Assessing Patients’ and Radiation Therapists’ Perceptions of Safety in Radiation Therapy and Using a Patient-Provider Collaborative Checklist to Engage Patients

by

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A thesis submitted in conformity with the requirements for the degree of Master of Health Science Clinical Engineering

IBBME
University of Toronto

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Abstract

Approximately 52% of cancer patients require radiation therapy during the progression of their illness. Radiation therapy is a safe procedure; however, errors may occur and have the potential to harm patients. Recent studies have looked at patient engagement as a means of preventing errors in healthcare. Through interviews and focus groups, this study looks at patients’ and radiation therapists’ current perceptions of safety in radiation therapy and whether they feel that patient engagement in the form of a patient-provider collaborative checklist can improve its safety or the perception of safety. Through workflow observations and literature reviews, a patient-provider collaborative checklist was developed. Furthermore, STAI surveys were conducted to document the progression of patient anxiety through treatment. Feedback from radiation therapists demonstrated their opinions on the usability of the final iteration of the patient-provider collaborative checklist and how it could fit into the clinical setting.
Acknowledgments

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Chapter 1
Introduction

1 Introduction

1.1 Radiation Therapy

Radiation therapy is a complex process that uses sophisticated technologies and well-trained clinicians to deliver treatment for a wide range of cancers at various stages of the illness. It involves coordination amongst many different staff groups and multiple steps; each step with its own associated complexity and risk [1]. Evidence-based studies have shown that radiation therapy is used to treat a large proportion of cancer patients. For example, in Australia, approximately 52.3% of cancer patients will require radiation therapy during the progression of their illness [2]. Despite this statistic, a significant number of patients view radiation therapy as a mysterious procedure due to its inability to be seen or felt. This mystery adds to its perception of danger [1]. Radiation therapy is a precise and safe procedure; however, errors do occur. The effects of these errors, including errors resulting from breakdowns in the safety protocols and procedures of the organization, can negatively impact the health of the affected individual [3].

1.1.1 Princess Margaret Hospital Radiation Department

Founded as the Ontario Cancer Institute in 1952 [4], the Princess Margaret Cancer Centre (PMCC) is part of the University Health Network (UHN) group of hospitals in Toronto, Ontario. PMCC has the “largest radiation treatment centre in Canada and one of the largest in the world” [5]. The hospital employs 2900 employees, houses 218 inpatient beds [6] and 17 radiation treatment machines [7]. In 2012, 10,150 courses of radiation therapy were delivered [6] and over 6,000 new radiation therapy patients were treated as part of the Radiation Medicine Program [8].
1.1.2 **Radiation Therapy Treatment Pathway**

The radiation therapy treatment pathway can be broken down into 5 main categories which are summarized and visualized on Figure 1 [9].
Figure 1: Diagram showing the treatment pathway undergone by patients.
1.1.3 Radiation Therapy Treatment Procedures and Protocols at Princess Margaret

At PMCC, policies and procedures are in place to guide the conduct of workers when it comes to patient safety. Each stage of the process has certain safety checks that must be adhered to in order to ensure patient safety; these checks are described in Table 1 [10].

Table 1: General procedures and protocols that must be carried out to ensure accurate treatment and patient safety.

