Health System Initiative to Reduce Unnecessary Daily X-Ray Image Guidance During Palliative Radiation Treatment

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Study Overview – Reducing Daily Palliative IGRT

1. **Study objective**
    a. To reduce preference sensitive, unnecessary daily imaging during palliative radiation treatment within 5 sites of Penn Radiation Oncology using a default prescription option
2. **Study arms**
    a. The intervention will consist of a default prescription order set that does not include daily imaging for palliative cases. Preceding the intervention, there will be a 12-month retrospective pre-intervention period that will establish baseline use of image guidance during palliative radiation at Penn. Implementation of the default will occur in an interrupted time series design with two comparison groups:
        i. **Intervention arm (Perelman Center for Advanced Medicine - PCAM)**
            1. 2/10/2017-3/9/2017: 1 month roll out
                a. Intervention announced to entire group at faculty meeting and by email
                b. Individual meetings with intervention group attendings to assure awareness and use of default prescription order
                c. Educational meetings with therapists to introduce new default prescription
            2. 3/10/2017-6/9/2017: 3 month intervention period
                a. Only the intervention arm (PCAM) has access to the default option and the usual practice group (satellites) does not undergo the intervention
            3. 6/10/2017-10/10/2017: Crossover period
                a. Default intervention is introduced to usual care group. Intervention group continues to practice without any change.
        ii. **Usual practice / control group (Pennsylvania Hospital, Chestnut Hill, Doylestown, Valley Forge)**
            1. 2/10/2017-6/9/2017: Control period
                a. Usual practice group does not undergo intervention and serves as control to intervention group during this time
            2. 6/10/2017-7/9/2017: 1 month roll out
                a. Intervention announced to usual practice group at faculty meeting and by email
                b. Individual meetings with usual care group attendings to assure awareness and use of default prescription order
                c. Educational meetings with therapists to introduce new default prescription
            3. 7/10/2017-10/10/2017: 3 month intervention period

a. Both arms undergo the intervention

3. **Default Intervention**
    a. Default prescription order set that does not include daily imaging for palliative cases
4. **Outcome measures**
    a. Primary Outcome
        i. Change in daily IGRT use from baseline pre-intervention period to intervention periods within the control and intervention arms
            1. Daily IGRT defined as at least 80% (i.e., 4 of 5 days, on average) of treated fractions in a treatment course have image guidance
        ii. Change in daily IGRT use between control and intervention arms during first intervention period (3/10/17-6/9/17)
    b. Secondary Outcomes
        i. Rate of images per total fractions (outcome as continuous variable)
            1. Change in rate of images per total fractions taken pre and post intervention in each arm
        ii. Multivariate analysis for factors associated with reduction in daily IGRT
            1. Cohort (intervention vs. control arms)
            2. Age
            3. Sex
            4. Race
            5. ECOG
            6. Insurance type (Commercial, Medicare , Medicaid, Uninsured, Unknown)
            7. Target type (Brain, bone, soft tissue, multiple sites, other)
            8. Prior radiation (course 1 vs. not course 1)
            9. Total number of fractions per course
            10. Dose per fraction
                a. Charles will send us a distribution of this data and we will bucket it accordingly.
            11. Attending
            12. Time of day
            13. Location (PCAM vs. satellite)
    c. Exploratory Analyses
        i. Change in treatment time (in minutes)
            1. Change in total treatment time between pre- and post-intervention periods in each arm
        ii. Cost analysis
            1. Change in cost before and after intervention implemented in each arm
                a. Use CPT codes (charges) and Medicare standardized reimbursements to determine change in healthcare costs pre and post default intervention

Commented [SS1]: Insurance status is from the Epic output as follows: Unknown, Blue Shield, Commercial, Managed Care, Managed Medicaid, Managed Medicare, Medicaid, Medicare, Self pay. These can probably be further consolidated - Perhaps: unknown, self pay, (Blue shield+commercial+managed care), (Managed Medicaid+Medicaid), (Managed medicare+medicare).

