment of the FMs, carried out by each of the team members. The possibility of performing this initial assessment collectively, to ensure the general understanding of the method and process by all the members was estimated; but this proposal was rejected because of bias that can arise during this type of assessment [16]. The calculation of the standard deviation to assess the discrepancy in the allocation of values of different members is considered a useful tool [13]. In 5 of the total FMs, the standard deviation of the values showed a lack of understanding of these FMs by all members. In 9 cases, it was evident that it was difficult to reach a consensus with individual members of the group having different views, demonstrating the subjectivity of the method. This had been previously shown in a similar risk analysis for other radiotherapy processes [16,17]. However, this occurred in only 6% of the susceptible FMs with a standard deviation demonstrating that the method is objective enough to enable a systematic evaluation of most process steps.

## Conclusions

The FMEA of treating non-melanoma skin cancer using the Esteya system allowed the discovery of some potential FMs that were not taken into account in the establishment of the QA program. This resulted in the development of new quality management tools to minimize risk and increase the quality of applied treatments. However, the clinical implementation of the process highlights the emergence of new potential FMs, so the present multidisciplinary team believes it is necessary to continue updating and renewing the FMEA process periodically.

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## Disclosure

Authors report no conflict of interest.

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