<table>
<thead>
<tr>
<th>Step in Treatment Process</th>
<th>Safety Procedures and Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Verification</td>
<td>• Performed daily&lt;br&gt;• Each staff member caring for the patient must verify patient identity with electronic medical record as per policy “Identification of Radiation Therapy Patients”:&lt;br&gt;- Patient or designate must be asked to state his/her birthday to verify against current information on patient record&lt;br&gt;- Patient’s photo in electronic medical record must be verified to ensure the correct patient was present with the correct electronic file opened.&lt;br&gt;• If any discrepancies exist, treatment must be suspended until issue is resolved</td>
</tr>
<tr>
<td>Pre-Treatment Setup</td>
<td>• Performed daily&lt;br&gt;• Patient’s file reviewed&lt;br&gt;• Examine Quality checklist, tech notes, patient care notes, Tx notes, assessment tab entries and images (for changes and review status)&lt;br&gt;• Set-up patient as per setup note&lt;br&gt;• Verify tattoo location&lt;br&gt;• Visual check of light field and isocentre position against the DCR&lt;br&gt;• Perform light field check of manually placed accessories against the relevant DCR&lt;br&gt;• One radiation therapist verbalizes treatment set-up information contained within “Tx Setup notes” in electronic medical record&lt;br&gt;• A second radiation therapist visually confirms and verbally agrees with all parameters</td>
</tr>
</tbody>
</table>
| Pre-Treatment Verification | • Day 1, Day 2 or after any changes:  
- prescription verified against treatment plan and monitor unit calculations  
- One radiation therapist verbalizes all parameters for each treatment beam as stated in the web-published plan (i.e. monitor units, beam energy, gantry, collimator, and all field jaw settings) just prior to its delivery.  
- A second therapist visually confirms the treatment parameters against the treatment console prior to delivering the treatment beam.  
• All other treatment days:  
- Both therapists verify that two full verifications have been completed for the treatment beams.  
- Both therapists confirm that the documented verification date agrees with the current approval date of all treatment beams.  
- One therapist verbalizes the monitor units and beam energy for each treatment beam as stated in the web-published plan and a second therapist visually confirms the treatment parameters against the treatment console prior to delivering each treatment beam. |
| Post Treatment Verification | • Verify delivery of proper dose has occurred and report any variance immediately  
• Verify dose in electronic medical record is correct |

These general procedures that are used to carry out radiation therapy while ensuring patient safety. However, different types of treatments require different verifications and checks before treatment can be delivered; a good example is the treatment of prostate cancer.

### 1.1.4 Prostate Cancer Treatment Delivery Protocol

Prostate cancer is considered to be the most common form of cancer to affect men. According to Prostate Cancer Canada, one in seven men will be diagnosed with prostate cancer in their lifetime. Prostate cancer cells are defined by their “uncontrolled growth, abnormal structure, and invasiveness” [11]. The likelihood of developing prostate cancer increases with age and it is
most common in men over the age of 50 [12]. One of the most common methods of testing for prostate cancer is the prostate-specific antigen (PSA) test. This antigen is detected in a simple blood test; elevated levels of PSA in the blood may indicate the possibility of prostate cancer [13].

Some methods of treating prostate cancer include radiation therapy or removal of the prostate, also known as a radical prostatectomy. The latter may be done in combination with radiation therapy [14]. Specifically, curative radiation therapy for intact prostate patients employs 78 Gray in daily fractions of 2 Gray for a total of 39 treatments or approximately 8.5 weeks. Post-operative radiation therapy for prostate cancer patients employs 66 Gray in 2 Gray daily fractions for a total of 33 treatments. At the Princess Margaret Cancer Centre, there are specific procedures and protocols in place for using radiation therapy to treat prostate cancer. These procedures include specific instructions about identifying the patient, ensuring proper preparation, and explaining potential side effects.

As seen in Table 2[15], there are a substantial number of checks that must be completed by the radiation therapists to ensure patient safety and proper delivery of treatment. It can be noted that many of the necessary tasks, especially those involving verifying patient identification, are done verbally and without the aid of checklists or memory aid tools.

**Table 2: Treatment delivery protocol for the education of patients with prostate cancer.**

<table>
<thead>
<tr>
<th>Step in Treatment Process</th>
<th>Procedures and Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1 patient education</td>
<td>• Verify date of birth as per policy</td>
</tr>
<tr>
<td></td>
<td>• Ensure patient has full bladder and empty rectum</td>
</tr>
<tr>
<td></td>
<td>• Verify patient drank two glasses of water one hour prior to treatment</td>
</tr>
</tbody>
</table>
Ensure patient has attended pre-treatment education and been given relevant materials
- Explain procedure, potential side effects and address patient’s questions and concerns

Weekly patient education
- Ensure patient care documentation and weekly side effects record questionnaire completed and documented in electronic medical record
- Ensure patient has attended weekly review with oncologist

Final Treatment Education
- Review side effects with patient, discuss discharge plan
- Confirm follow-up appointment with radiation oncologist
- Document discharge in electronic medical record

1.2 Background

1.2.1 Errors in healthcare

Errors are not uncommon in the medicine and can have potentially lethal consequences. A 1999 study done by the Kohn et al and the Institute of Medicine showed that every year in the United States, between 44,000 and 98,000 people die in hospitals as a result of medical errors \(^1\)\[16\]. Kohn et al stated that 70 percent of the errors were found to be preventable; the most common categories were technical errors, diagnosis and prevention to prevent injury [16] [17]. Due to the scale of these incidents\(^2\), they are often not as widely reported as other industries such as the airline industry. In a cited book by Parrow, it is stated that one of the greatest contributors to accidents is human error. Moreover, human error may contribute to 60-80 percent of accidents [16][18]. In recent years, health organizations have gradually shifted away from focusing on

\(^1\) Medical error: “a failure to carry out a planned action as intended or application of an incorrect plan, and may manifest by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission), at either the planning or execution phase” [3]

\(^2\) Patient Safety Incident: “an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient” [3]
personal blame for preventing errors and towards systematic factors that have contributed to these errors. If it is assumed that all humans are fallible, systems can be improved to safely catch, prevent and minimize the harm that derives from these errors [19][20]. Many of these errors can be attributed to poor teamwork and a failure in communication. A study conducted by Rabol et al., performed root-cause analysis on 84 adverse patient events in Danish hospitals and found that error in staff communication was a contributing factor in over half of the incidents. The findings from this study emphasize the need for improved verbal among health care staff to improve patient safety. Interventions to support teamwork and communication have a larger effect when supported by standardized techniques and checklists [21].

1.2.2 Improving Quality Assurance and Safety Using Patient Engagement

One potential method for increasing safety and reducing errors in healthcare could be through an increased use of patient engagement in quality initiatives. Recent studies have looked into the role of patients in improving the quality of their care and increasing safety of medical intervention. Coulter et al. have shown that engaging patients in actively participating in their care may in fact improve patient safety in a multitude of ways. However, the reduction of errors to improve safety can only be successful if the involvement of patients is valued and supported [22]. Coulter et al. also stated through the analysis of literature reviews that patients may be able

---

3 Adverse Event: “an incident which results in harm to a patient” [3]

4 Quality of care: The Institute of medicine addressed quality of health care in their recent publication “Crossing the Quality Chasm (2001)” that a health care system should address six major elements. That is, health care should be safe, effective, patient-centered, timely and equitable [81].
to play a significant role in quality and safety of care by being aware of safety issues, preventing errors and providing feedback on quality of care to clinicians. Furthermore, various interventions to improve care processes lead to better interactions between clinicians and patients, greater patient satisfaction, and may lead to better treatment adherence and health outcomes [23].

1.2.2.1 Patient Engagement in Chemotherapy

Two studies performed in 2010 by Schwappach et al. examined chemotherapy patients’ and oncology nurses’ perceptions of safety of treatment delivery and the role of patient engagement in preventing errors [24][25]. The study regarding patients looked at their perceptions of safety in two semi-structured meetings. The first meeting occurred early on in the treatment while the second occurred approximately nine weeks later. Patients were asked questions aimed to assess their experiences with chemotherapy and their general perceptions of safety. Initially, patients felt relatively safe and were not overly worried about errors. However, at follow-up interviews, patients’ awareness of the potential for error had increased along with their attentiveness towards actively participating in error prevention. Moreover, patients generally believed that they could help in preventing errors and that doing so would not affect their trust in their care providers. These patients indicated the importance of communication for preventing errors as well as “being proactive, asking questions, communicating with staff, reporting symptoms to clinicians and communicating any deviations from routines are contributions that patients can make” [24].

