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Scientific Article

Mitigating Risks in Cone Beam Computed Tomography Guided Online Adaptive Radiation Therapy: A Preventative Reference Planning Review Approach

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Purpose: Online adaptive radiation therapy (oART) treatment planning requires evaluating the temporal robustness of reference plans and anticipating the potential changes during treatment courses that may even lead to risks unique to the adaptive workflow. This study conducted a risk analysis of the cone beam computed tomography guided adaptive workflow and is the first to assess an adaptive-specific reference planning review that mitigates risk in the planning process to prevent events and treatment deficiencies during adaptation.

Methods and Materials: A quality management team of medical physicists, residents, physicians, and radiation therapists performed a fault tree analysis and failure mode and effects analysis. Fault trees were created for under/overdosing targets and treatment deficiencies and assisted in identifying failure modes for the failure mode and effects analysis. Treatment deficiency was defined as a nonideal oART plan resulting in treatment with a lower quality plan (either oART or scheduled plan), treatment delay, or canceling treatment for the day. A reference planning checklist was created to catch failure modes before reaching the patient. Risk priority numbers (RPNs = severity * detectability * occurrence) were scored with and without the reference planning checklist to quantify risk mitigation. A root cause analysis was conducted for an event where an adaptive plan failed to generate.

Results: The reference planning checklist (with items covering patient background, contouring/planning robustness for anatomy variability, and machine limitations) reduced the RPN for all failure modes. Only 1 failure mode with an RPN > 150 occurred with the reference planning checklist compared with 29 failure modes without, including 14 adaptive-specific failure modes. Contouring, planning, setup, scheduling, and documentation errors were identified during the fault tree analysis. Twenty-nine of 70 errors were adaptive-specific. The reference planning checklist could address 23 of 33 errors for over- or underdosing and 28 of 37 errors for treatment deficiency. The root cause analysis highlighted the need to check the setup prior to adaptive plan delivery and the time-out checklist.

Conclusions: The reference planning checklist improved the detection of the failure modes and improved the quality and robustness of the plans produced for oART. It is ideally performed before the physician plan review to prevent last-minute replan (before or after first adaptive treatment) and delay of patient start. The checklist presented can be modified based on failures specific to individual clinics

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All data generated and analyzed during this study are included in this published article (and its supplementary information files).

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and used at various planning steps based on available resources.

Introduction

Online adaptive radiation therapy (oART) continues to drive the primary radiation therapy goal of improving the therapeutic ratio by reducing the dose to the surrounding organ at risk while ensuring tumor coverage by adapting the initial treatment plan to the interfractional anatomic (and biological) changes over the course of treatment. However, this modality presents risks that are unique to its delivery workflow.[1] The oART workflow deviates from the usual external beam radiation therapy (EBRT) workflow in that on-console patient anatomy is contoured on the daily images, adaptive plans are then generated and compared with nonadaptive (scheduled) plans, and the higher quality plan is chosen and delivered to the patient.[2] Noel et al[1] demonstrated that compared with standard intensity modulated radiation therapy, this introduced different risks rather than greater risks to the patient. The faults with the highest risks for oART involved treatment planning, target and organs at risk delineation errors, communication errors, and equipment failures during treatment delivery.

In recent years, since magnetic resonance imaging- and cone beam computed tomography guided (CBCT-guided) oART adoption in clinics, there have been several institutions conducting risk analysis to identify high-priority risks and methods of mitigation. Many institutions have conducted failure mode and effects analysis (FMEA), often with the guidance of the American Association of Physicists in Medicine (AAPM) Task Group 100 (TG-100),[3] to determine the modes with the highest risks. FMEA is a failure identification tool that has been used by the military since the mid-20th century and is a major process in different manufacturing and production workflows for companies. FMEA is often used in radiation therapy for the implementation of emerging technologies.[4,5] As the time from plan generation to treatment is minimal in oART, FMEA has assisted in creating quality assurance (QA) tools for magnetic resonance guided (MR-guided) oART to mitigate errors during adaptation. Rippke et al[6] developed an automated QA tool that complemented secondary dose calculation to quantify the quality of a plan produced during adaptation. Others have introduced checklists during or postadaption or changed their protocol and workflow[7,8] (eg, documenting the chosen plan, verbally stating patient identifiers) to reduce the risk during adaptation and treatment delivery. Noel et al[1] described the technological tools that can be implemented for risk mitigation, and Green et al developed the practical workflow and QA tools for their online magnetic resonance imaging oART system.[2] For CBCT-guided oART, Wegener et al[9] conducted an FMEA, particularly focused on-console adaptive workflow, demonstrating the importance of standardization and clearly defined protocols. Nonetheless, it is vital to address pretreatment processes as those failure modes propagate to all treatments and can result in a higher severity than the daily oART process.[10]

While auto-contour generation and optimization in the CBCT-guided oART treatment delivery system allow for fast plan generation on-console with minimal human intervention, this process relies on the parameters set up at the time of reference planning. Users set up the contour generation and the plan optimization strategies at the time of reference planning,[11] and this set of parameters is applied automatically during the oART process. During oART, users can only adjust the contours offered by the system and, subsequently, the margin expansion and planning structure generation. The plan optimization is automatically performed based on the parameters set up at the reference planning stage. The automated workflow may generate low-quality plans, requiring safety measures to prevent this. Since the oART plan quality will be heavily dependent on the reference planning strategies, the planners need to plan with new considerations to project the potential changes of anatomy in the treatment course and properly "program" it during the reference planning phase. Infeasible contours or planning strategy could lead to online plan adaptation with inferior quality and require additional replanning to correct the strategy for the upcoming fractions. Therefore, a quality check during the reference planning stage may be vital to ensuring robust and quality oART plan generation during adaptive sessions.

