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# Failure modes and effects analysis of the daily adaptive proton therapy workflow at PSI

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Purpose:
Daily adaptive proton therapy (DAPT) differs significantly from established processes in conventional radiotherapy. Online adaptation is technologically challenging, needs to be fast and automated and involves new, non-routine steps (e.g., daily plan re-optimization). Therefore, a tailored design of the DAPT workflow, including QA procedures, is required to ensure its safe clinical implementation. To support this, a Failure-Mode-and-Effects-Analysis (FMEA) was performed to proactively identify/quantify risks and integrate mitigation measures into the workflow.

Methods:
A multidisciplinary expert team (oncologists/physicists/dosimetrists/therapists) identified potential failure modes (FMs) in the DAPT pre-treatment&online phases, with each FM assigned to a specific category (e.g., imaging). Each FM risk assessment was performed by quantifying its individual severity, probability and detectability {S,D,P} scores, based on (1-10) grading system. Potential effects/causes/mechanisms of each FM, current design control and recommended actions were identified. A few examples were performed together to avoid interobserver variability. Finally, the resulting scores, assigned by team members individually, were discussed and risk priority numbers (RPN=S*P*D) were calculated for each scenario.

Results:
In total, 90 FMs were identified. In both DAPT phases, ˜20% of the errors were classified as high-risk (RPN>200; pre-treatment=7, online=13). For these, the current design control and recommended actions were carefully analyzed, verifying also whether the item was DAPT- or PSI-specific. The most frequent FMs, i.e., treatment preparation or calculation/transfer of patient-specific correction vector, were associated with routine treatment steps that could have significantly impact the DAPT process. Human error, either routine or miscommunication, was the most common cause of failure, regardless of the workflow's step.

Conclusions:
New technologies, such as DAPT, require proactive risk assessment prior to clinical implementation, not only to ensure safety and development of customized QA-procedures, but also because of the non-existence of error records. Iterative DAPT risk assessment and QA integration has significantly improved the workflow and increased confidence by addressing potential drawbacks, including human-error-type failures. The resulting recommendations (e.g., planQA checks, DAPT-specific procedures) have been implemented and thanks to DAPT-dry-runs, safety of the workflow is tested in live system.

**Primary authors:** LOMAX, Antony John (PSI - Paul Scherrer Institut); MEIJERS, Arturs (PSI); WEBER, Damien Charles (PSI - Paul Scherrer Institut); LEISER, Dominic (PSI - Paul Scherrer Institut); CHOULILITSA, Evangelia (PSI - Paul Scherrer Institut); GRILLO RUGGIERI, Filippo (Paul Scherrer Institute Proton Therapy Center); ALBERTINI, Francesca (PSI - Paul Scherrer Institut); Dr EMERT, Frank (PSI - Paul Scherrer Institut); ANDACA, I; Mr HRBACEK, Jan (PSI - Paul Scherrer Institut); CZERSKA, Katarzyna (PSI - Paul Scherrer Institut); VAN HEERDEN, Michelle; VÁZQUEZ VARELA, Miriam (Paul Scherrer institut); TROSCH, S; JAKOBSEN, SC

**Presenter:** CZERSKA, Katarzyna (PSI - Paul Scherrer Institut)

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