A related study involved chemotherapy nurses in two focus group sessions to assess their experiences with patients serving as a method of catching and preventing errors; these two sessions were separated by ten weeks. In general, nurses reported several instances where patients had intervened to prevent an error. Nurses generally had positive attitudes towards
supporting patient engagement in safety and any opportunity to prevent errors. However, nurses reported that several constraints and barriers exist in engaging patients in preventing errors. Some challenges were activating patients to engage, time constraints, and discontinuity in teams and relationships with patients. Furthermore, younger patients were more receptive and interested in engaging; however, older patients were willing to participate. Nurses felt that the patient’s trust in care providers decreased after a medical error had been noted or avoided and that sometimes frustration could result if patients noticed an error but failed to properly communicate it to staff. Nurses stated that while participants could assist with error prevention, the responsibility fell on the nurses and patients’ vigilance was perceived as a complementary activity [25].

In general, both studies demonstrate how both patients and care providers perceive patient engagement as an effective means of preventing medical errors. However, both parties must support this engagement to ensure its success. Furthermore, these studies outline some of the barriers and challenges that may exist with respect to engaging patients in the clinical setting.

1.2.2.2 National Health Service Engagement Cycle

The National Health Service (NHS) in the United Kingdom looked at ways of engaging stakeholders such as patients, providers, and communities in recognition of its importance in improving the provisioning of health care services. InHealth Associates originally developed the ‘Engagement Cycle’ (Figure 2 [26]) for use by the Department of Health. This engagement cycle looks at ways of engaging patients, providers and all stakeholders at a collective level. The resource was specifically designed for commissioners of health services and outlines what steps
they should take in engaging patients, providers and the public about the provision of health services[27][28].

InHealth associates cite several important reasons for engaging the above-mentioned stakeholders in the commissioning process. These reasons include that stakeholders have a moral right to be engaged in decisions regarding healthcare and this will lead to better relationships with local stakeholders. Furthermore, engaging with patients and the public can lead to better health outcomes from services and is beneficial economically.

![Figure 2: The InHealth associates engagement cycle](image-url)
As seen in Figure 2, the Engagement Cycle outlines 5 stages where patients and the public should be engaged in commissioning decisions.

**Step 1: Community engagement to identify needs and aspirations**

This step involves health Commissioners working with local partners and communities to outline the specific needs of the people that belong to these communities. These groups work to develop a Joint Strategic Needs Assessment (JSNA) – a comprehensive picture of current and future health needs for adults and children, based on a wide range of quantitative and qualitative data, including patient, service user and community views [29].

**Step 2: Public engagement to develop priorities, strategies and plans**

Commissioners develop priorities and plans by consultation with the public as well as through informal engagement about reconfiguration or deconfiguration of services. The goals of engaging the public are to make locally-driven decisions, develop sustainable commissioning priorities and create more realistic operational plans [30].

**Stage 3: Patient and provider engagement to improve services**

The engagement cycle encourages commissioners to work with service providers, clinicians and frontline staff to improve services. The NHS does this by gathering qualitative and quantitative data as well as other types of data. This stage also encourages the use of experience-based design. Experience-based design leverages patient and provider feelings and experiences to improve services. Allowing providers and patients to share their experiences and stories aids in determining at which points in the care workflow their experiences are defined. Furthermore,
experience based design involves working with these users to redesign the experiences themselves [31].

**Stage 4: Patient, provider and public engagement to procure services**

Stage 4 involves engaging patients and providers more actively in the procurement process for health services. The engagement cycle indicates that people can be engaged in a number of ways which include but are not limited to: “identifying potential providers, making resource decisions, increasing public confidence in, and better relationships, with providers of services, focusing on identifying providers who better meet the needs of patients” [32].

