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

Study Protocol

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Outline

1. Abstract
2. Overall objectives
3. Aims
   3.1 Primary outcome
4. Background
   4.1 Value-based cancer care
   4.2 Image-guided radiotherapy
   4.3 Preliminary data
   4.4 Default options
   4.5 Quality improvement initiatives in the Radiation Oncology Department
5. Study design
   5.1 Design
   5.2 Study duration
   5.3 Target population
   5.4 Accrual
   5.5 Key inclusion criteria
   5.6 Key exclusion criteria
6. Subject recruitment
7. Subject compensation
8. Study procedures
   8.1 Consent
   8.2 Procedures
   8.3 Coin-flip to select initial site (randomization)
9. Analysis plan
10. Investigators
11. Human research protection
   11.1 Data confidentiality
   11.2 Subject confidentiality
   11.3 Subject privacy
   11.4 Data disclosure
   11.5 Data safety and monitoring
   11.6 Risk/benefit
      11.6.1 Potential study risks
      11.6.2 Potential study benefits
      11.6.3 Risk/benefit assessment
1. Abstract
The goal of this study is to reduce preference sensitive, unnecessary daily imaging during radiation treatment in which a pre-planned quality improvement default option for radiation treatment prescriptions will be introduced throughout the network of Penn Radiation Oncology. This study is a prospectively designed, observational trial with two comparison groups: (1) a usual practice group (control group) and (2) a default radiation treatment prescription group (intervention group), in which the usual practice group will subsequently rollover from control to intervention so that all sites and physicians in the practice network of Penn Radiation Oncology are exposed to intervention.

2. Overall objectives
The purpose of this study is to reduce preference sensitive, unnecessary daily imaging during radiation treatment with the implementation of a quality improvement initiative within 5 sites of Penn Radiation Oncology. We aim to leverage the introduction of a default prescription option to reduce the use of daily imaging in palliative intent cases where it has limited clinical benefit and adds to cost burden. Our objective is to encourage more patient-centric clinical practice.

3. Aims
3.1 Primary outcome
The primary objective of this study is to reduce unnecessary daily imaging during palliative radiation treatments.

4. Background
4.1 Value-based cancer care. With exponentially rising healthcare costs, providers practice medicine in an increasingly value conscious environment.\textsuperscript{1-5} Physicians are encouraged to reduce low-value care by eliminating unnecessary tests and procedures, thus, reducing healthcare costs at large. However, methods to optimally promote high value care are still under evaluation.

Radiation oncology, in specific, has come under scrutiny for expensive treatments and rising costs particularly with the advent of newer treatment technologies over the past 15 years.\textsuperscript{5-7} We aim to reduce low value care in a multi-site radiation oncology clinical practice.

4.2 Image-guided radiotherapy. Image-guided radiation therapy (IGRT) is a tool used in radiotherapy to ensure reproducible patient positioning during treatment. The two main technologies used to perform IGRT are kilovoltage x-ray images (KV), which are x-ray images to check patient alignment, and conebeam computed tomography (CBCT), which is a CT scan (also ‘x-ray’ based) done on the radiation treatment table. Regardless of whether IGRT is used, all patients have daily clinical positioning using immobilization devices and a calibrated treatment table with 3-dimensional lasers aligned to small tattoos placed on the body at the time of treatment planning.

The role of IGRT is evolving in the field of radiation oncology. While evidence for its clinical utility is uncertain or even limited in certain clinical situations,\textsuperscript{8,9} IGRT is used extensively amongst radiation oncologists and its use is projected to increase further.\textsuperscript{10} However, daily imaging beyond clinical positioning adds significant additional radiation exposure and increases the total time on the treatment table for patients who are often in pain or have limited mobility.
Given the limited evidence and lack of clarity regarding ideal use of IGRT, and the fact that all patients receive daily clinical positioning, insurance companies are increasingly denying the charges associated with such procedures. Furthermore, daily IGRT also places a considerable strain on clinic resources and efficiency.\textsuperscript{11}

Overuse of IGRT is particularly apparent during palliative radiation treatments. Our department has demonstrated that for the palliative treatment of brain metastases standard, clinical immobilization and setup techniques without the use of daily IGRT are sufficient for treatment in routine cases.\textsuperscript{8} Moreover, evidence-based guidelines clearly state that “IGRT generally is not medically necessary in the palliative setting.”\textsuperscript{12} Yet despite uncertain clinical need and decreasing reimbursements, physicians often reflexively order daily imaging for treatment.