In this study, both prospective risk analysis and retrospective root cause analysis (RCA) were conducted based on over 3000 fractions of adaptive therapy treatments to evaluate the utility of a reference planning checklist to be used during the initial planning process to mitigate upstream risks at the console. To the best of our knowledge, this is the first CBCT-guided oART risk analysis that investigates the use of a preventative planning checklist for on-console error mitigation. Using TG-100, process steps were identified for the patient treatment workflow from simulation to delivery to postdelivery steps. A fault tree analysis (FTA) was conducted, identifying on-console faults that were translated to a reference planning checklist for treatment planners to assess their plan quality prior to presenting to physicians for plan approval. FMEA was conducted to identify failure modes and score the risks with and without the reference planning checklist. The risk was scored considering severity, the likelihood of detectability, and the likelihood of occurrence for each failure mode. For

a singular quantitative metric of risk, the risk priority number (RPN = severity * detectability * occurrence) was also included for each failure mode.[3] An RCA was performed for 1 event that occurred during adaptation (lack of plan generation). The advantages and limitations of the reference planning checklist were discussed.

Methods and Materials

Quality management team

The quality management team was formed to assess the risk of the current clinical workflow after the delivery of over 3000 adaptive fractions and over 800 patients covering all body sites treated with the institutional CBCT-guided oART delivery system (Ethos, Varian Inc). The oncology information system (OIS) used in the institution was Aria (Varian Inc), and the treatment planning system (TPS) used was within the Ethos environment. The team consisted of 6 physicists, 1 physicist from an external CBCT-guided oART site, 2 medical physics residents, 1 radiation therapist, and 1 physician with expertise in planning, delivery, quality assurance, and workflow of specific disease sites (pelvis, head and neck, breast, and lung). The physicists and residents defined and revised the process steps, as shown in Fig. 1, based on the current clinical workflow at our institution. This is a generalized workflow for all treatment sites. In our institution, we implemented the reference plan checklist as a premedical doctor (MD) plan review check to catch the deficiency of the reference plan and correct it prior to physician plan review.

FTA and failure modes

FTA sought to identify failures and their causes during delivery involving treatment deficiency (Fig. 2) and the potential to overdose or underdose a patient[12] (Fig. 3). Treatment deficiency was defined as the following: a nonideal oART plan giving the users the option to accept a lower quality plan for 1 fraction, treat with the scheduled plan, start over if the issue is solvable (ie, treatment delay), or cancel for the day (fix plan and use new plan next day or later). The options result in either a lower quality plan or treatment delay. The potential causes were organized by logic gates, and the types of

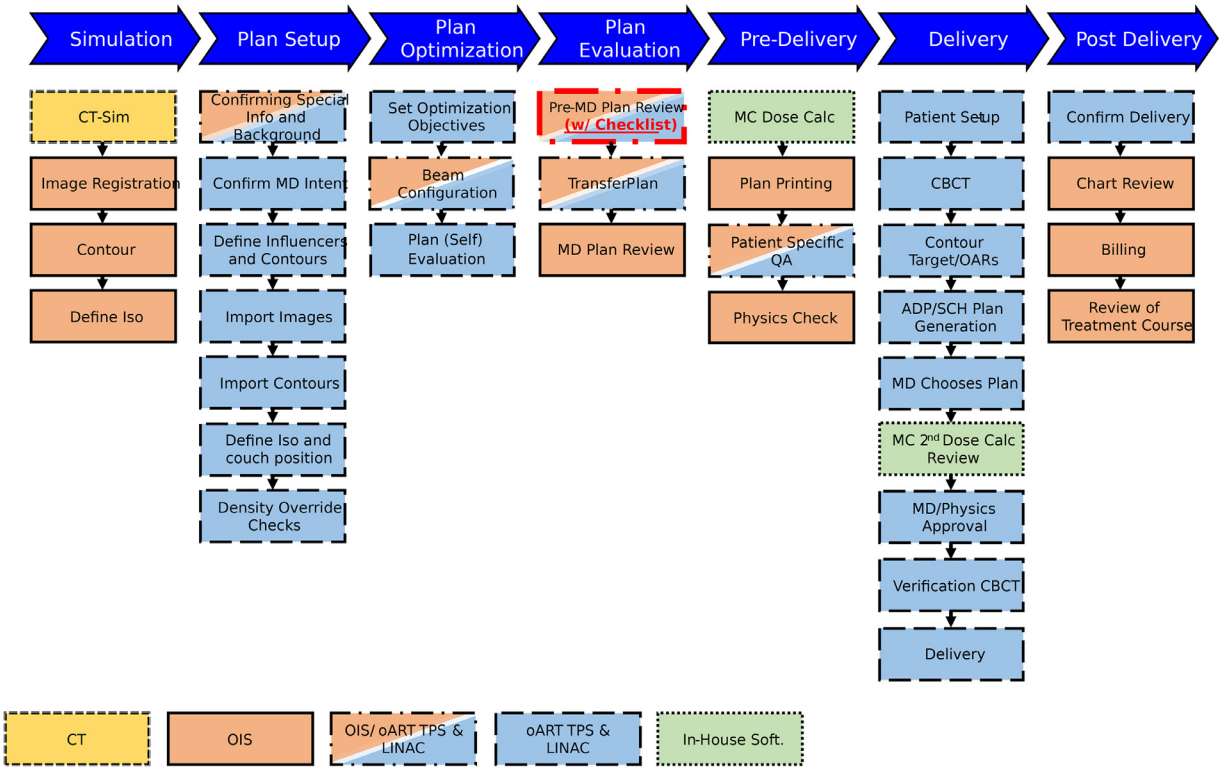

Figure 1 Process map for CBCT-guided online adaptive radiation therapy (oART). Failure modes and effects analysis were completed (identifying faults, effects, causes, and risk priority number scoring) on simulation, plan setup, and plan optimization process steps. The premedical doctor (MD) reference plan review step is where the checklist was introduced in this study, outlined and underlined in red.

Abbreviations: ADP = adapted plan; CT = computed tomography; CBCT = cone beam computed tomography; MC = Monte Carlo; OIS = oncology information system (Aria, Varian Inc); QA = quality assurance; SCH = scheduled plan; TPS = therapy treatment planning system (Ethos, Varian Inc).