**Stage 5: Patient and provider engagement to monitor services**

In this stage, commissioners should aim to procure contracts with providers that define how providers should solicit engagement from patients and providers and what data they should be collecting and reporting to monitor the services they are providing. Providers should find a way of acquiring patient experience data to monitor services and ensure that this data is available to others. Acquiring data may include involving patient directly in collecting and gathering data [33].

**1.2.2.3 Methods of Engaging Patients**

Rathert et al. stated that engaging patients in care may be important as patients interact with many care providers and thus may be the only consistent participant in their entire treatment processes. Some of the active roles that patients can play include monitoring and reporting errors and monitoring dose and treatment by understanding the associated side effects [34]. Patients can ensure staff members are complying with organizational standards on hygiene and infection
control and can assist in being properly identified prior to treatment[35][34]. Finally, hospitals may be able to engage patients in safety by facilitating patients to ask more questions or perhaps providing each patient with specific questions that they can ask their health care provider [34]. Patients can be provisioned with specific questions to ask their providers, as well as being made aware of important steps in their treatment process. One method by which this can be done is through the use of a checklist.

1.2.3 Checklists in Industry and Healthcare

A literature review by B. Hales et al. looked at various checklists\(^5\) in different industries, including healthcare. They noted that checklists have proven to be effective in preventing errors and improving performance in high stress and fast-paced environments. The primary aim of checklists in fast paced and high stress industries is to decrease errors of omission and to ensure compliance with safety procedures and protocols. The ideal checklist should reflect the important safety steps or policies necessary for that organization and these steps should be outlined in a way that is logical in the context of the actions being taken. Furthermore, completing the checklist should fit in to the workflow of the organization without causing the clinicians to become so overwhelmed with checklist duties that their ability to complete their work becomes compromised [36].

Checklists are a tool to improve communication, collaboration and accountability. However, the checklist can interfere with the workflow and may not be properly used if the culture of the

\(^5\) Checklist: “a list of action items, tasks or behaviours arranged in a consistent manner, which allows the evaluator to record the presence or absence of the individual items listed. Typically, each item is checked off as it is completed, verified, identified or answered, by placing a mark in a designated space.” [36]
organization is not supportive of the concept. As in the case of the surgical checklist, the most time consuming aspect of the checklist should be the design of the checklist itself [37].

Northwestern Memorial Hospital in Chicago, IL represents one example of an institution that currently uses checklists in radiation therapy. Currently they employ “Daily Timeout Checklists”, “First-Treatment Timeout Forms”, and “Post-Planning Timeout Forms”. The post-planning form is used so that all attending clinicians can reconcile the electronic medical record and patient chart such that the electronic record now becomes the clinicians’ sole source of information regarding that patient [38]. The checklist contains a “Timeout” section to ensure that the physics team leader and attending physician have followed all steps appropriately and verified all of the necessary information pertaining to the patient. The daily form is used to verify the correct side and site of treatment only prior to simulation. Furthermore, the daily checklist emphasizes a timeout that allows radiation therapists to make sure the patient was properly identified, that the site/side of treatment has been verified, all accessories have been included, and that the patient has been setup correctly [39]. A checklist is also completed by the therapist and attending physician at the first visit to verify patient identification, patient consent, correct images and accurate setup according to the electronic medical record [40]. The purpose of the checklist in all of these instances is to provide a visual reminder to individuals to ensure that all steps were completed properly when completing a complex multi-staged task.

There are currently documents that explain simple methodology that leads to effective and usable checklists. When developing medical checklists, one should consider context, content, structure, images and usability [36]. While no set rules exist for the design of checklists, there are studies
that outline the methodology used to develop checklists in healthcare, aviation and other industries.

1.2.3.1 **WHO Surgical Safety Checklist Implementation and Results**

One notable checklist that has been recently implemented in health care is the World Health Organization’s (WHO) Safe Surgery Saves Lives checklist. This checklist increases communication and verification among staff members during surgery and has yielded a substantial reduction in morbidity and mortality rates [41].