4.3. Preliminary data. At our institution, across the University of Pennsylvania Health System (UPHS) Radiation Oncology network, 71\% of palliative intent radiation courses over the past year (February 10, 2016 – February 9, 2017) utilized daily x-ray image guidance as part of the treatment paradigm. As shown in Table 1, despite clinical guidelines recommending against the use of daily IGRT in palliative cases, 68\% of cases at the Perelman Center for Advanced Medicine (PCAM) and 76\% of satellite palliative cases employed daily IGRT during the associated radiation treatment course.

Table 1: Use of Daily IGRT in Palliative Cases by UPHS Radiation Oncology Department Location

<table>
<thead>
<tr>
<th>Location</th>
<th>% Daily IGRT</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCAM</td>
<td>68.3%</td>
<td>404</td>
</tr>
<tr>
<td>Satellites</td>
<td>75.5%</td>
<td>229</td>
</tr>
<tr>
<td>Overall</td>
<td>70.9%</td>
<td>633</td>
</tr>
</tbody>
</table>

*Daily IGRT defined as at least 80\% (i.e., 4 of 5 days, on average) of treated fractions in a treatment course have IGRT

**PCAM: Perelman Center for Advanced Medicine
** Satellites: Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge

As shown in Table 1, the total number of palliative courses and associated daily IGRT varies across our main site and satellites. Our main site, the Perelman Center for Advanced Medicine (PCAM), has the highest volume of cases overall, and, hence, the highest number of palliative courses. All sites across the UPHS radiation oncology network, however, demonstrate high levels of daily IGRT usage in palliative courses. Over the past year, the number of palliative courses treated at each department and percentage of cases using daily imaging was roughly stable over time as shown in Tables 2 and 3.
Table 2: Monthly Frequency of Palliative Courses

<table>
<thead>
<tr>
<th></th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCAM</td>
<td>41</td>
<td>38</td>
<td>36</td>
<td>30</td>
<td>28</td>
<td>35</td>
<td>40</td>
<td>32</td>
<td>34</td>
<td>26</td>
<td>34</td>
<td>30</td>
</tr>
<tr>
<td>Satellites</td>
<td>14</td>
<td>21</td>
<td>18</td>
<td>24</td>
<td>22</td>
<td>17</td>
<td>10</td>
<td>28</td>
<td>18</td>
<td>23</td>
<td>19</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 3: % Daily IGRT Use by Month: PCAM vs. Satellites

<table>
<thead>
<tr>
<th></th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCAM</td>
<td>68.3%</td>
<td>78.9%</td>
<td>77.8%</td>
<td>80.0%</td>
<td>75.0%</td>
<td>62.9%</td>
<td>60.0%</td>
<td>62.5%</td>
<td>64.7%</td>
<td>69.2%</td>
<td>52.9%</td>
<td>70.0%</td>
</tr>
<tr>
<td>Satellites</td>
<td>85.7%</td>
<td>95.2%</td>
<td>66.7%</td>
<td>79.2%</td>
<td>72.7%</td>
<td>64.7%</td>
<td>100.0%</td>
<td>64.3%</td>
<td>83.3%</td>
<td>82.6%</td>
<td>63.2%</td>
<td>60.0%</td>
</tr>
</tbody>
</table>

4.4. Default options. We have described how default options can be an effective means of reducing low-value services in cancer care and other healthcare settings. Defaults may promote high-value care by introducing a treatment standard indicative of evidence-based
guidelines or institutional recommendations.\textsuperscript{15} For instance, in our own health system, a change in default drug prescription options in the electronic health record (EHR) has been successfully leveraged to reduce the prescription of low-value, brand name medications.\textsuperscript{13} Default options provide a unique means of influencing decision-making while preserving physician choice; importantly, default prescriptions may be altered by treating physicians to best serve the needs of their patients.\textsuperscript{15–17}

At Penn Radiation Oncology, default prescriptions for radiation are the norm. These defaults exist currently in non-palliative settings and involve template prescription order sets that contain default settings. These default prescription templates improve clinic workflow and standardize clinical care. Importantly, as always with default prescription options, physician choice is preserved.

