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Scientific Article

Enhancing Safety in AI-Driven Cone Beam CT-based Online Adaptive Radiation Therapy: Development and Implementation of an Interdisciplinary Workflow

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Purpose: The emerging online adaptive radiation therapy (OART) treatment strategy based on cone beam computed tomography allows for real-time replanning according to a patient's current anatomy. However, implementing this procedure requires a new approach across the patient's care path and monitoring of the "black box" adaptation process. This study identifies high-risk failure modes (FMs) associated with AI-driven OART and proposes an interdisciplinary workflow to mitigate potential medical errors from highly automated processes, enhance treatment efficiency, and reduce the burden on clinicians.

Methods and Materials: An interdisciplinary working group was formed to identify safety concerns in each process step using failure mode and effects analysis (FMEA). Based on the FMEA results, the team designed standardized procedures and safety checklists to prevent errors and ensure successful task completion. The Risk Priority Numbers (RPNs) for the top twenty FMs were calculated before and after implementing the proposed workflow to evaluate its effectiveness. Three hundred seventy-four adaptive sessions across 5 treatment sites were performed, and each session was evaluated for treatment safety and FMEA assessment.

Results: The OART workflow has 4 components, each with 4, 8, 13, and 4 sequentially executed tasks and safety checklists. Site-specific template preparation, which includes disease-specific physician directives and Intelligent Optimization Engine template testing, is one of the new procedures introduced. The interdisciplinary workflow significantly reduced the RPNs of the high-risk FMs, with an average decrease of 110 (maximum reduction of 305.5 and minimum reduction of 27.4).

Conclusions: This study underscores the importance of addressing high-risk FMs associated with AI-driven OART and emphasizes the significance of safety measures in its implementation. By proposing a structured interdisciplinary workflow and integrated checklists, the study provides valuable insights into ensuring the safe and efficient delivery of OART while facilitating its effective integration into clinical practice.

Introduction

Cone beam computed tomography (CBCT)-based online adaptive therapy (OART) is an emerging treatment strategy that involves replanning based on a patient's on-couch CBCT scan. OART can potentially improve target

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Research data are stored in an institutional repository and will be shared upon request to the corresponding author.

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coverage while sparing organ-at-risk (OAR) by accounting for interfractional variations in target position, shape, and surrounding OARs, thus facilitating isotoxic dose escalation. Preliminary dosimetric benefits of OART have been reported for various cancer sites,[1-7] but further clinical data are needed to demonstrate the superiority of OART over conventional treatment approaches.

The Varian Ethos treatment system (Varian, Palo Alto, United States) enables OART using Intelligent Optimization Engine (IOE) for automated planning, iterative kV CBCT reconstruction (iCBCT), artificial intelligence (AI), and deformable image registration techniques (DIR). This implementation of OART is a significant departure from the traditional external beam treatment process. Additional duties and standardized procedures for all personnel involved are required.

One primary difference in OART delivery is template-based treatment planning using IOE, enabling automated real-time dose optimization for intensity modulated radiation therapy (IMRT). Developing planning templates is crucial to generate clinically acceptable adaptive plans. Another difference is the manual inspection and modification of automated contouring, necessitating strategies to mitigate imaging artifacts and contouring errors.[8] Effective communication policies for OART are essential. For instance, treatment targets may be inaccurately contoured during the adaptive session by a covering physician unaware of the patient's specific treatment strategy. Additionally, the real-time replanning process adds time pressure for clinical personnel. To address these issues, a structured workflow and procedures are necessary to enhance treatment efficiency and monitor the adaptation process.

Despite a few published articles on commissioning and dosimetric studies of the CBCT-based OART platform,[9-13] a pressing need remains for published guidance on the comprehensive treatment workflow and individual responsibilities. In this study, we conducted a failure mode and effects analysis (FMEA) to identify high-risk failure modes and developed logistically feasible clinical workflows for OART, which are categorized into 4 components:[1] site-specific templates preparation,[2] pretreatment planning and verification,[3] on-treatment procedures, and[4] posttreatment verification, along with safety checklists. The goal is to establish an interdisciplinary workflow for high-quality adaptive planning, precise treatment delivery, and seamless integration of CBCT-based OART into clinical practice, providing insights into safety measures for AI-driven OART.

