Online Supplement to "Risk Factors and Mitigation Strategies in Radiation Therapy: A Study of Patient Safety Events From 40 Hospitals"

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This supplementary material has been provided by the authors to give readers additional information and strategies to help detect and prevent the risk factors in radiation therapy identified in the study.

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Online Supplement Appendix S1. Strategies to Mitigate Risk of Patient Harm by Phase and Risk Factor

Phases of RT	Risk Factors	Strategies
All Phases	**All risk factors**	• Use an ILS to document and learn from patient safety events, including near misses. For example, this strategy could be used to address events related to patient positioning, simulation documentation, and malfunctions of hardware/software.[12,34,35,47,48] • Foster a culture of safety where any individual is empowered to request additional resources and time to complete their task accurately, even in a busy environment. This will help to prevent rushing and a range of associated errors, such as errors involving scheduling and simulation documentation.[11,49]
Before Simulation	**Error involving consent form** (e.g., listed wrong side, site, or body part; missing patient signature)	• Implement a standardized, site-specific consent form template that clearly outlines the treatment site, side, and body part.[47,50] • Utilize a checklist to ensure all required fields on the consent form are completed, including patient signature and date, before proceeding with simulation.[27,51] • Require a double-check of the consent form by two independent qualified staff members (e.g., the ordering physician/provider and a member of the simulation team) to verify accuracy against the referral and initial order prior to the simulation appointment.[52]
	Error involving patient medical history (e.g., wrong or missing diagnostic imaging, failure to account for patient's implant/device)	• Develop a protocol requiring the collection and review of relevant prior diagnostic imaging (e.g., CT, MRI, PET) prior to simulation to accurately define the target and organs at risk. This may involve direct download from PACS if available.[47,53] • Implement a standardized form or checklist to document the review of the patient's medical history, specifically noting any implants, devices (e.g., pacemakers), and prior treatments, which may impact simulation and treatment planning.[13,27,52-54] • Establish a communication pathway between the ordering physician/provider and the simulation team to ensure all necessary medical history and relevant information are shared and reviewed before the simulation appointment. Daily morning huddles can facilitate this communication.[53] • Establish a robust process for obtaining and creating a plan sum of records (i.e., composite summary of past treatments) for patients with prior RT at outside facilities. This will inform the current treatment course, allowing sufficient time for this complex task. Longer simulation-to-start time frames may be necessary in such cases.[11]
	Error involving scheduling or ordering (e.g., failure to send referral, referral sent to wrong scheduling pool, order for right side instead of left)	• Establish a clear and standardized process for referral submission and order entry, including defined roles and responsibilities for each step.[53] • Implement a verification step to confirm receipt of the referral and accuracy of the order (e.g., correct patient, site, side) by the scheduling team.[53] • Consider utilizing an EHR system with built-in checks to ensure referrals are sent to the correct pool and orders match the intended treatment plan.[53]
Simulation	**Error in simulation documentation** (e.g., wrong setup notes, wrong patient photograph)	• Implement and consistently use comprehensive simulation checklists to ensure accurate documentation of patient setup, immobilization, imaging parameters, and specific instructions (e.g., breath hold, markers).[47] • Utilize OIS-integrated, logic-driven systems for simulation directives to ensure accurate and complete documentation based on selected procedures (e.g., 4D scan prompts for motion management documentation).[53] • Develop and strictly adhere to SOPs outlining clear documentation requirements for all simulation aspects, specifying content, recording methods, and storage locations (e.g., paper, OIS, EHR).[47] • Provide comprehensive training to all staff involved in simulation on proper documentation procedures, emphasizing the importance of accuracy and completeness. Training should cover the specific documentation requirements outlined in the SOPs and the use of any relevant documentation tools, including electronic systems and checklists. Competency should be assessed regularly.[53] • Standardize the format and terminology used in simulation documentation. This can reduce ambiguity and the potential for misinterpretation. Clear and consistent language in setup notes, position descriptions, and other documentation elements is essential.[34,36] • Implement a system for reviewing simulation documentation as part of the overall quality assurance process.[53] This review can identify incomplete or inaccurate documentation and provide an opportunity for correction before treatment planning proceeds. • Ensure that any changes or deviations from the standard simulation protocol are clearly documented with appropriate signatures and justifications. This is particularly important for factors like patient position or breath-hold techniques.[11] • Incorporate documentation requirements into FMEA and other risk analysis processes to proactively identify potential documentation errors and design mitigation strategies.[47] • Consider electronic systems with built-in checks and prompts to guide documentation, reducing errors and facilitating seamless information transfer to subsequent treatment stages.[34] • Establish clear communication channels and protocols between simulation staff and other team members (e.g., radiation oncologists, dosimetrists) regarding any specific documentation needs or clarifications. Miscommunication can lead to errors in documentation.[27,36]