In the initiative proposed herein, we aim to introduce a default prescription template in the palliative setting. This effort is part of the department’s overarching quality improvement initiative to standardize treatment approaches. With defaults, the physician has the option to alter default order sets to fit their clinical decisions. This is true for all other default prescription order sets already in use in our clinic. In other words, default options for curative, non-palliative treatments are currently standard of care in our clinic as a means of improving efficiency and standardizing care across our network, and we plan to rollout default options for palliative treatments in order to reduce unnecessary daily image guided radiation.

4.5 Quality Improvement Initiatives in the Radiation Oncology Department: The Penn Medicine Department of Radiation Oncology (also called Penn Radiation Oncology) has a long history of excellence in quality improvement and safety initiatives. QI initiatives are typically implemented first at either PCAM or non-PCAM sites and then rolled out to the entire clinical practice. Continuous quality improvement is conducted though monitoring and comparisons of physician and site rates of care delivery, depending on the focus of the QI initiative, and iterative changes to improve initiatives are then implemented over time. In this study, we leverage the existing departmental processes for QI implementation, and we will choose the first site of intervention implementation by coin flip rather than arbitrarily as has been done in the past.

Our study is sponsored and approved by our health systems partners including the Office of the Chair of Radiation Oncology and the Penn Medicine Nudge Unit.

5. Study design

5.1 Design

In this study, we propose to leverage a pre-planned departmental initiative of default prescriptions to reduce unnecessary daily x-ray imaging in palliative radiation treatments.

This study follows an observational interrupted time series design with two comparison groups: (1) a usual practice group (control group) and (2) a default radiation treatment prescription group (intervention group), in which the usual practice group will subsequently rollover from control to intervention. One group is comprised of physicians who practice at the Perelman Center for Advanced Medicine (PCAM). Another group is comprised of non-PCAM physicians at our network satellites (Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and
As is standard practice for implementation of QI initiatives in our department, we will implement the intervention at one network site prior to implementing the intervention at all sites. These groups will be assigned to the intervention or usual care at the start of the study by coin flip. Subsequently, the usual practice group will rollover into the default intervention.

**Intervention.** The default intervention will be started in February 2017. It will be comprised of default prescription order sets that do not include daily imaging for brain/CNS, bone, and soft tissue metastases (See Figure 1). The defaults will be immediately preceded by a department wide session with intervention group physicians and therapy staff announcing the initiation of the intervention. Thus, as is usual practice in the department, physicians and department staff will be aware and educated on the QI initiative at the time of implementation. Default prescription order sets will be created in Aria (the radiation oncology electronic health record) for palliative treatment indications, such as brain/CNS, bone, soft tissue, and other palliative cases.

**Figure 1:** Example of Default IGRT Prescription for Palliative Cases

<table>
<thead>
<tr>
<th>IGRT-LOCALIZATION INSTRUCTIONS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRIMARY (Match for Treatment)</strong></td>
<td><strong>SECONDARY (EVAL)</strong></td>
</tr>
<tr>
<td>Modality: None</td>
<td>Modality: None</td>
</tr>
<tr>
<td>Frequency: Other</td>
<td>Frequency: Other</td>
</tr>
<tr>
<td>Match Instructions: Set up with attention to immobilization, tattoo markers, and weekly MV portal films</td>
<td>Additional / Special Instructions: do not take KV-KV image</td>
</tr>
<tr>
<td>Additional / Special Instructions: do not take KV-KV image</td>
<td></td>
</tr>
<tr>
<td>Localization Instructions For CD Or Other If Different From Initial:</td>
<td></td>
</tr>
</tbody>
</table>
Figure 2: Study Framework

*Coin flip to determine initial intervention vs. usual care group:
Group 1: PCAM Physicians
Group 2: Non-PCAM Physicians (Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge)

The study will involve our entire physician network across the UPHS Radiation Oncology network, including both PCAM and regional network facilities (Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge).

