A Failure Mode and Effects Analysis of deep inspiration breath-hold for left-sided breast cancer radiation therapy

Dražan Jaroš[1,2], Goran Kolarević[1,2], Chryssa Paraskevopoulou[3], Katia Katsari[3]
[1]Center for Radiation Therapy, International Medical Centers, Affidea, Banja Luka, Bosnia and Herzegovina
[2]Faculty of Medicine, University of Banja Luka, Save Mrkalja 14, 78000 Banja Luka, Bosnia and Herzegovina
[3]Affidea B.V., Amsterdam, The Netherlands

1. Background/Aim

The goal of radiation therapy is to safely deliver the correct dose to the correct localization. Failure mode and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a process and their impact on the process outcome. FMEA should identify the potential failures, how likely they can be detected and how severe their consequences might be. The aim of this study was to assess the possible failure modes and analyze their consequences and effects in deep inspiration breath-hold (DIBH) for left-sided breast cancer radiation therapy .

2. Methods

The FMEA was developed by a multidisciplinary team including all healthcare professionals involved in patient's radiotherapy process. Each step of the patient pathway for DIBH radiation therapy was defined and four major process steps were created (Figure 1). For each process step 4-16 potential failure modes and effects were identified.

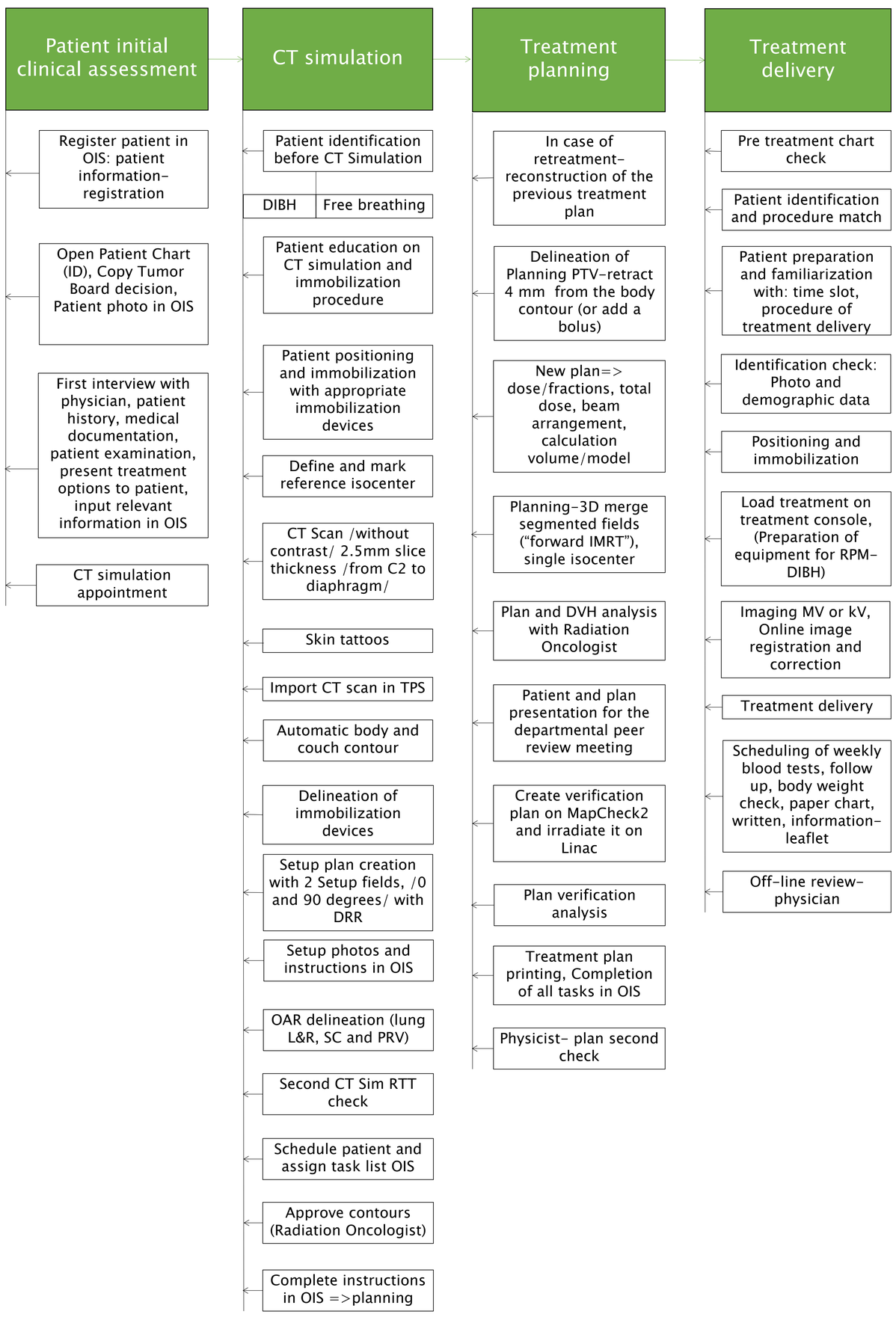

Figure 1. Deep inspiration breath-hold radiation therapy process tree

Each potential failure mode was scored for the likelihood of occurrence 'O', potential severity 'S' and detectability 'D', depending on current departmental controls. 'O' ranges from 1 (failure unlikely, <0.01%) to 10 (failure likelihood is substantial, more than 5% of the time). 'S' ranges from 1 (no danger, minimal disturbance of clinical routine) to 10 (catastrophic). 'D' ranges from 1 (easily detected, <0.01%) to 10 (very difficult to detect, >20).[1] Risk priority numbers (RPNs) were calculated as the product of occurrence, severity and detectability based on Task Group (TG)-100 scale.[1]