Simulation	**Error involving patient medical history** (e.g., failure to account for patient's implant/device, previous treatment, physiological tolerance of simulation, missing or wrong document attached to EHR)	• Implement comprehensive checklists for simulation procedures that include verification of relevant medical history, such as previous treatments and presence of implants/devices.[13,27,52-54] Huq et al. provide example checklists for pre-IMRT workup and preparation of patient data for planning,[54] which include verifying previous treatments and correct image datasets. • Establish clear protocols and procedures for reviewing the patient's medical history before and during simulation, ensuring all relevant information is accessible and considered by the involved staff (radiation oncologists, medical physicists, dosimetrists, and therapists).[53] • Ensure effective communication between all members of the radiation oncology team regarding the patient's medical history and any special considerations for simulation.[34] Poor communication is a common causal factor in RT events.[12] • Utilize the EHR effectively to store and display relevant medical history, ensuring that all necessary documents (e.g., prior treatment plans, device information) are attached and readily available during simulation. • Employ image registration techniques to compare current simulation images with prior imaging studies, especially when accounting for previous treatments. • Perform thorough reviews of simulation data before proceeding to treatment planning, involving multiple qualified professionals to identify any discrepancies or missing information related to the patient's medical history.[26] Prior literature describes the process of physics plan review which could potentially catch errors originating from inaccurate simulation due to unaccounted medical history.[26]
	Failure in ongoing QA (e.g., calibration expired, failure to maintain hardware/ software)	• Establish and adhere to QM programs, encompassing both QC and QA activities, to prevent failures related to equipment maintenance and overall processes. • Implement rigorous QC procedures for all equipment, including regular checks, adherence to tolerance levels, and documented procedures, as essential for a comprehensive QA program.[32] • Ensure proper and independently verified equipment calibration to prevent dose errors, addressing issues like misinterpretation, insufficient education, and lack of procedures.[55] • Develop and follow vetted, regularly updated, and accessible SOPs for equipment maintenance and calibration to prevent errors and rushing.[55] • Vendor should perform preventative maintenance for all clinical hardware and software to address defective equipment, including regular maintenance, updates, and retesting.[55] • Implement independent checks and redundancies in processes related to equipment QA to enhance safety. For example, independent verification of commissioning measurements, potentially performed sometime after the initial verification, can evaluate stability.[55] • Utilize checklists to help standardize procedures related to equipment checks and maintenance, ensuring critical steps are completed and verified.[16] • Providing adequate training and competency assessments for staff on equipment operation, maintenance, and QA procedures is crucial.[16] • Regularly review and update the QM program using an ILS, log books, and risk assessments (e.g., FMEA, FTA) to proactively identify and mitigate hardware/software failure modes and develop effective QA measures.[48] • Utilize automation and forcing functions in equipment operation and QA where practical to minimize manual errors.[16,56] • Conduct thorough acceptance testing and clinical commissioning for new RT systems, considering design, capabilities, tolerances, hazards, training, usability, and technical specifications, ideally with independent external validation. • Maintaining data transfer integrity between systems, such as the treatment planning system and treatment delivery system, is also important and relies on properly functioning hardware and software.[11,32,47,52,53]

Simulation	**Malfunction of hardware/software** (e.g., artifact in CT scan, CT hardware failure)	• Implement comprehensive QA procedures for simulation equipment, including regular hardware and software checks and maintenance, with medical physicists responsible for program consistency and accuracy.[47,52] • Establish processes for identifying and addressing image artifacts that may arise due to hardware or software issues during simulation.[57] This might involve departmental protocols for artifact correction.[53] • Provide thorough training to staff on how to recognize and respond to simulation equipment malfunctions.[47,53,58] This training should cover the efficient and effective use of complex TPS hardware and software. Competency assessment should be provided at orientation and prior to changes in protocols. • Incorporate automation for QA checks during simulation where possible.[34,53,57] Logic-driven systems for developing simulation directives can help eliminate errors. Automated plan checking can identify inconsistencies and potential problems early in the process. • Employ checklists for individual QC steps during simulation.[27,53] These checklists can ensure that critical parameters and procedures are correctly followed (e.g., correct patient orientation, appropriate calculation algorithm). Checklists are more effective if they are focused and believed in by the user, and their use is enforced. • Implement peer review processes that include aspects of the simulation process, such as target volume definition on simulation images.[52,53] Peer review of general treatment strategy should occur before the planning process. • Ensure thorough commissioning of new or upgraded simulation hardware and software.[47,52,53] Information obtained during commissioning should establish baseline performance. • Consider end-to-end tests that encompass the simulation process to validate the delivered dose and overall system integrity.[16,52] • Proactively identify hardware/software failure modes in simulation using risk analysis methods (e.g., FMEA, FTA, as recommended by Task Group 100 of the American Association of Physicists in Medicine on risk assessment methodologies) to design mitigation strategies.[12,28,47,53] • Implement independent checks of critical parameters and data transfers related to simulation.[53] This can include verifying the correct transfer of data from the simulation system to the treatment planning system. • Strive for standardization in simulation protocols, including nomenclature for targets and OARs, which can reduce confusion and the likelihood of errors.[28,53] Standard treatment practices should be vetted through a review committee. • Develop logic-driven systems for simulation and treatment planning directives/orders to help prevent errors.[53] • Perform regular reviews of workflows, policies, and procedures to ensure they remain relevant to current practice.[53] An FMEA approach can be used for such reviews. • Consider designing systems for success by using simplification, standardization, and automation, and forcing functions to create robust workflows.[53]
	Wrong position (e.g., supine instead of prone, error in breath-hold technique, failure to evaluate breath-hold scans, missing or wrong marker, incorrect chin position)	• Select a reproducible and appropriate patient treatment position. This selection should consider the target location, anticipated treatment beam orientation, and patient comfort. A personalized approach is needed, considering the patient's unique anatomy.[53] • Utilize appropriate patient positioning and immobilization devices (e.g., masks, alpha cradles) to allow for reproducible positioning. The selection or construction of these devices should facilitate treatment but not restrict the technique.[53] • Clearly document the selected patient position (e.g., supine, prone) in the SOPs and on checklists used during the simulation process. This ensures that the intended position is communicated to all staff involved.[6,11] • Provide thorough training to staff on proper patient positioning techniques for various treatment sites and the use of immobilization devices. This training should emphasize the importance of adhering to established protocols and recognizing potential positioning errors.[59] • Establish clear protocols for breath holds that include instructions for the patient, the method of monitoring breath-hold, and the acquisition and evaluation of breath-hold scans. Failure to evaluate breath-hold scans can lead to treatment without verifying the intended respiratory state.[47] • Utilize markers (e.g., wires, ball bearings, fiducials) as needed to facilitate planning. Ensure that the placement of markers is accurate and well-documented on simulation images and in the patient's record. Missing or wrongly placed markers can lead to incorrect isocenter localization.[28,53] • Pay attention to specific positioning details such as chin position, which can affect the treatment of head and neck regions. Standardized protocols should address these specific requirements for different treatment sites.[53] • Implement image-based patient position verification (e.g., portal images, CBCT) on day 1 and throughout treatment to detect and correct discrepancies and setup errors (e.g., wrong shifts, alignment to incorrect landmarks).[11,48] • Establish a policy for reviewing setup images and any deviations from the planned position. Some facilities may have a policy requiring physician review for shifts greater than a certain threshold.[11] • Conduct a prospective peer review before initiating treatment. This review can include verification of the planned patient position and setup based on the simulation documentation and images.[11] • Consider designing systems for success by using simplification, standardization, and automation, and forcing functions to create robust workflows.[53] For complex cases or treatments involving reirradiation, collect all prior treatment plans and imaging data to ensure the correct anatomical site and position are targeted.[11] • Clearly communicate all aspects of the patient's required position and setup instructions to all members of the treatment team (radiation oncologist, medical physicist, dosimetrist, therapist). Poor communication can contribute to setup errors.[11,36] • Use checklists for individual QC steps during simulation and setup, including verification of the patient's position relative to the intended position (e.g., supine vs. prone).[11] • Implement, for spine treatments, more comprehensive setup field images and potentially CBCT with a larger field of view to ensure correct vertebral body alignment. Mislabeling vertebral bodies is a known source of risk due a lack of distinct external landmarks. Contouring adjacent structures as landmarks in DRR can also be a mitigation strategy.[59]

Treatment Planning	**Absent accessory** (e.g., bolus was missing from the field)	• Implement QM checks for the first day of treatment to verify the correctness of parameters and treatment accessories defined or added to the plan. This check should ensure that these additions are correctly continued through the treatment course.[47] • Perform a QM check of the entire treatment delivery script before treatment and automation.[47] • Develop procedures for changes needed in the treatment process, including necessary QA.[55] • Avoid rushing to prevent issues with incorrect, missing, mislabeled, misused, or damaged treatment accessories.[11,52]
	Error in clearance (e.g., gantry collides with patient and/or supporting structure)	Include checks in treatment planning and setup procedures to ensure the planned isocenter and associated setup parameters are within the physical limits of the equipment and patient/support structure geometry.[57]
	Error involving patient medical history (e.g., failure to account for patient's implant/device or previous treatment)	• Identify patients with prior radiation history and account for other patient-specific considerations that were documented during the initial consultation.[53] • In cases of reirradiation, collect all prior radiation plans, including DICOM data when available, to delineate the areas of prior radiation. This is crucial for targeting the correct region and ensuring the new treatment course is safe by accounting for prior radiation.[11] • Include in the initial directive a statement of previous treatment and request a review of previous treatments; the prescription must account for any previous treatments.[47] • Dosimetrists should perform QC checks of the inputs into the planning process by comparison against the treatment protocol, which includes reviewing previous treatments.[47] • Use more comprehensive downstream physics checks of the plan that use the same information for the final QA check, including reviewing previous treatments.[47] • Use chart rounds to ensure accounting of previous treatment.[37] • Consider implementing prospective peer review for complex cases or procedures like reirradiation.[7]
	Inaccurate or missing field (e.g., wrong location, wrong size, incorrect beam time factor)	• Select appropriate beam sizes and shapes to adequately cover the target volumes.[7] • Ensure that all parts of the plan are validated before treatment, including verifying the correctness of parameters and accessories added to the plan on the first day of treatment (day 1).[11] • Provide longer simulation-to-start time frames to allow for thorough checks during complex cases or procedures.[11] • Implement checklists for critical workflow steps like simulation and planning.[47] • Develop a policy describing the process for day-1 imaging, setup, and verification of patient position and treatment isocenter(s). Patient-positioning errors need to be corrected via the appropriate image guidance strategy.[47] • Standardize patient class tolerances for setup accuracy (e.g., prostate vs. lung) beforehand to remove ambiguity and possible errors at the time of imaging.[47] • Consider implementing automated field-labeling in the TPS as an option for users.[26]
	Wrong contour (e.g., wrong segmentation, incorrect expansion of volume, low-quality fusion)	• Radiation oncologists should review treatment plan(s) generated during the dosimetric planning process, including a review of image fusion/registration and OARs delineated by planning staff, for accuracy.[16] • Compare plans against a documented standard, such as output from a knowledge-based planning system or a practice's protocol.[16] • Radiation oncologists should take the lead in developing QM for this step, as they are the only personnel with the specialized knowledge needed to define the contouring protocols for most radiotherapy targets and other critical structures.[47] • QA check of the target volumes defined by the prescribing physician, before significant planning effort takes place, is likely the most efficient way to prevent this risk factor, which is virtually undetectable otherwise. This check should include labeling of images to distinguish between those used for delineation and those used for the treatment plan.[47] • Address failures to utilize correct Boolean combinations of delineated structures by including the process of Boolean combination, including standardized structure creation, in standardized site-specific protocols. A QA check to intercept these errors can be incorporated into the dosimetrist/attending physician preplanning contour check.[47] • Consider the application of automatic localization and segmentation of contours as potential solutions to mislabeling and contouring errors. However, time-saving tools like auto-segmentation require manual checks for accuracy.[47] • Peer review of key physician inputs to planning, before planning starts, is a QC step that should be embraced more frequently.[47]
	Wrong dose prescribed (e.g., prescribed 68 Gy instead of 73 Gy)	• Radiation oncologists should review treatment plan(s) and quantitative metrics describing the dose to the target(s) and OARs. They must verify that the plan satisfies the clinical requirements and prescription(s).[16] • Independent checks of treatment plans and calculations can be used to detect dose errors.[55] • Avoid certain dose/fraction errors by having the correct dose prescription digitally entered and approved into the TPS by the radiation oncologist and linked to the plan.[26,55] • Use of a standardized prescription structure could help by limiting crucial communications to approved pathways and standardizing the communication between physician and planner to confirm key plan elements.[34]

Treatment Planning	**Wrong fractionation** (e.g., wrong dose per fraction or wrong number of fractions)	• Ensure the fractional dose and total dose in the prescription agrees with the treatment plan.[16] • Develop written procedures for treatment prescription to avoid errors arising from unclear verbal prescriptions or complex plans.[55] • Implement a system where a "stop" mark is placed in each patient's daily treatment log indicating the projected final day of treatment for each site, for complex treatments involving different fraction numbers per site.[55] • Independent checks of treatment plans (treatment times) are a safety provision and are effective for identifying a change in the regimen.[55] • Use independent reviews to help identify instances where there was confusion of fractional dose and total dose.[55] • Avoid certain dose/fraction errors by having the correct dose prescription digitally entered and approved into the TPS by the radiation oncologist and linked to the plan.[26,55]
	Wrong isocenter (e.g., isocenter was not correctly adjusted from CT origin)	• Provide to the treatment planner documentation of isocenter coordinates, measurements, patient positioning, etc., from the simulator.[47] • Implement QM procedures to mitigate the risk of high-severity treatment failure that may result if an incorrect isocenter placement remains uncorrected or if anatomy is misidentified/misinterpreted during the day-1 procedure.[47] • Implement a prompt into the TPS if the isocenter was not set by the user.[26]
	Wrong laterality (e.g., selected wrong side in directive, incorrectly labeled laterality of target)	• Ensure that the correct target is identified in both the plan and documentation.[34] • Verification at the point of care, by involving the patient, can be a last line of defense.[34] • Use software automation to check for accuracy of labeled laterality.[34,53]
	Wrong or absent constraint. (e.g., physician chose wrong protocol, OAR constraints were missing)	• Define site-specific treatment planning and delivery protocols that serve as the basis for QM procedures. These protocols should be vetted through a review committee and regularly updated. They should be easily accessible.[47] • Agree on standard approaches and nomenclature for common diseases, targets, and OARs to avoid confusion.[47] • Specify optimization goals and limits, using applicable departmental or other protocols. • Develop a patient-specific form based on the treatment protocol to be inserted in the patient's chart. Default or standard choices (e.g., DVH planning or evaluation constraints) should be printed, and deviations written by hand to eliminate transcription error, while being aware of the potential failure of using the default in error.[47] • Dosimetrists should perform QC on the inputs to treatment planning and subsequent steps by comparing against the treatment protocol, which should include specified goals and constraints. This check should detect variances from established policies and provide a mechanism for negotiating either compliance or a documented variance with the attending physician.[47]
	Wrong or low-quality images (e.g., wrong image orientation, low-quality image registration, low-quality image, diagnostic image used for volumes)	• Radiation oncologists should obtain up-to-date imaging data sets.[25] • Radiation oncologists should leverage all tools at their disposal, such as a review with neuroradiology or neurosurgery, implementing radiation oncology segmentation rounds, or obtaining postoperative imaging in the treatment position as necessary.[25] • Check image datasets input into the planning process for correct dataset choice (correct study of the correct patient), documentation, quality, etc.[11] • Verify correct orientation of images.[11] • Document achieved registration accuracy of primary and secondary datasets during image registration cases.[47] • Correct image artifacts (e.g., contrast, metal) per department protocols.[47] • Physicians should specify image sets to be used for target delineation, particularly when obtained outside a radiation oncology department (e.g., number of images and date).[47] • Make errors in secondary-to-primary image registration more detectable by ensuring that treatment protocol documents specify the standard registration process to be used for the given clinical site (which image set is primary, type of registration, which landmarks to align, etc.).[47]
	Wrong shift (e.g., wrong shift values, wrong table height)	• Develop a policy describing the process for day-1 imaging, setup, and verification of patient position and treatment isocenter(s), including patient-positioning errors needing correction via appropriate image guidance.[34,47] • Use automation to verify the correct shift.[56]
	Other (e.g., The following were wrong: couch tolerance, plan notes, motion management or MLC file, linked prescription, target label)	• Ensure treatment planning instructions are clear and unambiguous.[47] • Standardize treatment practices and QA mechanisms through a review committee and regular updates. Standard treatment practices and protocols should be easily accessible.[47] • Use automated QA functions, such as comparing target volumes and OAR doses to constraints.[11] • Consider using treatment planning templates where many parameters are already set, limiting manual (error-prone) interaction by the user.[26] • Consider using artificial intelligence to check treatment plans for quality and inconsistencies, potentially detecting errors such as wrong dose/number of fractions or wrong gantry angle.[26] • Implement technical barriers in the TPS that can detect errors by denying final approval until correction.[26] • Ensure adequate commissioning of equipment and software, determining limits of reliable operation and types of errors with misuse. This includes thorough commissioning and validation of the TPS.[55] • Address hardware/software failures and design deficiencies through commissioning, periodic QA, and preventive maintenance.[55] • Verify all fluence patterns to confirm their correct behavior and resulting intensity distributions before any clinical use. This will help to reduce potential for day N (each day of treatment) delivery problems, such as lost MLC trajectories during plan transfer.[47] • Ensure complete and accurate documentation of patient charts for all aspects of treatment planning. Avoid misleading workflow documentation.[36]