5.2 Study duration
The duration of the study will be 29 months, including the 12 retrospective pre-intervention study period, 1 month for the intervention, 3 months for the first post-intervention study period, 1 month for the control to cross over to the intervention, and 3 additional months for observation in which all physicians are exposed. Analysis of data and dissemination of results will occur in the 9 month period following the 2nd post-intervention period.

5.3 Target population
The study will include a total of ~29 subjects (UPHS radiation oncologists) and 5 sites across the UPHS network (Perelman Center for Advanced Medicine, Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge) that treat over 600 palliative patients a year. The University of Pennsylvania Radiation Oncology network (both PCAM and satellites) will be the only site of this study.

5.4 Accrual
Radiation oncology physicians will be recruited from the University of Pennsylvania Health System.
5.5 Key inclusion criteria
- Radiation treatment courses with palliative intent
- Palliative treatment of bone, soft tissue, and intracranial metastases
- Photon radiation with 3D conformal therapy (3DCRT) only

5.6 Key exclusion criteria
- Use of intensity modulated radiation (IMRT), volumetric modulated arc therapy (VMAT), stereotactic body radiation (SBRT), or electron therapy as radiation treatment modality
- Proton radiation
- Single fraction treatments as these treatments do not include daily imaging after initial patient set up

6. Subject recruitment
Not applicable. Subjects will include all UPHS radiation oncologists. As a result, no recruitment will be needed in this study.

7. Subject compensation
No compensation will be offered in this study.

8. Study procedures
  8.1 Consent
A waiver of informed consent is requested. This is a departmental quality improvement initiative that will be implemented regardless of the study we propose. The study is to evaluate that quality improvement initiative. Without a waiver of the consent, the initiative would still be implemented by the health system, but the study would be infeasible. Additionally, consenting every patient and physician would make the study impossible to conduct. As mentioned, this initiative would occur with or without the study of it. Furthermore, if physician members of the usual care group were consented, they would know they were being studied and this could bias their behavior, which would make our findings difficult to interpret. Moreover, physicians are not being forced to change their prescription of image guidance in radiation. Instead, they are being reminded of evidence-based guidelines and offered a default option which can be altered. The physician would continue to prescribe radiation treatment and whichever imaging they believe is appropriate for the patient. The intervention is simply a default option for the physician and makes their care process easier to conduct.

  8.2 Procedures
Data on use of daily imaging will be obtained from Aria. De-identified patient-level demographic and disease-specific data will also be obtained from EPIC, including patient age, race, gender, cancer diagnosis, and insurance provider. Billing information associated with the IGRT CPT codes used in the pre and post-intervention radiation courses will be obtained from our revenues department.

  8.3 Coin-flip to select initial site (randomization)
Group 1 (PCAM physicians) and 2 (non-PCAM physicians) will be assigned to either the intervention or control group prior to study initiation by coin flip (rather than arbitrarily as has been done in past QI efforts). The control group will then rollover to the intervention arm after a 1 month intervention implementation period and 3 months of the intervention period months.

9. Analysis plan
The primary analysis will use a mixed effects logistic regression model, where the unit of analysis is an individual patient, the outcome is use of daily x-ray imaging and the explanatory variables are time (pre-intervention vs. post-intervention period), dummy variable for whether the intervention is received, group (PCAM vs. satellite providers) and physician random effects. The coefficient of interest is the coefficient of whether the intervention is received. The physician random effects account for the clustering by physician. The study is analyzed at the physician level (patients clustered within physicians) rather than the practices site level because there are only two practice sites. Of the two practice sites – PCAM vs. non-PCAM sites – one group will be assigned to the intervention for the entire intervention period by coin flip, and the other group of providers will be assigned to the control for the first three months of the intervention period and then the intervention for the remaining four periods of the intervention. Randomly assigning the order of practice sites exposed to the intervention helps to blunt selection bias.