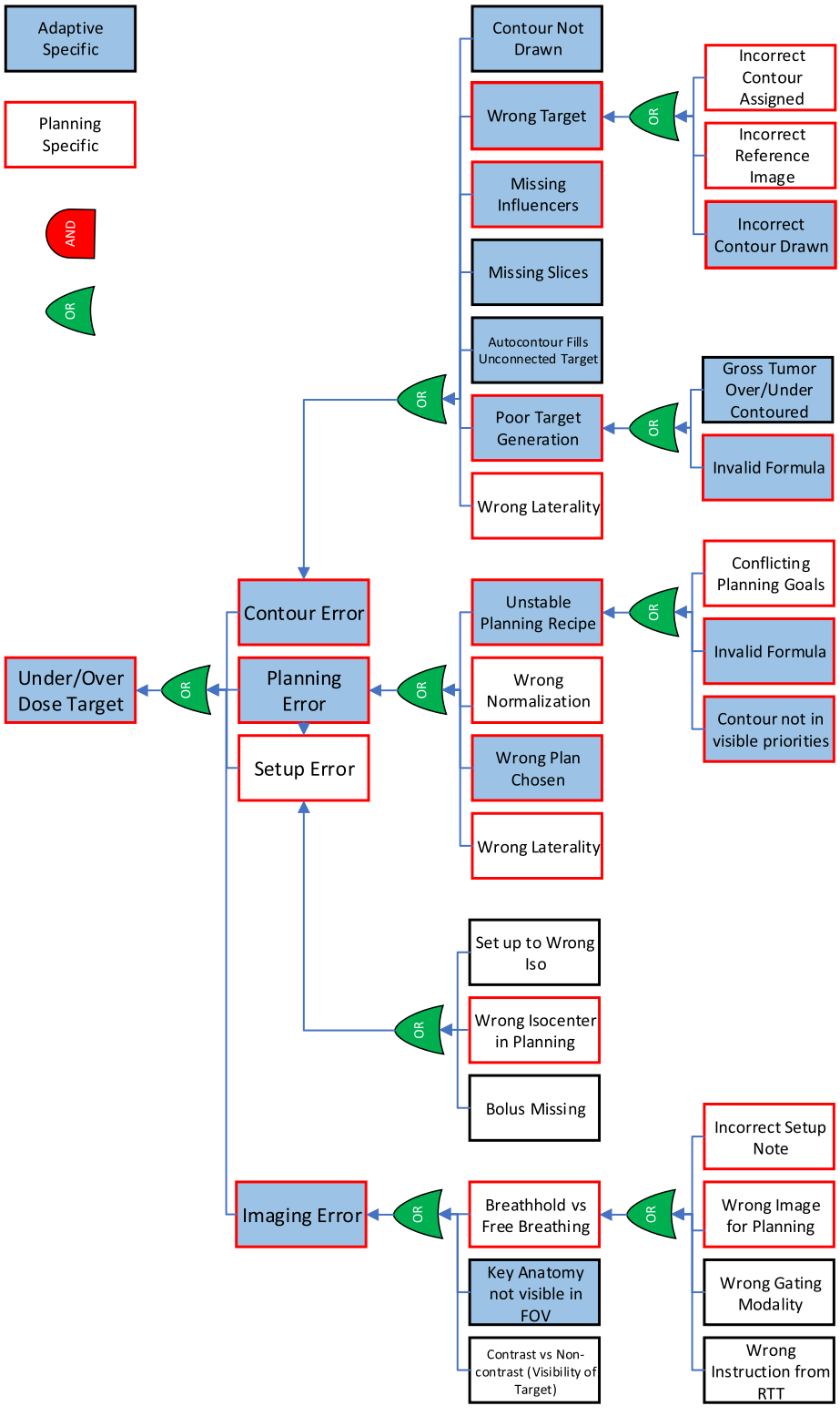

Figure 2 Fault tree illustrating faults on the console during delivery process steps and adaptive sessions that can result in underdosing or overdosing the target. The blue shade specifies faults that are specific to the adaptive workflow. The red outline specifies faults that could have been addressed during the planning process.
Abbreviation: FOV = field of view; Iso = isocenter; RTT = radiation therapy technologist.