1. **Descriptive Analysis**
    a. Calculate the data for Table 1. Variables listed below
        i. Cohort (intervention vs. control arms)
        ii. Age
        iii. Sex
        iv. Race
        v. ECOG
        vi. Insurance type (Commercial, Medicare , Medicaid, Uninsured, Unknown)
        vii. Target type (Brain, bone, soft tissue, other)
        viii. Prior radiation (course 1 vs. not course 1)
        ix. Total number of fractions per course (median with interquartile range)
        x. Total dose (median with interquartile range; followed by buckets)
        xi. Dose per fraction (median with interquartile range; followed by buckets)
        xii. Time of day
2. **Unadjusted Analysis**
    a. **Daily IGRT**
        i. Calculate daily IGRT use during pre-intervention period (2/10/16-2/9/17)
            1. Display graphically by month and cohort (PCAM vs. satellites)
        ii. Calculate daily IGRT use at PCAM and satellites after intervention implemented (2/10/17-10/10/17)
            1. Display graphically by month and cohort (PCAM vs. satellite)
            2. Indicate on graph when intervention occurred at PCAM (2/10/17) and satellites (6/10/17)
        iii. Conduct statistical analysis of change in daily IGRT pre and post intervention with 95% CI and p values
            1. Change in daily IGRT use from baseline pre-intervention period to intervention periods in both the control and intervention arms
                a. Intervention group: Pre-intervention period (2/10/16-2/9/17) use of daily IGRT vs. Post-intervention period (3/10-17-10/10/17) use of daily IGRT
                b. Control group: Pre-intervention period (2/10/16-6/9/17) use of daily IGRT vs. Post-intervention period (7/10-17-10/10/17) use of daily IGRT
            2. Change in daily IGRT use during first intervention period (3/10/17-6/9/17) between usual care group (control) and intervention arms
    b. **Rate of images per total fractions (outcome as continuous variable)**
        i. Change in rate of images per total fractions taken pre and post intervention in each arm with 95% CI and p values
            1. Calculate this separately for PCAM vs. satellites
                a. PCAM: pre intervention (2/10/16-2/9/17) vs. post intervention (3/10/17-10/10/17)
                b. Satellites: pre intervention (2/10/16-6/9/17) vs. post intervention (7/10/17-10/10/17)

Commented [DMG2]: Would make cohort columns to compare populations

Should look like this for example:

	PCAM		Satellite	
	Pre	Post	Pre	Post
Race				
Age				
ECOG				
etc				

Commented [SS3]: Excludes the 1 month roll out period (2/10/17-3/9/17)

JB: Make sure Dylan agrees **

10/15/17 Update: Dylan agrees that we should exclude roll out month

Commented [SS4]: Does preintervention period for control group end 2/9/17 or 6/9/17?

Need to confirm w Dylan**

10/15/17 Update: Dylan says preintervention period ends 6/9/17 for satellites

Commented [SS5]: Excludes 1 month roll out (6/10/17-7/9/17)

SS: Confirm with Dylan**

10/15/17 Update: Dylan agrees that we should exclude roll out month

2. Change in rate of images per total fractions between PCAM (intervention group) and satellites (control group) during first intervention period (3/10/17-6/9/17)

c. **Treatment time**
   i. We have 3 times recorded for each patient at the level of each fraction
      1. Activity time
         a. This is the time until treatment start (while patient is being set up for treatment), and is the window during which IGRT would be acquired
         b. We will need to account for small percentage (~4%) of missing data in activity time
      2. Treatment start (won't really use this)
      3. Treatment end
   ii. Create variable to calculate "total treatment time" (treatment end – activity time start)
      1. Total treatment time = activity (set up) time + treatment time
   iii. Following comparisons needed with 95% CI and p values:
      1. Change in **activity time** between pre and post intervention periods
         a. Calculate this separately for PCAM vs. satellites
            i. PCAM: pre intervention (2/10/16-2/9/17) vs. post intervention (3/10/17-10/10/17)
            ii. Satellites: pre intervention (2/10/16-2/9/17) vs. post intervention (7/10/17-10/10/17)
      2. Change in **activity time** between PCAM (intervention group) and satellites (control group) during first intervention period (3/10/17-6/9/17)
      3. Change in **total treatment time** between pre and post intervention periods
         a. Calculate this separately for PCAM vs. satellites
            i. PCAM: pre intervention (2/10/16-2/9/17) vs. post intervention (3/10/17-10/10/17)
            ii. Satellites: pre intervention (2/10/16-2/9/17) vs. post intervention (7/10/17-10/10/17)
      4. Change in **total treatment time** between PCAM (intervention group) and satellites (control group) during first intervention period (3/10/17-6/9/17)

d. **Cost analysis**
   i. We will evaluate radiotherapy-related expenditures during the course of radiotherapy, calculated according to prior methods by summing the reimbursement of claims for radiotherapy simulation, planning, physics, delivery, and management (Current Procedural Terminology [CPT] codes 77261 and 77999).[1] Because patients have a mix of commercial and government insurers, we will utilize the national Medicare base rate to normalize reimbursement for each CPT code, and in secondary analyses will utilize actual

claims paid reimbursements. We will compare adjusted mean expenditures between the intervention and usual groups using generalized linear models with gamma distribution and log-link function. We will estimate adjusted mean differences by first exponentiating the model-based linear predictions for the average intervention and usual care groups separately and then calculating their arithmetic difference.

1. [1] Bekelman JE, Epstein AJ, Emanuel EJ. Single- vs multiple-fraction radiotherapy for bone metastases from prostate cancer. JAMA. 2013;310(14):1501-1502.

ii. CPT codes
   1. G6002
      a. This will capture all KV imaging with any modality
   2. 77014 (with the 26 modifier attached)
      a. This will capture all CBCT imaging with any modality

3. Adjusted Analysis

a. Primary model
   i. Adjust for:
      1. Intervention
      2. Attending (clustering at level of attending)
      3. Location (PCAM vs. Satellites)
      4. Time

Commented [SS6]: Time defined as days from intervention?

b. Primary model + relevant patient level factors
      1. Intervention
      2. Attending (clustering at level of attending)
      3. Location
      4. Time?
      5. Age
      6. ECOG
      7. Prior radiation
      8. Insurance type (Commercial, Medicare , Medicaid, Uninsured, Unknown)
      9. Total number of fractions per course

c. Sensitivity model
   i. Covariates:
      1. Cohort (intervention vs. control arms)
      2. Age
      3. Sex
      4. Race
      5. ECOG
      6. Insurance type (Commercial, Medicare , Medicaid, Uninsured, Unknown)
      7. Target type (Brain, bone, soft tissue, multiple sites, other)
      8. Prior radiation (course 1 vs. not course 1)
      9. Total number of fractions per course

10. Dose per fraction
11. Attending
12. Time of day
13. Location (PCAM vs. satellite)

d. Assess missing data
e. Unadjusted and adjusted analyses for covariates in relation to primary outcome (daily IGRT use)

Methods:

For the main analysis model, we used PROC GENMOD to fit models based on generalized estimating equations with a logit link and an independence correlation structure using the attending physician as the clustering unit with month and site as covariates. In sensitivity analyses, the main model was estimated by also adjusting for patient characteristics including age, sex, race,...,...,,etc.

To obtain the adjusted difference in the percentage of patients receiving daily IGRT imaging between intervention and non-intervention groups and 95% confidence intervals (CIs), we used the bootstrap method, resampling patients 1000 times. Resampling of patients was by physician to maintain clustering at the physician level. All analyses were conducted in SAS version 9.4.

Commented [SS7]: CR: Note: It's possible we might use a different correlation structure. We can modify what goes in the list of the covariates for the sensitivity model.