We considered the power for a study in which PCAM would be assigned to the treatment for the six study months and the satellite centers would be assigned to the control for the first three months and the treatment for the last three months. We assumed that the distribution of patients seen per physician at each site would be the same as in the corresponding months of the year prior to the study, and that the control outcomes would have the same distribution as in the year prior to the study. For this analysis, we have 90% power to detect an effect of the intervention that reduces the probability of daily imaging with absolute reduction of 0.15 or a relative reduction of 0.18.

10. Investigators
Sonam Sharma, MD: Principal Investigator (PI), Chief Resident, Department of Radiation Oncology at the Perelman School of Medicine at the University of Pennsylvania

Justin Bekelman, MD: Co-investigator, Associate Professor of Radiation Oncology and Medical Ethics & Health Policy Faculty, Senior Fellow at the Leonard Davis Institute for Health Economics.

Mitesh Patel, MD, MBA, MS: Director, Penn Medicine Nudge Unit, Assistant Professor of Medicine and Health Care Management at the Perelman School of Medicine at the University of Pennsylvania

Greg Kurtzman, BA: Clinical Research Coordinator, Penn Medicine Nudge Unit at the Perelman School of Medicine at the University of Pennsylvania

Dylan Small: Professor, Department of Statistics, The Wharton School at the University of Pennsylvania
11. Human research protection

11.1 Data confidentiality
Data will be collected on HIPAA-secure UPHS computers and computer-based files will be password-protected and available only to study personnel. When possible, patient identifiers will be removed from data files. Any patient or physician level data obtained will be used only for research purposes. All members of the research team will complete HIPAA and CITI training to remain compliant with PHI protection. Only trained study staff will have access to the code that links the unique identifier to the subject’s identity. Electronic data will be stored on secure, password-protected firewalled servers at UPHS.

11.2 Subject confidentiality
Data on physicians and patients will be obtained from EPIC. Any information that is obtained will be used for research purposes only. Information on patients will only be disclosed within the study team. All study staff will be reminded of the confidential nature of the data collected and contained in these databases.

11.3 Subject privacy
All efforts will be made by study staff to ensure subject privacy. Data will be evaluated in a de-identified manner whenever possible.

11.4 Data disclosure
Information on patients will only be disclosed within the study team.

11.5 Data safety and monitoring
The investigator will provide oversight for the study evaluation of this intervention. Physician practices will follow their standards of care to treat patients with palliative radiation. The study PI will be responsible for ensuring the ongoing quality and integrity of the research study.

11.6 Risk/benefit
11.6.1 Potential study risks
The potential risks from this study and the intervention are minimal. Patients will continue to receive the standard of care in terms of radiation treatment as per their physician provider. Subjects in the study (UPHS radiation oncologists) will have minimal risk of harm. Breach of data is a potential risk that will be addressed as described above with the use of HIPAA compliant, password-protected electronic files, and secure data servers at UPHS.
11.6.2 Potential study benefits
The direct benefits of this study to the study participants (UPHS radiation oncologists) are minimal. The intervention to change defaults will promote evidence-based decision making. It will also have the indirect benefit of reducing radiation exposure for patients by decreasing the number of unnecessary images taken for patient positioning during treatment. Additional indirect benefits may include reducing costs and improving efficiency in the clinic by decreasing the use of daily imaging and patient time on the treatment table.

11.6.3 Risk/benefit assessment
Given the minimal risks to study participants and patients with an intervention to promote high-value care while maintaining standard radiation treatments, the benefits of this study (reducing low-value care, decreasing costs, reducing patient radiation exposure, improving clinic efficiency) outweigh the potential, minimal risks associated with the intervention.
References:


