# Risk Informed Workflow and Disease Specific Milestones Ensure Safe Patient Transfer and Treatment between Proton Therapy Centers

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## HYPOTHESIS

- When proton centers face intermittent down time, uninterrupted treatment can be maintained via safe and effective patient transfer and continued treatment between clinics.

## INTRODUCTION

- Proton RT clinics grew dramatically in number in the last two decades, but along with it there is a growing concern of postponing patient treatment due to machine maintenance.
- While for some cases, photon RT as an alternative is common, for pediatrics and re-irradiation cases, with greater concern for normal tissue dose, proton is the first option.
- Prior studies explored the dosimetric impact of transferring across treatment machines
- This study focused on establishing a safe treatment planning workflow, and implementation of quality management tools

## METHODS

- Quality Management (QM) team included members with prior experiences of patient transfer with other proton centers
- QM team involved multi-institutional group of physicians, physicists, dosimetrists, and vendor representative to:
  - Establish workflow, process map, and checks for future transfers between institutions
  - Conduct prospective failure modes and effects analysis (FMEA)
  - Generate an itemized checklist to confirm the feasibility of patient transfer
  - Discuss Mitigation methods of failures and recommend milestones based on treated disease site.

## CONCLUSION

- QM team developed a safe workflow of patient transfer across proton RT institutions and identified prominent risks of transferring patients
- **Greatest risk to patients involved:** integrity of patient data transferred, treatment files transferred, CT frame of reference and calibration curve, beam models and dose files, reirradiation cases, implantable devices, accuracy of delivered fractions
- **Risk Mitigation Methods include:** initial and EOT chart check items, automated scripting data transfer integrity checks, designated staffing
- Tools and workflow presented can be modified for used by other proton clinics especially as the number of centers grow

## References

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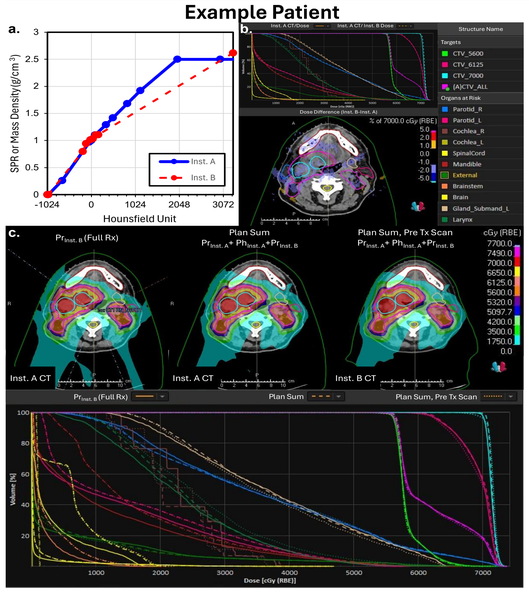
## PATIENT TRANSFER BETWEEN PROTON INSTITUTIONS IS FEASIBLE WITH A RISK-INFORMED FRAMEWORK TO MITIGATE HIGH-RISK FAILURES, MAINTAINING SAFETY AND TREATMENT QUALITY.

### ADOPTING THE PLAN INTO THE SECOND INSTITUTION'S TREATMENT PLANNING SYSTEM WITH ITS NATIVE BEAM MODEL, AND CT CALIBRATION CURVE ENSURES SAFE TRANSFER.




- **D95% target coverage agreed within 0.3%**
- **OAR DVH Metrics agreed on average within 3.3%**
- **Near equivalent commissioning beam data**

**Figure 1.** Items evaluated by physics and dosimetry team prior to treatment of an example transferred patient. **a.** CT calibration curve of the two institutions **b.** Dose comparison of the proton plan with the institution A vs. institution B beam model, with the CT from institution A **c.** Treatment course photon and proton RT. The three dose distribution/DVH present the proton plan from institution B on institution A CT, the plan sum of photon and proton plans (both institutions) on institution A CT, and plan sum of the plan on institution B CT acquire during Pre-Tx QA CT scan.

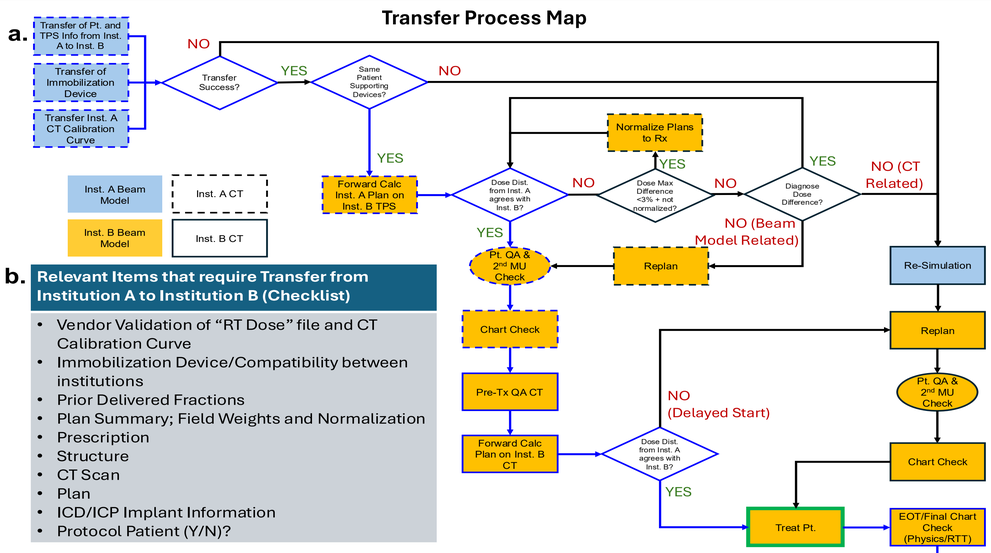



**Figure 2. a.** Process Map of transferring patients from institution A to Institution B. The process steps are rectangle, decisions are diamonds, quality assurance step are ovals. **b.** A checklist prior to accepting the patient to confirm transferability and treatment in institution B. The process steps taken for the example patient was highlighted in blue.