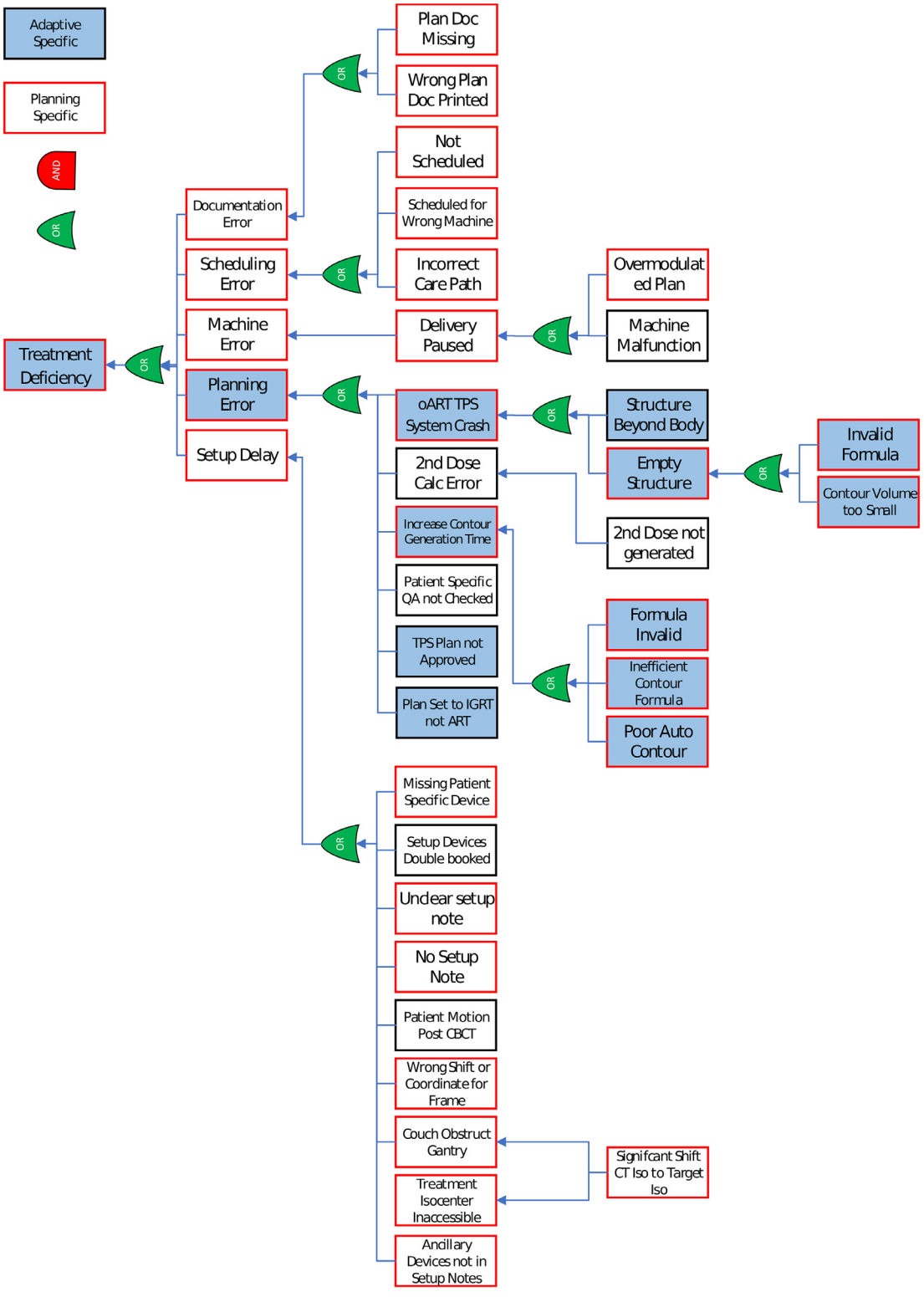

Figure 3 Fault tree illustrating faults on the console during delivery process steps and adaptive sessions that can result in treatment deficiency for the patient. The blue shade specifies faults that are specific to the adaptive workflow. The red outline specifies faults that could have been addressed during the planning process.

Abbreviations: ART = adaptive radiation therapy; CBCT = cone beam computed tomography; CT = computed tomography; IGRT = image guided radiation therapy; Iso = isocenter; oART = online adaptive radiation therapy; QA = quality assurance; TPS = therapy treatment planning system.

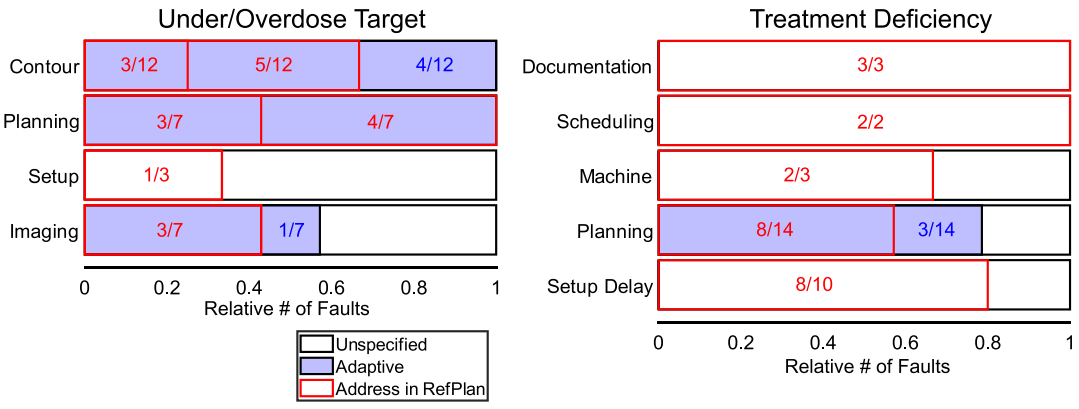

Figure 4 Summary of fault tree analysis for an under- or overdosing target (Fig. 2) and treatment deficiency (Fig. 3) illustrated as relative bar graphs of faults that can be addressed in the reference plan and adaptive-specific faults based on the type of error (eg, documentation, setup, etc). Fraction of faults that can be addressed in the reference plan are labeled in red (including adaptive), and other adaptive faults are labeled in blue.

faults[3] were also identified into subcategories such as contour, imaging, setup, machine, planning, scheduling errors, etc.

The fault trees and process map assisted in identifying failure modes that can occur during planning and risk treatment deficiency or result in unintended doses to patients. As the institution sought to identify failure modes during the planning steps that can lead to suboptimal treatment delivery at the console, the failure modes were identified for the first 3 process steps, where the planner is involved (Fig. 1): simulation, plan setup, and plan optimization. The failure modes, along with potential causes, effects, and RPN scoring, are included in Table E1 (and discussed further in the section "FMEA").

Reference planning checklist

While the pre-MD reference plan review was informally conducted since CBCT-guided oART was in its infancy stage at the institution, there has been a recent standardization of the checklist and items to assess plan quality during adaptation and deliverability. The review involved the items on the planning checklist that planners or reviewers may go through after the planning process (simulation, plan setup, and plan optimization process steps) to detect potential faults and improve robustness and plan quality. The items of this checklist, shown in Fig. 4, were chosen based on our adaptive planning experiences to mitigate errors on the console during the delivery of treatments and address the failure modes identified from the process map, the FTA, and FMEA. The checklist is currently a standard of practice in the clinic, allowing for a comparison of the risk of failure modes with and without the checklist.