3. Results

RPNs for all process steps are presented in figure 2. RPNs were ranked from highest to lowest. Online imaging registration and patient positioning correction during treatment delivery, patient positioning and immobilization and patient preparation and coaching for deep inspiration breath-hold had the highest RPN 378, 210 and 168, respectively. Treatment planning check by a second medical physicist, patient positioning and set up instructions in the oncology information system had the lowest RPN score 10 and 32, respectively.

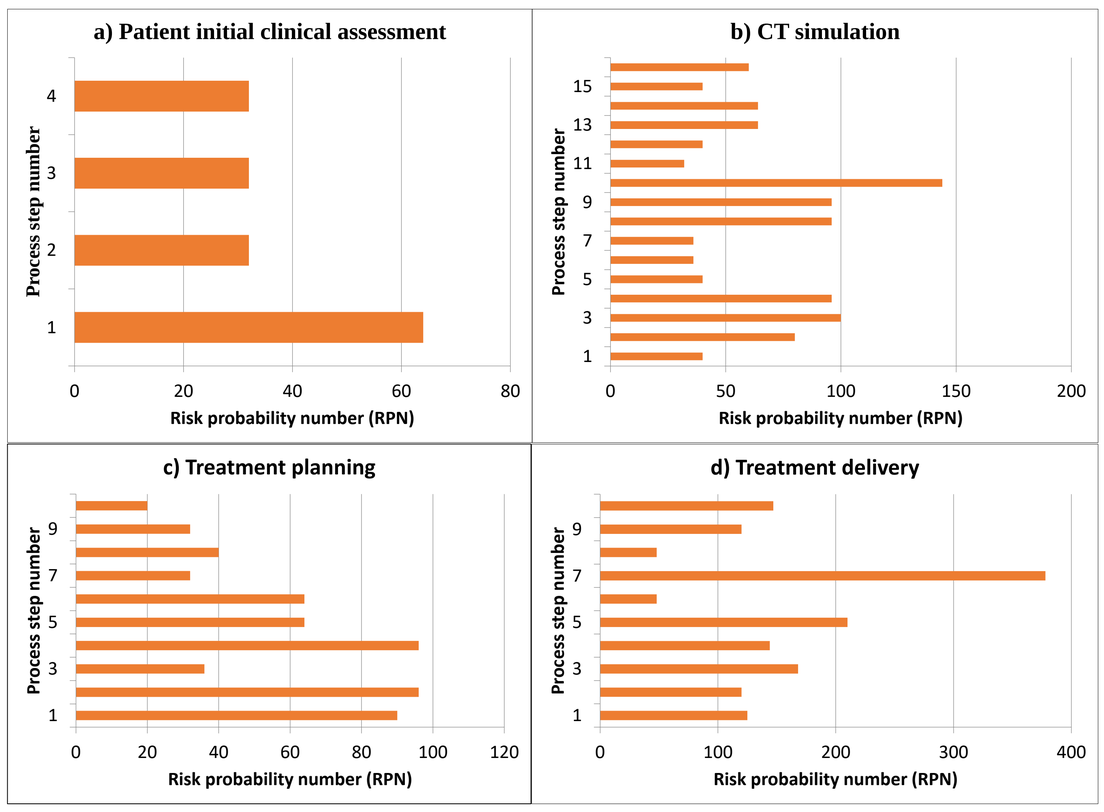

Figure 2. Risk priority numbers for all process steps in: a) Patient initial clinical assessment, b) CT simulation, c) Treatment planning and d) Treatment delivery.
Numbers of potential failure modes and effects in figure 2 were assigned to each major process step from figure 1 with ascending order (i.e. Number 1 for CT simulation is Patient identification before CT simulation, Number 5 for Treatment delivery is Positioning and immobilization).

4. Conclusion

TG-100 recommends that FMEAs can be used as a tool for risk and hazard analysis. An FMEA evaluation of deep inspiration breath-hold for left-sided breast cancer radiotherapy treatment can identify significant improvements in processes and increase in quality and safety of treatment delivery. Process steps with the highest RPNs must be addressed and new procedures must be introduced to minimize possible failures.

References

[1] Huq MS, Fraass BA, Dunscombe PB, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016;43(7):4209-4262. doi:10.1118/1.4947547.

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drazan.jaros@affidea.com