Pretreatment QA Review	**Error involving scheduling** (e.g., scheduled on wrong machine, failure to schedule replan, failure to schedule care tasks)	• Establish reasonable timelines by assessing where and how rushing is introduced into the workflow and adjust standard or specialized timelines as necessary. Provide longer simulation-to-start time frames for complex cases.[11,49] • Implement mechanisms to protect time for critical steps in the process. A "no-fly policy" is one option, mandating that workflow processes adhere to designated timelines and rescheduling treatment if deadlines are not met.[49] • Schedule more staff during peak periods, if rushes are known to occur at certain times. This will counteract unsafe conditions.[49] • Consider adjusting patient loads and start times, potentially by "batching of cases," to manage workload and promote patient safety. Analyzing rushing trends can help identify times of day when therapists should be given more time between treating patients.[47] • Improve scheduling practices as a quality management tool.[47] • Recognize workflow issues that can lead to compressed timelines, such as coordinating with other healthcare providers (e.g., chemotherapy/infusion) or dealing with incomplete pretreatment steps (e.g., no consent at simulation, undocumented pacemaker).[49]
	Failure in ongoing QA (e.g., failure to perform patient specific QA, manual calculation error, unable to reproduce imaging)	• Create and maintain a periodic (e.g., monthly or biannual) QA program for treatment planning and delivery systems. This should be consistent with the desired accuracy for the treatment technique.[52] • Standardize site-specific treatment planning and delivery protocols, including written procedures and staff education, to address common failure modes and prevent training/procedure lapses.[47,52] • Implement independent checks of critical parameters. Employ "defense-in-depth" measures, such as having multiple checks of the treatment plan or machine output. The assignment of functions and lines of authority should ensure no gaps and establish necessary human redundancy.[55] • Address imaging-related issues by documenting standard registration processes in treatment protocols and check inputs against these protocols. Specify in protocols which images are used for tasks like ITV creation, dose calculation, and DRR generation for techniques like 4D motion management. Review motion management techniques during physics plan review. Prepare IGRT reference data (annotated DRRs or data for CBCT comparisons) as required for techniques like SBRT.[47] • Improve dose calculation verification by implementing robust automated checks of delivery-system parameters, using process control charts for variability, and defining QM goals (e.g., dose uncertainty limits).[47] • Automate checks and use forcing functions (e.g., computerized verification, automated monitoring, order entry) where possible, as these are more effective than relying solely on policies and procedures.[16,52] • Consolidate QM steps by identifying recurring causes in fault trees/process maps, improving efficiency, and positioning early checks (e.g., preplanning) to cover multiple downstream failures.[47] • Implement a departmentwide preventive maintenance program for all clinical hardware and software to address the cause of "defective equipment." Periodic testing and preventive maintenance are components of ongoing QA.[47] • Ensure continuous improvement of QM programs through detailed analysis, systematic process redesign, and FMEA to optimize procedures, requiring ongoing team enhancement and updates.[47]
Treatment Delivery	**Absent or wrong accessory** (e.g., missing vac lock, wrong electron cutout, missing bolus, wrong bolus location, wrong head cup, device not FDA approved)	• Verify treatment accessories as part of routine procedures.[48] Use manual checks or automation during verification. • During day-1 QM, verify the correctness of parameters and treatment accessories that may have been defined or added to the plan in a way that bypasses the standard flow and checks. Ensure these are correctly continued through the treatment course.[47] • Implement a QM check of the entire treatment delivery script before treatment to validate all parts of the plan, including accessories.[47] • Ensure efficient procedures are in place for checking key parts, such as the tube connector for brachytherapy, before treatment.[55] • Use effective procedures or noncompliance checks to ensure the technologist observes the patient during irradiation, which can help detect issues like incorrect machine settings related to accessories.[55] • Implement procedures for the commissioning and maintenance of brachytherapy applicators.[55] • Address potential errors related to incorrect, missing, mislabeled, misused, or damaged treatment accessories.[11]
	Error involving patient medical history (e.g., failure to account for patient's previous treatment, or failure to account for or monitor implant/device)	• Collect all prior radiation plans, including DICOM data when available, to delineate the areas of prior radiation. This is important both for ensuring the correct lesion is targeted and that the new treatment course is safe by accounting for prior radiation.[11] • Generate a composite plan to help decrease the error rate in this complex process.[11] • Utilize prospective peer review to help decrease the error rate in reirradiation cases.[11] • Use vendor partners to help streamline the transfer of calculated dose between planning systems for a more effective composite plan review.[11]