Methods

Interdisciplinary OART Working Group and FMEA Implementation

After installing and commissioning the Ethos adaptive radiation therapy platform, a 10-member interdisciplinary OART working group (IOWG) was established, comprising 3 radiation oncologists routinely prescribing and performing OART treatments, 4 medical physicists, responsible for adaptive template development, treatment planning, and online procedures, one medical dosimetrist contributing to adaptive template development, and 2 radiologic technologists, actively involved in patient setup and OART treatment delivery. The IOWG meets weekly to devise adaptive treatment strategies for specific diseases, identify failure modes based on team members' experiences and reported near-miss events, and enhance the workflow with safety barriers. Each IOWG member assigned Risk Priority Numbers (RPNs) to the identified failure modes based on severity, occurrence, and detectability, following the framework from the American Association of Physicists in Medicine Task Group 100.[14] The RPN formula used was RPN = severity × occurrence × detectability. The IOWG calculated the average RPN for each FM and periodically evaluated and adjusted the final RPNs to ensure role-agnostic objectivity in FMEA. To evaluate the effectiveness of the proposed workflow, RPN scores for the top-ranked twenty failure modes (RPN $\geq$ 37) were calculated before and after implementing the proposed workflow. A total of 3 hundred seventy-four adaptive sessions were performed across 5 treatment sites (pancreas, bladder, prostate, rectum, and anus). Each session was evaluated for treatment safety and FMEA refinement.

CBCT-based OART Special Considerations

Pretreatment considerations

To maximize the adaptive benefits to patients, the IOWG discussed potential disease site candidates considering factors such as the nature of the patient's disease, normal tissue interfractional movement, change in morphology, and overall external body contour. The physicians assessed the patient's ability to maintain the treatment position for the prolonged on-couch time, considering patient compliance, performance status, and comorbidities. High-density materials near the treatment area, such as prostheses or fiducials, were considered as they can generate artifacts during CBCT, affecting target and OAR delineation, as shown in Fig. 1.

Template development is a complex process that requires new workflows. Each site-specific template, like a treatment plan, needs a physician-approved directive. To achieve reasonable plans, the treating physician must define the importance of each dose constraint and contouring guidelines. Ethos IOE uses "quality functions" (Q-functions) to mimic a treatment planner, controlling the optimization process based on user-defined dose constraint prioritization in the IOE template. Unmet constraints with higher priority receive attention before those

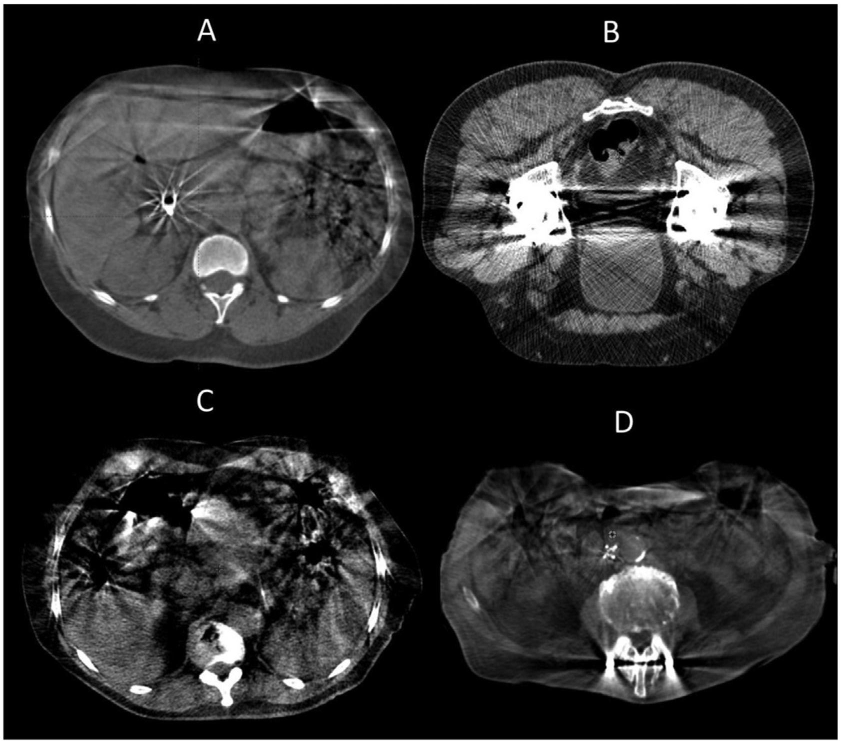

Figure 1 Ethos CBCT artifacts: (A) biliary stent, (B) hip prosthesis, (C) gas pockets, and (D) spine implants can affect online target and OAR delineation.

with lower priority.[15] All hard OAR dose constraints are ranked higher than target constraints, while optional constraints are ranked lower to avoid underdosing the target or overdosing the OAR, particularly when the OAR overlaps with the target (Fig. 2). Unrealistic OAR constraints are excluded from the template.

On-treatment considerations

For each OART treatment fraction, On-Couch Session Manager (OSM) automatically delineates template-defined target and OAR structures. However, physician review and editing of the generated contours using daily CBCT imaging are necessary. Thus, the CBCT protocol and imaging quality are crucial. The CBCT acquisition should fully capture targets, OARs, and external body contour with adequate margins. The Ethos platform offers iCBCT, which improves image quality using statistical penalized likelihood (PL). Although iCBCT reduces noise and enhances contrast compared with analytical Feldkamp-Davis-Kress (FDK) methods, it is sensitive to anatomic motion during imaging acquisition.[8] A fast-scanning protocol is also available for position verification during the OART process despite providing inferior image quality compared with standard CBCT.