FMEA

American Association of Physicists in Medicine's TG-100 methods were implemented for FMEA.[3] For each failure mode, the team members identified potential causes and effects. They scored severity, detectability, and occurrence based on rubrics provided in the TG-100. Note that the pre-MD plan review step is where the reference planning checklist was introduced in this study (Fig. 1), and the study sought to evaluate the risk mitigation from implementing the reference planning checklist, so the failure modes presented occurred or potentially occurred during the planning process steps (simulation, plan setup, and plan optimization). The team met to discuss FMEA scoring and standardized the process, including establishing the rubric (ie, TG-100 Tables 1 and 2 in Huq et al[3]). The team generated a list of failure modes and scored it with and without the reference planning checklist. The team then met again to finalize the scores, and RPNs were calculated. The average and SD of the severity, detectability, occurrence, and RPN (RPN = occurrence * severity * detectability) from the team members' score for each fault are consolidated in Table E1, and the results are discussed further in the section "Reference planning checklist during pre-MD plan review mitigating risk."

Root cause analysis

Team members identified events that occurred in the clinic to conduct a root cause analysis and agreed on an event where, during a single fraction of adaptive treatment of the abdomen, an adaptive plan failed to generate. To identify the root cause(s) the team consulted with the therapist on console and any physicist with information on the patient and event. The team also examined any

other information that can be found in the TPS, OIS, and electronic medical records and documentation on the date of treatment. The findings are presented in the section "Root cause of failed adaptive plan generation."

Results

FTA

Figures 2 and 3 illustrate the faults that can occur during the delivery on the console, which can result in over- or underdosing the target and treatment deficiency, respectively. The planning process includes simulation, plan setup, and plan optimization process (Fig. 1) and can contribute to faults that result in errors on-console. The faults specific to the adaptive workflow are shaded blue in Figs. 2 and 3. For over- or underdosing, one of the setup errors can be attributed to the planning process. Contouring, planning, and imaging errors (Fig. 2) can often be attributed to the planning process or are specific to the adaptive treatment workflow. Figure 4 summarizes the errors from FTA in Figs. 2 and 3, highlighting the faults that can be addressed during the reference plan, including adaptive-specific faults. Nine of 12 faults that can cause the contouring error are adaptive specific, and 8 of 12 (not necessarily the same) of the contouring errors can be addressed during the planning process or by checking one's plan. All the planning errors can be addressed during the planning process, 4 of 7 of which are adaptive specific. One out of 7 imaging errors are adaptive specific, and 3 of 7 can be addressed during the planning process.

Treatment deficiencies can be predominantly avoided with corrections during the planning process, and most of the planning errors were specific to the adaptive workflow, as shown in Figs. 3 and 4. The machine, scheduling, documentation, and setup delay are predominantly caused by faults during and can be addressed in the planning stage (2/3, 3/3, 2/2, and 8/10, respectively). Eleven out of 14 faults for the planning errors are adaptive specific, but 8 of those faults can be prevented during the planning process by the planner.

Reference planning checklist during pre-MD plan review mitigating risk

Figure 5 shows the categories and individual items in the reference planning checklist used to mitigate the risks of the failure modes and faults identified by the quality management team. The categories in the checklist included background, physician intent, contour, technical structure (eg, isocenter, couch location), dose review, and final action.

Figure 6 consolidated the failure modes identified in the planning process steps and the RPN (the FMEA table is included in Table E1). While the pre-MD reference plan review process cannot change the severity of the failure mode, it can particularly improve the detectability of failure modes. With the reference planning checklist, the average RPN was reduced by an average of 87.9 (median, 85.4), and the detectability was reduced by an average of 2.9 (median, 2.8). Without the reference planning checklist, 31 failure modes had an RPN score larger than 150, while with the reference planning checklist, there was only 1 failure mode that had an RPN score larger than 150 (failure mode was inaccurate contours, which is not specific to the adaptive workflow). The reference planning checklist reduced the RPN score of 14 adaptive-specific failure modes below 150 (23 adaptive-specific failure modes identified). Adaptive-specific failure modes can be subcategorized as related to contours (eg, invalid or no expansion formula, contour beyond the body), autogenerated contours (eg, missing slices, connecting unconnected structure), imported imaging set(s), adaptive planning optimization recipe (eg, conflicted goals of autogenerated contours and tuning structures or illogical), and adapt scheduling. RPN scores for failure modes that are not specific to the adaptive workflow were also reduced with the reference planning checklist.

Root cause of failed adaptive plan generation

Figure 7 illustrates the event that occurred during a single fraction of treating the abdomen with CBCT-guided oART: failure to generate an adaptive plan. The treatment isocenter on the day of the oART was too far from the target, and the multileaf collimator could not reach the treating area. While superficially, from Fig. 6a, b, this can be attributed to the setup isocenter of the patient being drastically different from the simulation isocenter, and there are several root causes identified by the quality management team. One root cause is the multiple prior radiation treatments of the patient, resulting in multiple setup coordinate documents being available in the EMR system. In this case, a wrong setup body frame coordinate document was used for patient setup. Another root cause is that the current CBCT-guided oART system does not have a fusion image review on the CBCT image acquisition to allow users to verify that the patient setup matches the planning setup and causes the users to proceed with the oART planning process. Another root cause is that at the time this occurred, very early in the implementation of oART in the clinic, there was no QA checks on the isocenter and position of the patient during setup. Currently, in the clinic, the protocol is for clinical physicists to check the patient positioning and isocenter positioning after setup (ie, postdelivery time-out process),