	Failure to confirm patient identification (e.g., failure to verify name and/or date of birth)	Verify patient identity as the initial step for radiation therapists by two independent verification methods, such as full name, birthdate, address, Social Security number, and/or treatment site.[60]

Treatment Delivery	**Inaccurate or missing field** (e.g., used the QA field instead of treatment field, wrong MUs input following use of service mode)	• Implement independent checks of all delivery-system treatment-plan parameters against those originally approved for use.[47] • Develop robust automated checks of these parameters, which is crucial for modern treatments with many parameters.[47] • Establish policies that implement electronic and procedural "permissions" so that change approvals (such as changes to prescription dose or MU) are performed by appropriate staff.[47] • Use file checksums to confirm the validity of files, which can increase the detectability of issues like file corruption or incorrect leaf motions.[47] • Implement automated monitoring that might demonstrate MLC descriptions were identical and unchanged day to day (e.g., use of EPID dose or dose back-calculated from MLC log-files with corresponding calculations from the TPS or with pretreatment data).[47] • Test all fluence patterns to confirm their correct behavior and resulting intensity distributions before any clinical use.[47] • Verify that the combination of calculational checks and generic MLC performance QA can truly confirm the correctness of a delivery. Physical deliveries of any new fluence pattern and confirmation of their correctness are recommended if this verification is not possible.[47] • Use day N checks to confirm the accuracy of patient delivery and dosimetric recording.[47] • Address errors related to wrong data transfer or setting.[13] • Implement independent verification of treatment parameters.[52] • Include inspection of the resulting isodose distribution as a check.[52] • Ensure written procedures for treatment prescription are followed to avoid misunderstandings, especially for complex treatments.[52] • Implement independent checks of calculations, especially when treatment plans are revised.[52] • Ensure personnel have sufficient awareness when performing calculations, particularly for unusual treatments or changes.[61] • Ensure staff are appropriately trained and follow standardized procedures to prevent human failures in calculations.[16,25]
	Malfunction of hardware/software (e.g., issues with hardware, software, and interconnectivity among the following equipment: chiller, MLC, treatment table, ultrasound, HDR accessories, linac imaging)	• Maintain sufficient hardware and software redundancy.[47] • Implement a departmentwide preventive maintenance program for all clinical hardware and software.[32,47,52] • Detect and compensate for hardware/software failures during commissioning or via periodic QA and preventive maintenance.[47] • Adequately commission all IMRT hardware/software changes (e.g., new, replacements, upgrades) to determine reliable operation limits and misuse-related errors.[47] • Use commissioning information to establish the baseline performance of systems for periodic QA.[53] • Address the impact of equipment changes on training needs and policy/procedure documents.[53] • Ensure the interconnectivity and interoperability of devices and systems.[52,53] • Verify data transfer integrity across the entire system chain (e.g., CT simulator to TPS to TMS to TDS) as part of the QA process.[53] • Create and use a robust information technology infrastructure, which is a critical requirement.[47] • Implement periodic (e.g., monthly) beam data integrity checks.[61] • Address equipment failures, including intermittent, unresolved issues.[58] • Implement and ensure compliance with procedures for transferring the machine to and from the maintenance technician.[62] • Ensure the accelerator cannot be operated in a "nonclinical mode" that disables safety features.[55] • Address deficiencies in the design of accessories or machines.[55] • Use file checksums to confirm file validity and increase problem detectability.[47] • Develop efficient and effective routine check features within treatment management systems.[47] • Implement procedures for checking key parts, such as the tube connector, before brachytherapy treatment.[55] • Address errors related to incorrect operation of the treatment machine.[55] • Investigate the root causes for QA failures, including examining equipment performance QA method/equipment used.[52]
	Wrong or missing patient-specific adaptation (e.g., failure to account for patient weight change or change in target)	• Restart the double-check process if there is a change in the patient geometry or other factor that requires a new simulation and/or a new treatment plan.[52] • Routine checks throughout the treatment course should confirm the accuracy of patient setup, delivery, dosimetric recording of the treatment information, and documentation, and correctness of image guidance decisions by physicians and other staff.[47] • Conduct day N checks for highly hypofractionated treatments.[47] • Address issues such as the immobilization device allowing movement during treatment.[52] • If the patient shows unusual toxicity, review the treatment plan and QA, review patient setup (positioning, beam placement), verify accuracy of data in TMS, review possible confounding clinical factors (e.g., medication use, chemotherapy), and consider performing supplemental measurements on a phantom or the patient (e.g., in vivo measurements).[52] • Recognize workflow challenges that can lead to compressed timelines, such as coordinating with other healthcare providers or dealing with incomplete pretreatment steps.[52] • Implement automation or weekly physics chart checks to detect for physician's change in prescribed dose.[47]