Daily adaptive plans address interfractional anatomic changes, but intrafractional uncertainties and organ motion remain unresolved in OART. The OART procedure time, from CBCT acquisition to treatment delivery, is longer than that of a non-ART fraction, increasing the potential effect of intrafractional changes. For instance, De Jong et al[5] reported insufficient target coverage due to the intrafractional motion of a large gas pocket in the rectum. OART fractional procedure time varies based on the treatment site and clinician familiarity, typically ranging from 12 to 30 minutes.[1-3] Defining personnel roles during the online procedure reduces delays, optimizing team efficiency. Policies requiring team member physical presence before CBCT acquisition, intradepartmental credentialling for covering physicians and physicists, and standard quality control checks (eg, second CBCT before OART fraction delivery) mitigate and respond to intrafractional changes.

The current Ethos platform uses electron density information from the synthetic CT (sCT), generated by deforming the planning CT to the CBCT, for online dose calculation. During the initial planning, any air bubbles, hardware, or contrast agents in the planning CT can be delineated to override the electron density to the value of water if absent during OART delivery. To ensure accurate electron density representation from the sCT deformation, the evaluation of deformation relies on displayed high-density and external body structures generated from sCT. If they correspond well with the CBCT anatomy, the sCT is considered suitable for dose calculation. Fig. 3 shows a side-by-side comparison of patients' CBCT and sCT images containing a biliary stent, air bubbles, and bolus. To address the discrepancy in air bubbles between sCT and CBCT (Fig. 3(b)), the air bubbles on the sCT are

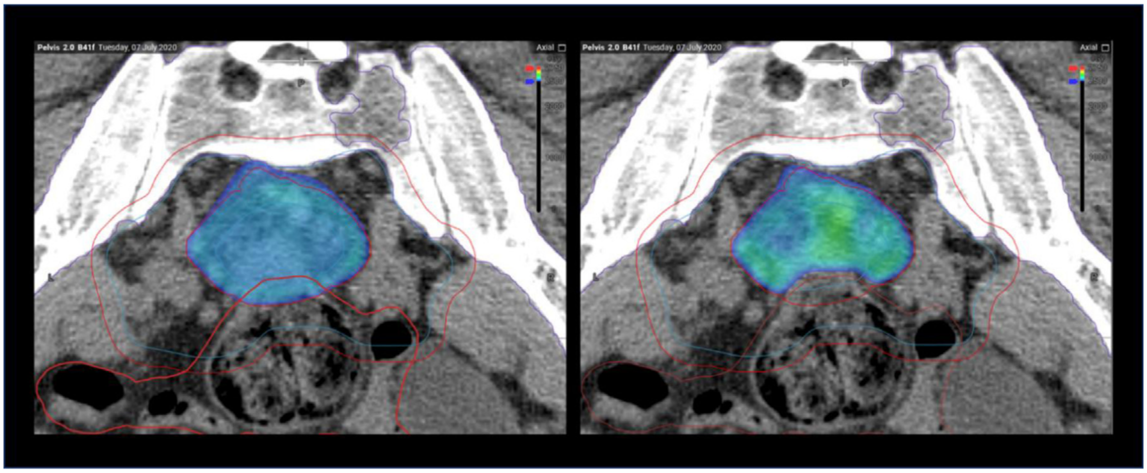

Figure 2 IOE treatment plans with different constraint prioritization: Bowel constraint, D0.03 cc <25 Gy, prioritized lower (left) and higher (right) than PTV coverage constraints. The 25 Gy dose cloud is displayed.

carefully overridden as water during the initial planning, excluding them from the online dose calculation. Before each treatment session, the presence of gas on CBCT is vigilantly monitored or removed, if deemed necessary. This approach is consistent with the investigation conducted by Kisling et al.[10]

Posttreatment considerations

The current version of the Ethos treatment system does not interface directly with any commercially available radiation therapy information management system (ROIS). To overcome this limitation, a "dummy" plan is created in the department's ROIS, Varian ARIA, to manually record per fraction delivery, documentation, and charge codes. The Ethos management system estimates dose accumulation over the treatment course based on the deformation matrix between the planning CT and daily CBCT. Uncertainties exist in the accumulation results, and their magnitude is unclear. Radiation oncologists should consider these limitations when using it for clinical decisions.