### 45 TRANSFER-SPECIFIC FAILURE MODES IDENTIFIED: HIGHEST RISK FROM CT CALIB. CURVE, PATIENT ORIENTATION, AND PRIOR RT.

| Process Step | Failure Modes | Average | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Occurrence | S.D. | Severity | S.D. | Detectability | S.D. | RPN | S.D |
| Transfer of Pt. and TPS Info from Inst. A to Inst. B | Wrong Pt Files sent | 3.7 | 1.9 | 8.7 | 2.8 | 2.4 | 1.4 | 79 | 14 |
| | TPS Frame of Reference or Pt Orientiation differences | 4.0 | 1.8 | 8.6 | 2.1 | 6.0 | 1.3 | **206** | 18 |
| Transfer Inst. A Calibration Curve | Wrong/Old Calibration curve data | 4.9 | 2.0 | 5.9 | 2.2 | 8.3 | 1.7 | **236** | 21 |
| Replan | Implanted device info not implemented in planning | 3.0 | 1.8 | 8.6 | 1.2 | 4.9 | 1.6 | 125 | 15 |
| | Frequency and intended fractions not implemented properly in planning. | 3.6 | 2.3 | 8.7 | 1.0 | 4.3 | 2.2 | 133 | 19 |
| | Prior RT in Inst A not considered in planning | 3.6 | 2.5 | 9.1 | 0.8 | 5.1 | 2.7 | **168** | 23 |
| Re-Simulation | ICD/ICP not confirmed with patient prior to scan | 2.7 | 1.0 | 8.4 | 1.8 | 3.9 | 1.2 | 88 | 10 |
| Chart Check | Prescrption/fractionation/ adjust # of fractions not confirmed | 2.4 | 0.5 | 8.9 | 1.0 | 5.4 | 1.8 | 117 | 10 |
| EOT/Final Chart Check (Physics/RTT) | Too few or too many fractions treated | 2.0 | 0.5 | 9.4 | 1.0 | 4.7 | 1.6 | 89 | 8 |
| PT Tx Info and EOT Doc Sent to Inst. A | Too few or too many fractions recorded | 2.1 | 0.3 | 9.3 | 1.0 | 6.1 | 2.2 | 122 | 11 |

**Table 1.** Scored failure modes by the QM team for process steps that were determined to have high severity (≥8) or high risk, RPN≥150. Score of occurrence, severity, detectability, and RPN are provided. High severity (≥8) and high RPN (≥150) are highlighted in red, and bolded, respectively.

### QUALITY MANAGEMENT TEAM ESTABLISHED SITE SPECIFIC MILESTONES TO DEEM PATIENT IS TRANSFERRED SAFELY FOR TREATMENT

| Disease Site | Patient Supporting Devices Transferred | Commissioned Devices/Specific Scan | Chart Check Considerations | Dose Verification on TPS/Pre-Tx QA CT Eval. | EOT Considerations |
|---|---|---|---|---|---|
| **Lung** | ○ Chest compression device<br>○ Motion Strategy | ○ Gating Device<br>○ FB/BH<br>○ 4DCT | ○ Gating enabled<br>○ Implanted device Material<br>○ SBRT<br>○ Prior RT | ○ 4DCT<br>○ FB/BH<br>○ Implanted device Material<br>○ Prior RT | |
| **Breast** | ○ Breast Board<br>○ Motion Strategy<br>○ Bolus | ○ Range Shifters<br>○ Gating Device<br>○ FB/BH<br>○ 4DCT | ○ Skin Dose<br>○ Implanted device Material<br>○ Prior RT | ○ Positioning (supine, prone, arms)<br>○ Skin Dose<br>○ Implanted device Material<br>○ Prior RT | ○ Bolus |
| **CNS/Brain** | ○ Frame<br>○ Mask | ○ U-shaped Bolus | ○ Implanted device Material<br>○ SRS/SBRT<br>○ Prior RT | ○ Implanted device Material<br>○ Prior RT | ○ Mask |
| **Gynecology Or Prostate** | ○ Immobilization (Vaclok) bag<br>○ Clamp (Prostate only) | | ○ Implanted device Material<br>○ Hip Prosthesis<br>○ Prior RT<br>○ SBRT | ○ Positioning (Straight vs Frog Leg)<br>○ Rectal Fill<br>○ Bladder Fill<br>○ Rectal Spacer<br>○ Implanted device Material<br>○ Hip Prosthesis<br>○ Prior RT | ○ Immobilization (Vaclok) bag<br>○ Clamp (Prostate Only) |
| **Head and neck** | ○ Bite block<br>○ Shoulder depressor<br>○ Tongue Depressor<br>○ Frame<br>○ Mask<br>○ Bolus | ○ Range Shifters<br>○ U shaped Bolus | ○ Implanted device Material<br>○ Prior RT | ○ Implanted device Material<br>○ Prior RT<br>○ Patient external | ○ Mask<br>○ Bolus<br>○ Bite Block<br>○ Tongue depressor |

**Risk Mitigation Methods Include:**
- **Transfer specific initial and EOT chart check items**
- **Scripting for automated check for integrity of transferred files**
- **Designating one or few physicists to lead efforts on transferred patients**

**Table 2.** Representative disease specific milestones and considerations for successful transfer of patients for treatment to new proton clinic. Other sites milestones were defined for included pediatrics, Gastrointestinal, and extremity.