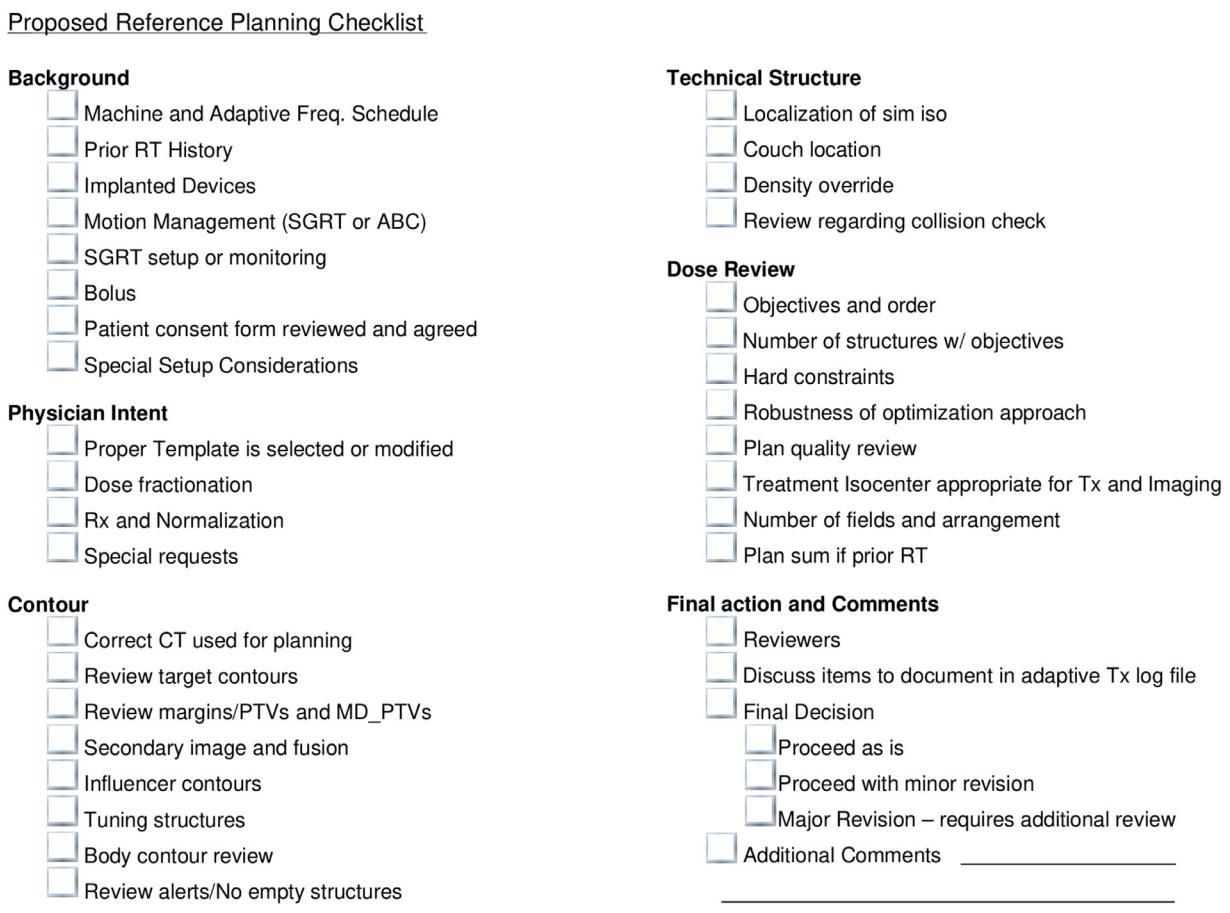

Figure 5 Reference planning checklist used during the plan evaluation process step (premedical doctor [MD] plan review). The failure mode and effects analysis risk priority number for each fault was scored with and without the use of the reference planning checklist.

Abbreviations: ABC = active breathing control; CT = computed tomography; PTV = planning target volume; RT = radiation therapy; Rx = prescription; SGRT = surface guided radiation therapy; Tx = treatment.

and surface image guidance was implemented to serve as an independent isocenter verification tool to ensure the patient is set up correctly before CBCT acquisition to improve the detectability of such events.

Discussion

The reference planning checklist is an opportunity to assess one's plan quality from an adaptive perspective. While many items are not specific to the adaptive workflow, they were included as the planner would need to be cognizant of them even for standard EBRT treatment. For example, the "background" set of items could apply to any EBRT, such as bolus, implanted devices, prior radiation, etc. However, the subsequent items and categories in the reference planning checklist include predominantly items that sought to produce contours and planning recipes that are robust and can optimize dose plans efficiently (preventing errors or suboptimal adaptive plan) even with changing patient anatomy or setup variability. For example, throughout the reference planning checklist, supporting images, simulation/treatment isocenter, and the evaluation of the plan optimization recipe, contours and pretreatment plan quality are assessed with the consideration of how this plan may change during adaptation. The "Final action and comments" allow one to determine the next steps, including providing the staff on the console with details that are unique to this patient (eg, explicitly stating unique contour formulas given by the physician), allowing the staff to take precautions during the adaptive sessions.

The proposed adaptive reference planning checklist items can be implemented as a planner's self-check or a physics plan quality check. In our institution, this checklist was implemented as a physics plan quality check prior to the physician's plan review with the intent of preventing the propagation of errors leading to high-risk failure modes during adaptation or replan after the patient started with a suboptimal online adapted plan. This provides an opportunity for early detection of errors and prevents last-minute replans when used as part of the physicist's initial chart check, which usually occurs after the physician plan review and 1 to 2 days before patients start treatment. This is evident from Fig. 6, as the pre-MD plan review can be used

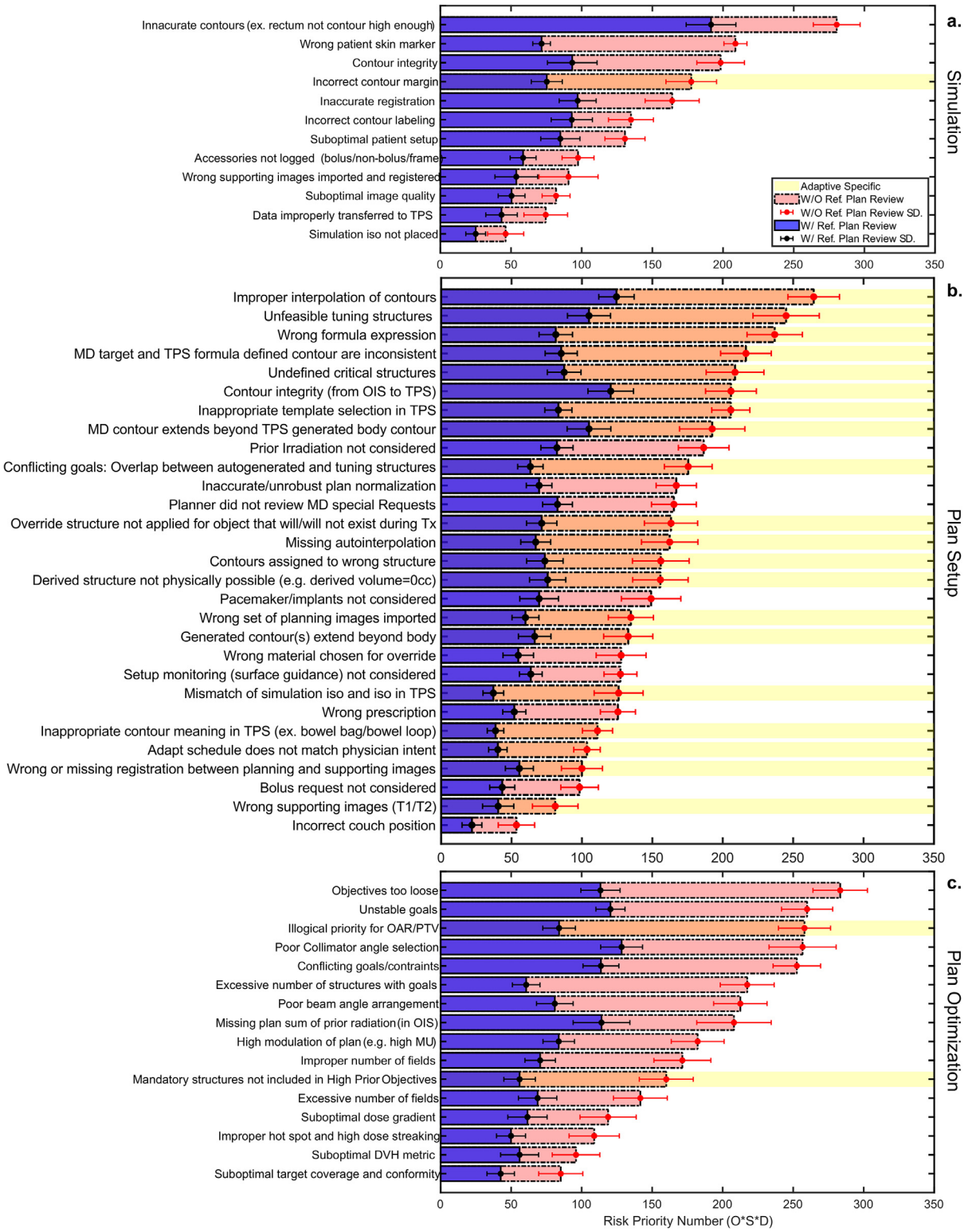

Figure 6 Risk priority number scoring with (W/) and without (W/O) reference planning review during the premedical doctor (MD) reference plan review based on failure mode and effects analysis of the faults from (a) simulation, (b) plan setup, and (c) plan optimization process steps. Error bars show the mean and SD of team members' risk priority number (risk priority number scoring is also included in table format in Table E1). Risk priority number = occurrence (O) * severity (S) * detectability (D).
Abbreviations: DVH = Dose Volume Histogram; MU = monitor units; OAR = organ at risk; OIS = oncology information system; PTV = planning target volume; TPS = therapy treatment planning system; Tx = treatment.

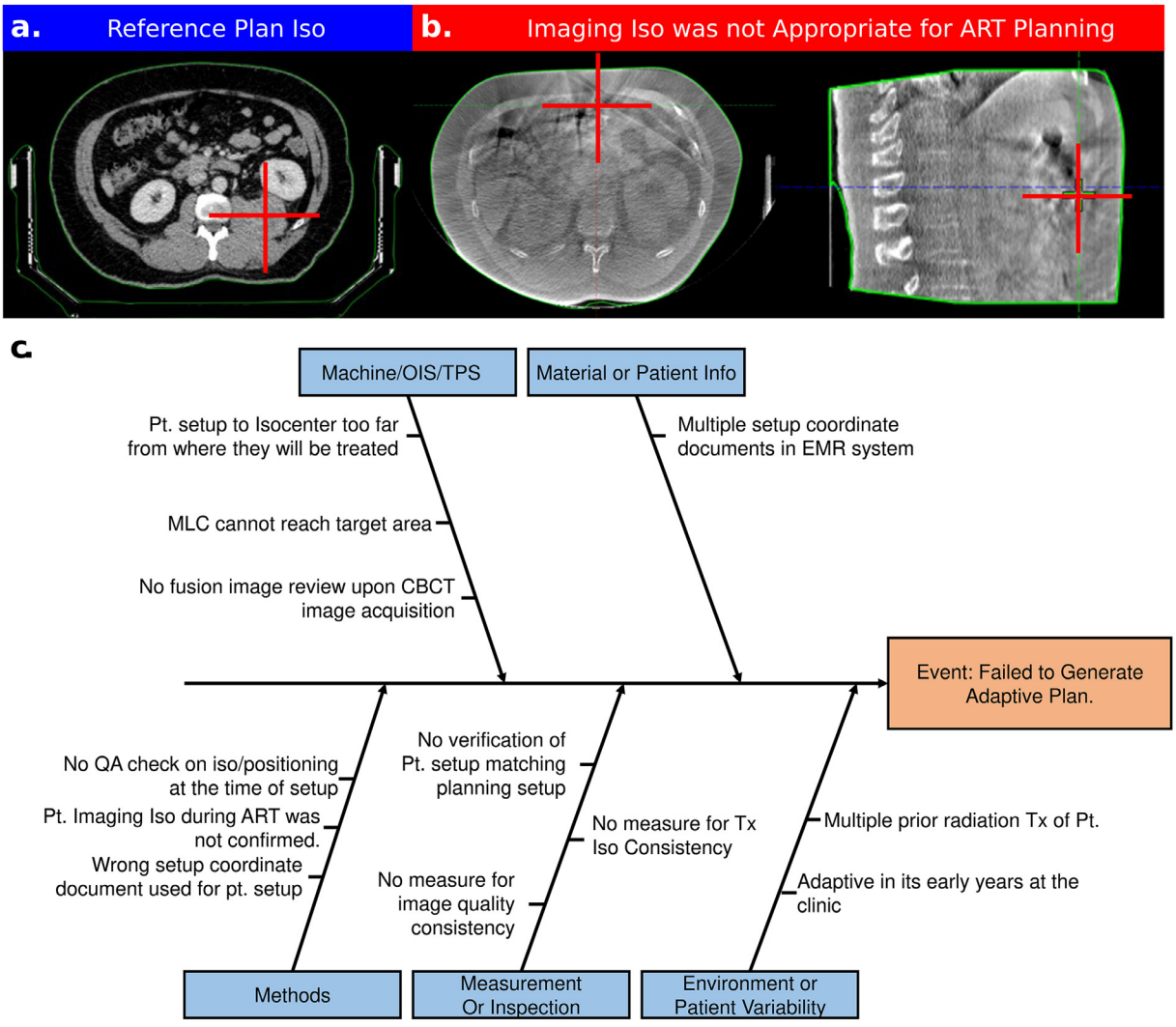

Figure 7 Root cause analysis on an event where an adaptive plan was not generated. (a) Computed tomography with the original isocenter (Iso) from the simulation marked. (b) CBCT was acquired after patient setup in an axial and sagittal view with the setup Iso marked. (c) Fishbone diagram illustrating the root cause analysis.

Abbreviations: ART = adaptive radiation therapy; CBCT = cone beam computed tomography; EMR = electronic medical record; MLC = multileaf collimator; OIS = oncology information system; Pt = patient; QA = quality assurance; TPS = therapy treatment planning system; Tx = treatment.

for both addressing adaptive and nonadaptive specific failure modes. It is worth noting that the errors with the highest risk (eg, contouring, auto-contouring, and simulation isocenter) are consistent with other institutions conducting FMEA[1,6] on adaptive services. However, our FMEA also considered plan quality and how the checklist can reduce the chance of unrobust adaptive plans with failure modes such as contours or tuning structure with conflicting goals, unrobust plan normalization, and derived structure formula that may become impossible during an adaptive session (all of which had a reduced RPN score with the use of the reference planning checklist). Another important aspect of prevention provided by the reference planning checklist is the comments section, which gives essential details specific to the patient and the adaptive planning strategy for the staff on-console.

The implementation of this planning checklist has the advantage of a large group of physicists/planners who can assess one another's adaptive pretreatment plan quality during pre-MD reference plan review sessions. This provides an educational opportunity for newer planners while providing the more experienced planners with the opportunity to provide feedback efficiently and explicitly on how to improve a plan. While the detectability has been shown to improve with the checklist, the plan review process may lead to reduced occurrences of failure modes by improving planning. A future study could compare plan quality and errors before and after the implementation of the checklist. While the pre-MD reference plan review process may be specific to our institution, the reference planning checklist can potentially reduce risk for those in other

clinics, specifically addressing the robustness of plans, contours, and deliverability.

The FMEA also highlights some of the advantages and limitations of automation used in the adaptive planning process. Auto-contour generation, auto-registration, and auto-planning can help reduce the time between patient setup and treatment delivery, but the plans generated require oversight. For example, contours can be inaccurate due to unintended or improper auto-interpolation, another risk that can be mitigated during planning, as shown in Fig. 5 (the planner can also include a note of this for the on-console staff). Nonetheless, automated tools can also be used to mitigate errors on the console without increased time of adaptation prior to delivery,[6] such as standalone tools outside of the treatment delivery system. Automation in the reference planning process can also be used, like Simiele et al,[4] to check for isocenter-related failure modes. In our institution, automation in the planning process is used for data transfer between adaptive therapy TPS and OIS, and treatment site-specific template plans are used to streamline robust treatment planning.

While the FMEA and the reference planning checklist may mitigate the risk of all the identified failure modes, the preventative approach may not necessarily mitigate the risk of unpredictable events, such as the one where an adaptive plan was not generated in Fig. 7. Some of the root causes (no machine or QA check for patient position, resulting in no adaptive plan) could potentially be detected through automated tools for isocenter checks like in Simiele et al[4] and implemented during adaption. However, as prior risk analysis has mentioned,[9] the CBCT-guided oART treatment delivery system adaptive workflow is, in many ways, a closed system without being able to access the data on the console for automation. Thus, currently, at our clinic, physicists are there with therapists on the console to ensure the quality of patient position and setup. A postdelivery checklist can also be introduced to assess delivery quality (ie, a time-out process). Another technological solution would be surface guided radiation therapy, which can allow set up with the patient's surface[13] (currently implemented in the clinic) instead of patient markers. This also reduces the chances of aligning the patient to the wrong mark. Nonetheless, this study demonstrated that the reference planning checklist prior to MD approval can reduce the risk of the failure modes identified. Other clinics can add to or even modify such a checklist for failure modes revealed from events specific to their workflow.

Conclusions

This study demonstrated that implementing a preventative reference planning checklist mitigated risk during online adaptive treatment. The planning checklist before the physician's review and physics approval provides the opportunity to reduce the propagation of the failure modes throughout the workflow and all adaptive fractions. Conducting the FMEA and RCA improved awareness of the potential console faults, while the planning checklist has provided the opportunity for increased detection (and potentially reduced occurrence with more robust planning strategies). While the planning checklist cannot prepare for all unpredictable events, it can prevent the identified failure modes well before delivery of the treatment. Clinics can modify or add to this checklist based on their specific workflow and failure modes they identify.

Disclosures

Dennis Stanley reports travel costs for attending conference meetings and presentations from Varian Medical Systems. Bin Cai reports speaker fees and travel costs from RefleXion Medical System and Varian Medical System as an invited speaker.

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Mahbubur Rahman performed the statistical analysis.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.adro.2024.101614.

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