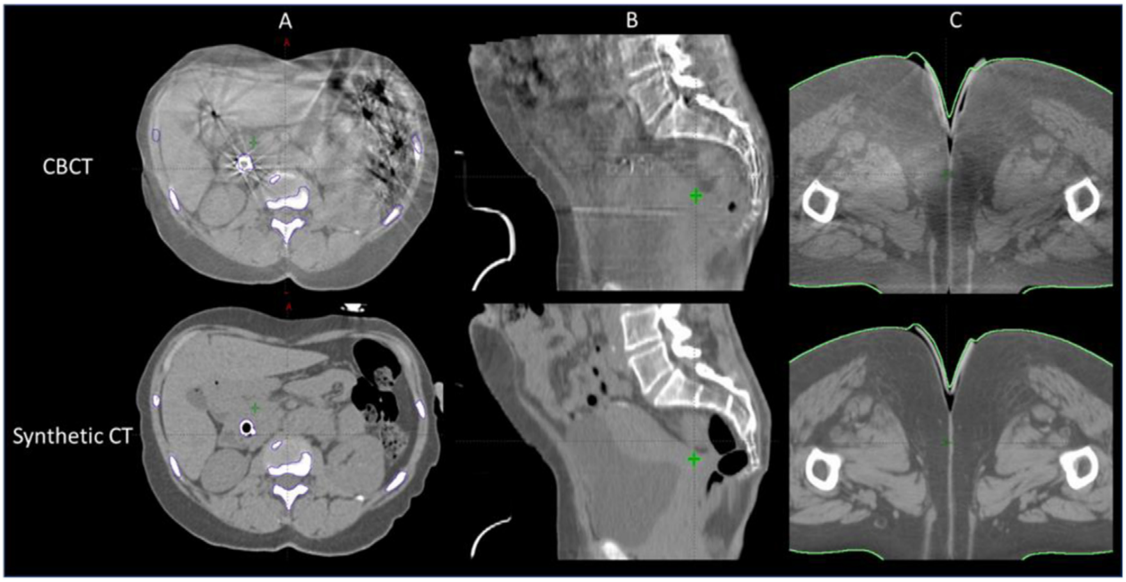

Figure 3 Comparison of CBCT and synthetic CT images with (A) biliary stent, (B) air bubbles, and (C) bolus. (A) The purple-colored high-density structure from the synthetic CT overlaps with the biliary stent on the CBCT, enabling acceptable dose calculation. (B) Air bubbles appear in the target on the synthetic CT, although they are not present on the CBCT. (C) The external body contour (green) on the synthetic CT aligns with the daily bolus placement on the CBCT, ensuring reliable dose calculation.

Results

Failure Mode and Effects Analysis

The results of the FMEA, both before and after implementing safety procedures, along with the corresponding procedures, are provided in Table 1. Among the identified high-priority failure modes, 9 have the potential to result in incorrect dose delivery and subsequent adverse clinical outcomes (Severity > 8). Detecting eleven of these failure modes is challenging when safety policies are not in place (Detectability > 5). Online contouring errors, suboptimal auto-planning templates, and communication issues among professionals were directly or indirectly associated with 9, 5, and 6 of these failure modes, respectively. Implementing safety policies and procedures markedly reduced the RPN, with an average decrease of 110.0 (maximum reduction of 305.5 and minimum reduction of 27.4).

An Interdisciplinary OART Workflow

The developed interdisciplinary OART workflow diagram is shown in Fig. 4. The workflow is divided into 4 components: (1) pretreatment site-specific template preparation, (2) pretreatment initial planning and verification, (3) on-treatment procedure, and (4) posttreatment evaluation, involving 4, 8, 13, and 4 separate sequential tasks. Task checklists (Appendix E) were created to evaluate the process of the tasks highlighted in the shaded boxes of Fig. 4. The workflow process is described below.

Pretreatment Site-specific Template Preparation

The template preparation process begins with an adaptive template directive approved by the treating physician. This directive is achieved through multidisciplinary discussions among professionals, ensuring that the auto-planning template accurately reflects the physician's intentions. A complete checklist guiding the development of an adaptive template directive is provided in Appendix E1. The IOE planning template is set up based on the directive, ranking target, and OAR constraints according to the prioritization. Derived structures are defined following contouring guidelines, such as the planning target volume (PTV) derived by adding a defined margin to the clinical target volume (CTV).

To assess the clinical utility of a new OART template, treatment plans generated using the template are compared with those created using the department's external-beam treatment planning system, Eclipse (Varian, Palo Alto, United States). Eclipse plans are generated using an equivalent beam model and dose calculation algorithm (ie, AccurosXB) consistent with Ethos. Furthermore, the template's effectiveness in accommodating interfractional anatomic variations within a generalized treatment site is evaluated by generating treatment plans for ten patients with diverse anatomies. Medical physicists or dosimetrists create additional planning constraints or structures and optimize the constraints prioritization by assessing the template's qualitative and quantitative performance across diverse single-site anatomies. Once the template has been completed and verified, it is approved by the physician and the physicist before clinical release. Once approved, the site-specific OART template is used for all OART treatments using the same treatment site and fractionation scheme. The OART template evaluation checklist is presented in Appendix E1.

Pretreatment Initial Planning and Verification

Entering the path of care, a patient selected for OART is immobilized in the treatment position, and a traditional CT simulation is performed. The patient's ability to comfortably maintain the treatment position for an extended on-couch time is evaluated. Any potential source of CBCT imaging artifact is identified and assessed during CT simulation. Any sources of dosimetric uncertainty (eg, gas pockets, bolus, high-density implants, contrast agents) present during simulation but not treatment are evaluated. Organ-filling strategies to ensure minimal intrafractional anatomic changes are paramount to mitigating the treatment uncertainties. Motion management strategies, such as abdominal compression devices or respiratory gating, can reduce motion artifacts and aid ITV delineation on CBCT. A checklist for the planning CT acquisition is presented in Appendix E1.

The physician contours the targets and OARs on the simulation CT images. Automatic IMRT planning is performed using the site-specific template. If needed, constraints prioritization may be fine-tuned based on the patient's specific anatomic features. The final treatment plan and applied template are reviewed and approved by the attending physician and medical physicist. Procedure notes with the contouring guidelines, plan evaluation criteria, and structure modification instructions are provided to the covering clinicians. This step is particularly important when interfractional anatomic changes are likely, or patient-unique approaches must be followed to account for appliances, prior disease, or existing anatomic irregularities. Patient-specific quality assurance (QA) and monitor unit (MU) checks are performed before the first OART treatment. Checklists for the template planning and plan review are listed in Appendix E1.

On-treatment Procedure

On the day-of-treatment (DoT), the patient is positioned, and the software for virtual QA is prepared. All relevant personnel (radiation oncologists, physicists, and radiologic technologists) are required to be present. CBCT images are acquired following established OART CBCT protocols for online replanning. Once imaging is

Table 1 The twenty potential failure modes with the highest average risk priority numbers (RPNs), along with their corresponding effects of failures, causes of failures, actions taken, and RPN values before and after implementing corrective actions.

									Workflow Results				
Rank	**Step**	**Potential failure mode**	**Potential effect of failure**	**Potential cause**	**Sev**	**Occur**	**Det**	**R.P.N.**	**Actions Taken**	**Sev**	**Occur**	**Det**	**R.P.N.**
1	Online contours review and editing	Incorrect contouring for online optimization	Very wrong dose distribution (10%-20%), very wrong location for dose (> 5 mm), very wrong volume (geographic miss or complication)	Lack of standardized procedures, inadequate training, human failures (inattention, inadequate assessment), lack of staff	9	6.5	5.8	339.3	Implementation of a standardized procedure requiring physician assessment of contours in each treatment, physics second check, and adequate training	9	1.5	2.5	33.8
2	Automatic treatment plan optimization	Clinically unacceptable adaptive plan generated	Wrong dose distribution (5%-10%), suboptimal plan	Incorrect prioritization of constraints in the automated planning template, suboptimal planning template	7.2	6.9	6.5	322.9	Development of a template directive from physician specifying constraints prioritization and implementation of a standardized procedure for template testing and quality assurance	7.2	2.3	2.5	41.4
3	Online contours review and editing	Incorrect contouring for online optimization	Wrong location for dose (3-5 mm)	Suboptimal CBCT image quality caused by incorrect imaging protocol selection	5	6.5	6.9	224.3	Establishment of a standardized imaging protocol for each site, physicist's evaluation of image quality before contouring	5	2.3	3.3	38.0
4	Online contours review and editing	Incorrect contouring for online optimization	Very wrong dose distribution (10%-20%), very wrong location for dose (> 5 mm), very wrong volume (geographic miss or complication)	Lack of familiarity of covering physician with patient-specific contouring guidelines	9	3.2	7.2	207.4	Implementation of a standardized procedure requiring the creation of a procedure note for covering clinicians	9	2.3	1.5	31.0
5	Online contours review and editing	Incorrect contouring for online optimization	Very wrong location for dose (> 5 mm)	Suboptimal CBCT image quality caused by artifacts from high density materials	8.8	4.8	4.5	190.1	Implementation of a standardized procedure requiring physicist's assessment of potential sources of artifacts during initial and online planning	8.8	1.5	2.3	30.4
6	Automatic treatment plan optimization	Clinically unacceptable adaptive plan generated	Wrong dose distribution (5%-10%), suboptimal plan	Incorrect version of the IOE template used for initial planning	8	2.8	6.9	154.6	Implementation of a standardized procedure for initial plan check and comprehensive documentation of the developed template and all subsequent revisions	8	2.2	2.5	44.0
7	Automatic targets and OARs contouring	Erroneous automated contouring of derived structures	Very wrong dose distribution (10%-20%), very wrong location for dose (> 5 mm), very wrong volume (geographic miss or complication)	Inaccurate target definition, target margin, OAR definition setup in planning template	9	3.2	5.2	149.8	Implementation of a standardized procedure for template testing and quality assurance	9	1.5	2.3	31.1
8	Second CBCT for patient positioning verification	Excessive intrafractional anatomic changes observed on second CBCT scan	Wrong location for dose (3-5 mm), suboptimal treatment plan delivered	Extended online procedure duration and variations in organ filling (Rectum, bladder, bowel)	6.5	4.5	5	146.3	Implementation of standardized online treatment procedures to minimize online planning time, utilization of organ filling strategies to mitigate intrafractional changes, and acquisition of a second CBCT before treatment delivery	6.5	3.1	1.5	30.2

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Table 1 (*Continued*)

									Workflow Results				
Rank	Step	Potential failure mode	Potential effect of failure	Potential cause	Sev	Occur	Det	R.P.N.	Actions Taken	Sev	Occur	Det	R.P.N.
9	Online contours review and editing	Substantial patient motion during online planning	Wrong dose distribution (5%-10%), Wrong location for dose (3-5 mm)	Inadequate motion management or immobilization, compromised patient compliance, and performance status	7.2	3.5	5.2	131	Establishment of motion management strategies for motion artifact reduction, physicist's evaluation of image quality before contouring, therapist monitoring of patient motion	7.2	3.1	1.5	33.5
10	Automatic treatment plan optimization	Clinically unacceptable adaptive plan generated	Wrong dose distribution (5%-10%), suboptimal plan	Inadequate CBCT scanning range to encompass the targets or OARs	6.7	4.2	4.5	126.6	Physicist's evaluation of CBCT scanning range before contouring	6.7	1.2	1.5	12.1
11	Treatment plans review and selection	Selection of incorrect treatment plan	Wrong dose distribution (5%-10%), suboptimal plan	Plan evaluation using erroneous contours or constraints	6.7	3.2	5.2	111.5	Implementation of a standardized procedure for online physician and physics plan review and approval	6.7	1.5	2.5	25.1
12	Online treatment plan dose calculation	Differences in the presence of high- or low-density materials between simulation CT and CBCT scans	Wrong dose distribution (5%-10%), suboptimal plan	Lack of standardized procedures, unawareness of anatomy discrepancies by treating clinicians	7.2	3.5	4.3	108.4	Implementation of a standardized procedure requiring physicist's assessment of the presence of high- or low-density materials during initial and online planning	7.2	1.2	2.3	19.9
13	Online treatment plan dose calculation	Generation of inaccurate synthetic CT for online dose calculation	Wrong dose distribution (5%-10%), suboptimal plan	Inaccurate deformable registration for synthetic CT generation caused by substantial anatomy changes	5.6	2.8	6.8	106.6	Implementation of a standardized procedure requiring physicist's assessment of the deformable registration for synthetic CT generation	5.6	2.2	2.2	27.1
14	Online contours review and editing	Incorrect contouring for online optimization	Very wrong dose distribution (10%-20%), very wrong location for dose (> 5 mm), very wrong volume (geographic miss or complication)	Automatic contour interpolation for disconnected organ structures	9	1.5	6.5	87.8	Implementation of a standardized procedure requiring physician assessment of contours in each treatment, physics second check, and comprehensive training	9	1.5	2.5	33.8
15	Initial planning – planning CT acquisition	Incorrect simulation CT images imported for planning	Very wrong dose distribution (10%-20%), very wrong location for dose (> 5 mm), very wrong volume (geographic miss or complication)	Lack of communication, presence of multiple simulation CTs for import, ambiguous image labeling	8.2	2.1	4.5	77.5	Implementation of standardized treatment planning procedures and checklist for initial physics and physician plan review	8.2	1.2	2.3	22.6
16	Treatment plans review and selection	Selection of incorrect treatment plan	Wrong dose distribution (5%-10%), suboptimal plan	Lack of standardized procedures, inadequate training, human failures (inattention, inadequate assessment)	6.7	3.0	3.2	64.3	Implementation of a standardized procedure for online physician and physics plan review and approval, therapist verification of accurate plan transfer for treatment delivery	6.7	2.3	1.5	23.1
17	Online contours review and editing	Missing structures for editing during online contouring	Suboptimal plan, inconvenience-patient	Inaccurate structures contoured or configured for online contouring in the template	4	3.5	4.3	60.2	Implementation of a standardized procedure for template testing and quality assurance, development of a template directive from physician outlining contours to be edited	4	2.3	2.5	23.0

(*continued on next page*)

Table 1 (*Continued*)