Treatment Delivery	**Wrong position** (e.g., incorrect extremity position, error in breath-hold technique, error in empty/full bladder, wrong shift, wrong SSD)	• Perform day-1 patient setup, including confirmation of setup and use image guidance often to position the patient. Document the correctness of the patient's position.[47] • Day N checks should include confirming the accuracy of patient setup.[47] • Address errors related to wrong patient position, setup point, or shift.[28,59] • Develop a detailed and comprehensive policy on 4D motion management. This protocol should address which images are used for tasks like ITV creation, dose calculation, and DRR generation.[47] • Address issues involved in registering 4D images, such as which landmarks are to be used by therapists in performing online registration. These should be addressed in the protocol.[47] • Use written procedures that clearly identify indications for techniques like gated treatment, including immobilization, setup, and intrafraction motion monitoring.[47] • Ensure adequate immobilization is employed to mitigate external motion.[52] • Use motion management and planning techniques to account for internal changes such as breathing or bladder/bowel filling.[52] • Prepare IGRT reference data (annotated DRRs or data for CBCT comparisons) as required for techniques like SBRT.[47] • Implement the time-out procedure before starting treatment to catch setup errors like treating the wrong site.[11] • Consider revising procedures to require cone beam CT for localization of spine fields to prevent setup errors.[36] • Address mislabeling vertebral bodies, which can cause positioning errors, by contouring adjacent structures within the treatment field to act as landmarks during image guidance or considering the application of automatic localization and segmentation of vertebral bodies.[29,37,59] • If toxicity is observed, review patient setup (i.e., positioning, beam placement).[52] • Ensure procedures for simulation are successful in ensuring the technologist understands the treatment plan.[55] • Perform radiographic verification of the location of the source during brachytherapy to detect issues like a kinked catheter.[55,63] • Use dummy seeds to test the proper movement of sources before brachytherapy implants.[55] • Observe the patient during irradiation.[16]
	Other (e.g., insufficient staff, miscommunication, wrong type of imaging)	• Ensure adequate staffing to prevent human failures caused by rushing, lack of time, or fatigue, as it is fundamental for quality.[47] • Address miscommunication issues, because inadequate direction or information exchange is a common cause of patient safety events.[33] Improve communication between the radiation oncologist and radiation technologist during simulation.[55] • Recognize workflow challenges that can lead to compressed timelines, such as coordinating with other healthcare providers or dealing with incomplete pretreatment steps.[11] • Ensure effective communication/transfer of essential information between technical systems.[61] • Ensure physicians provide dosimetrists and medical physicists with clear, unambiguous documented guidance.[34] • Mitigate communication errors by using a standardized prescription structure and standardizing communication to confirm key plan elements.[34] • Implement time-out/verbalization/callback procedures.[48] • Address wrong imaging type by clearly specifying image sets for target delineation (especially external ones), as physician detection of incorrect datasets is crucial due to independent verification limitations.[47] • Specify image sets to be used for ITV creation, dose calculation, and DRR generation in protocols.[47] • Address errors related to using the wrong CT image or wrong registration.[28] • Perform QA for imaging devices.[53]
After Treatment Completion	**Failure to close plan** (e.g., Loaded past plan that should have been closed out)	Establish and enforce clear policies and procedures for closing out completed treatment plans or courses within the R&V System or the TMS.[11,47]

Note: "Day N" represents each day the patient is treated between the first and last day of treatment. CBCT=cone beam computed tomography, CT=computerized tomography, DICOM=Digital Imaging and Communications in Medicine, DRR=digitally reconstructed radiograph, DVH=dose-volume histogram, EHR=electronic health record, EPID=electronic portal imaging devices, FDA=Food and Drug Administration, FMEA=failure modes and effects analysis, FTA=fault tree analysis, Gy=standard radiation dose value is given in Gray, HDR=high-dose rate, IGRT=image-guided radiation therapy, ILS=incident learning system, IMRT=intensity-modulated radiation therapy, ITV=internal target volume, MLC=multileaf collimator, MU=monitor unit, MRI=magnetic resonance imaging, OAR=organ at risk, OIS=oncology information systems, PACS= picture archiving and communication system, PET=positron emission tomography, QA=quality assurance, QC=quality control, QM=quality management, RT=radiation therapy, R&V=record and verify system, SOP=standard operating procedure, SBRT=stereotactic body radiotherapy, SSD=source-to-surface distance, TDS=treatment delivery system, TMS=treatment management system, TPS=treatment planning system

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