									Workflow Results				
Rank	Step	Potential failure mode	Potential effect of failure	Potential cause	Sev	Occur	Det	R.P.N.	Actions Taken	Sev	Occur	Det	R.P.N.
18	Online contours review and editing	Severely inaccurate automated contouring	Very wrong dose distribution (10%-20%), very wrong location for dose (> 5 mm), very wrong volume (geographic miss or complication)	Inaccurate manual contours by physician during initial planning, substantial anatomy changes	8.8	2.1	3.2	59.1	Standardized procedure and checklist in place for initial plan check, adequate training for physician contouring on Ethos TPS	8.8	1.5	2.1	27.7
19	Initial planning – add RT intent in TPS	Erroneous dose scheme and constraints entered in the initial plan	Very wrong dose distribution (10%-20%), very wrong absolute dose (10%-20%)	Lack of communication, inadequate training, human failures (inattention, inadequate plan check)	8.8	2.1	2.5	46.2	Implementation of standardized treatment planning procedures and checklist for initial physics and physician plan review	8.8	1.2	1.2	12.7
20	On-couch adaptive treatment	Inability of patients to tolerate treatment position during extended on-couch treatment time	Inconvenience-patient	Lack of standardized procedures for selection of adaptive candidates	3	3	4.2	37.8	Physician's assessment of patient status during treatment consultation	3	1.5	2.3	10.4

completed, the radiologic technologists monitor the patient for any movement while the physician and physicist focus on replanning. The physician and physicist evaluate CBCT artifacts, organ filling, and the presence of high-density materials or air gases immediately after DoT CBCT acquisition. Using machine learning, Ethos OSM automatically segments influencer structures based on the OART template. The influencer structures are then modified by the physician and used to generate the target contours automatically through structure-guided DIR. The physician and physicist review the contours, with the physician making any necessary edits to the target and OAR structures. The physicist evaluates the accuracy of sCT generation based on the body and high-density contours from the sCT images.

An adaptive plan is automatically generated using the same IOE template as the initial treatment planning. The physician and physicist compare the dosimetry of the initial plan recalculated on the DoT CBCT structure set (referred to as the "scheduled plan") with the new adapted plan before the treatment plan selection. It is crucial to confirm that any observed dose discrepancies between the 2 plans are due to interfractional changes rather than contouring errors. The physicist evaluates the MUs and gamma metrics of the selected plan using a virtual QA algorithm (Mobius Medical System) for secondary dose calculation.[16]

A second CBCT scan is performed before fraction delivery to verify patient positioning and detect remarkable anatomic changes during the adaptive session. Minor changes may be mitigated by applying cartesian couch shifts.

The detailed checklists for initial CBCT review, editing auto-contoured structures, plan selection, and pretreatment CBCT review are provided in Appendix E2.

Posttreatment Evaluation

The delivered treatment plan and QA report are uploaded to the ROIS. The physician and physicist assess the trend of interfractional and intrafractional anatomic changes and the adaptive benefit of each patient. The physician documents the rationale for their selection of the treatment plan. This is generally performed immediately following the treatment. The larger interdisciplinary team reviews the treatment results weekly for workflow improvement, identification of challenging patient fractions, and template evaluation. A checklist for posttreatment evaluation is provided in Appendix E3.

Discussion

Nascent technologies employed for OART, such as automatic contouring, automatic planning, and improved CBCT imaging, disrupt established clinical practices. To systematically implement a safe, high-quality, efficient

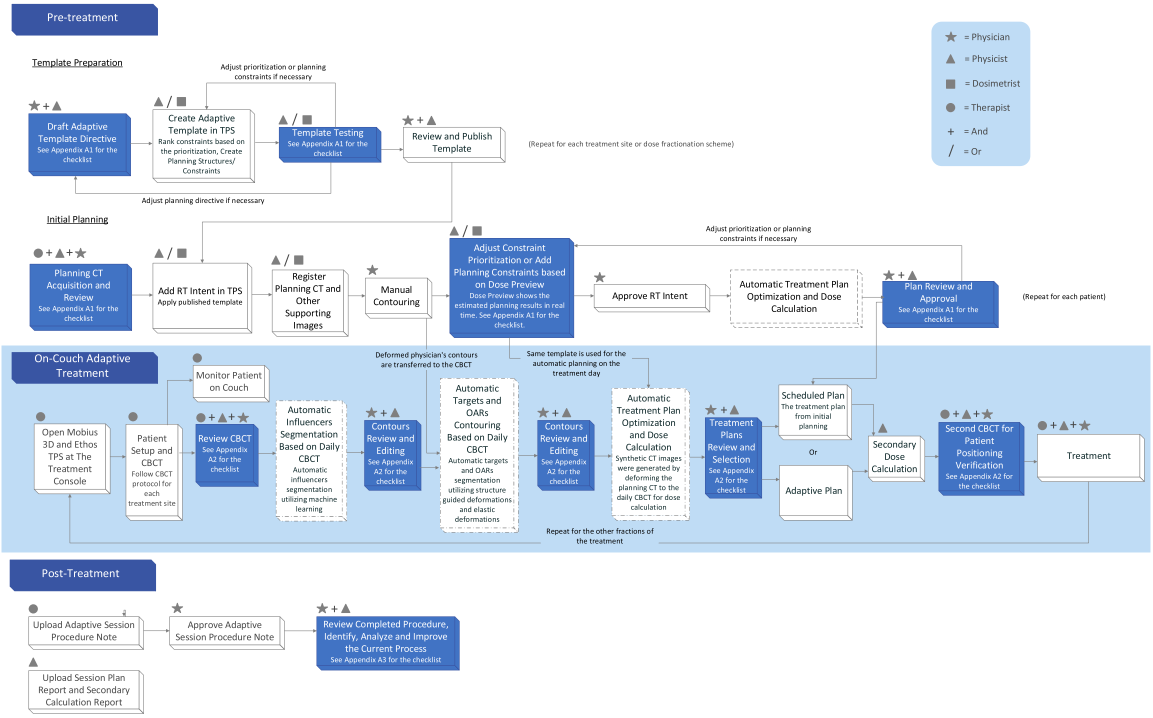

Figure 4 Interdisciplinary OART workflow diagram. The workflow was divided into 4 components: (A) pretreatment site-specific template preparation, (B) pretreatment initial planning and verification, (C) on-treatment procedure, and (D) posttreatment evaluation, involving 4, 8, 13, and 4 separate, sequential tasks.

OART service, a unique, standardized workflow, and checklists were developed by an interdisciplinary team.

Vigilant verification of auto-contouring is crucial to prevent high-risk failures. Although the auto-contours are generated using contours initially defined by a physician, when presented at the time of OART, they are recontoured using machine learning or deformed via image registration. Physicians must review contours slice-by-slice to prevent dosimetric errors. During the initial planning, clinicians were instructed to follow precise definitions when contouring organ structures to ensure segmentation consistency by the automation algorithm. Although automated structure delineation reduces the online procedure time and improves contouring consistency, most require minor or even significant editing by physicians based on our experience with the system and published preliminary studies.[1]

The current workflow lacks accounting for intra- and interphysician variability in daily CBCT structure delineation, leading to treatment uncertainties. Previous studies show significant interphysician variability, with target volumes ranging from +109% to -86% relative to the mean. As for intraphysician variability, the shape of the target varied by up to ±1.6 cm, influenced by the complexity of target delineation and image quality.[17] A study revealed that participants achieved reasonable contouring precision when artifacts were absent, but larger variations (1 SD = 8 mm for cranial/caudal boundary) occurred when image artifacts obscured the structure.[18] Physicians and physicists must possess knowledge about imaging artifacts and remain vigilant of their presence. To enhance the online contouring process, future advancements should include online QA tools for detecting contouring variation, improved CBCT image quality, and advanced segmentation algorithms.

The template planning workflow significantly reduces initial planning time compared with traditional practices. Despite the additional step of site-specific template development, a well-developed template enables the generation of high-quality IMRT plans within minutes for all patients with the same dose scheme. Unlike traditional planning with iterative optimization and physician feedback, minimal or no modification is typically needed for each patient. Adopting this workflow minimizes human errors, reduces plan check time, and improves planning efficiency. However, since template development is a new process, it requires the establishment of consensus QA guidelines to evaluate its accuracy and robustness.

This study presents a comprehensive analysis of high-risk failure modes associated with the OART approach. The highest-ranked risks were identified in template planning, online contouring, and communication, all of which are addressed by the proposed workflow and integrated checklists. For instance, the physician template directive facilitates the transfer of information among different professionals. Written procedure notes from the physician provide patient details for the covering clinicians. The use of written checklists prevents incomplete checks of technical and planning parameters, particularly during online replanning. Moreover, a dedicated template preparation process ensures optimal optimization during the adaptive session. Moving forward, implementing automatic safety checks, QA measures, and remote capabilities can help minimize the burden on clinicians.

Conclusion

AI-driven CBCT-based OART offers promising possibilities for enhancing treatment efficiency, optimizing target coverage, and minimizing damage to organs-at-risk. However, the resource-intensive nature of AI automation and associated risks necessitate a novel approach to care. In response to these challenges, this study identified high-risk failure modes and provided valuable insights into safety measures associated with AI-driven OART. Additional responsibilities and safety checklists were assigned to health care professionals. The implementation of this unique OART workflow promotes effective communication, error prevention, and enhanced patient safety.

Disclosures

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.adro.2023.101399.

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