In January 2007, the World Health Organization held two-day meetings in Geneva with multiple clinicians and patients from around the world; the goal was to develop a global program to curb avoidable deaths and harm stemming from surgery. These meetings resulted in a surgery checklist developed to ensure necessary safety checks were done at three critical points. These points were prior to inducing anaesthesia, also known as “Sign In”, after anaesthetizing the patient but prior to the incision, also known as “Time Out”, and after the operation, also known as “Sign out” (See Figure 3) [42].
Figure 3: WHO Surgical Safety Checklist that was piloted in 8 hospitals.
This checklist was to be piloted in multiple hospitals around the world [43]. Specifically, the checklist was piloted in 8 hospitals in 8 cities; rate of complications were observed 30 days after each operation for baseline and using the checklist. Initial piloting showed a reduction in post-operative mortality from 1.5% to 0.8% and morbidity from 11% to 7% [44]. In one hospital, the checklist yielded a noticeable improvement in timely use of prophylactic antibiotics from 57% to 77% [45]. In addition to changes in compliance with safety procedures, the checklist was also associated with positive changes in clinician perception of teamwork and safety that correlated with decreases in mortality and morbidity [46]. At Helsinki University Central Hospital, 76% of clinicians thought that the checklist would improve safety while 93% indicated they would want it used if they were undergoing surgery. Compliance rates for the Sign in, Time out and Sign out periods were 62.3%, 61.1% and 53.6% respectively [47]. A 1400 bed hospital in Thailand also piloted the checklist and measured compliance rates in different categories. Some of these compliance rates included 91.4% of patients identifying themselves, the surgical site was marked 19.4% of the time, anesthesia was verified 90.3% of the time and the pulse oximeter was applied and verified in 95.1% of cases [48].

1.2.3.2 Checklists and the Hierarchy of Intervention Effectiveness

As previously stated, checklists have become a popular form of intervention tool for trying to address errors and improve safety in various industries. However, some studies have pointed to the fact that checklists may not be the most effective means of preventing errors. Specifically, checklists rank as fourth out of six types of interventions on the Institute for Safe Medication Practices’ Hierarchy of Intervention Effectiveness [49]. The other types of error prevention that rank higher include: forcing functions and constraints, automation and computerization, and
simplification and standardization [49][50]. Forcing functions and constraints means that systems are designed in such a way that errors are almost impossible or difficult to make; limiting a user’s ability to make a mistake by rendering it impossible. Automation and computerization seeks to reduce the reliance on memory by using technology and computer systems to perform tasks safely and reduce the likelihood of human error. Standardization and simplification seeks to improve safety by standardizing methods such as the way in which information is communicated from one individual to another or the types of standard forms that are used. The two interventions that rank lower than checklists on this hierarchy are: rules and policies, and education and information. Adding new rules and developing policy seeks to control individual behavior but does not necessarily address problems with the actual system. Furthermore providing individuals with education and information is the least effective method as it does not compensate for issues in the system and relies heavily on human performance [49].

Part of the difficulty with assessing the effectiveness of checklists is the fact that the implementation of checklists is often coupled with changes to other aspects of the treatment processes. Checklists may face resistance due to cultural or social barriers in the clinical setting and thus, may require an individual or group to lead the implementation of the checklist and communicate with users to consistently identify and solve problems related to the checklist. In the case of the WHO surgical safety checklist, the intervention was supported through significant cultural change. Thus, checklists must be supported by changes in user attitudes and addressing potential challenges and barriers before they can be successful. Without individuals or groups to support and ensure the proper implementation and use of the checklist by users, the intervention can fail to be impactful [51].
One method to address the cultural resistance to the use of a checklist in the clinical setting may be to include patient engagement in the checking process. Ways in which patients can engage have recently included “participating in infection control initiatives, checking the accuracy of medical records”, and “observing and checking care processes”. A specific example of patients engaging includes patients requesting that healthcare providers follow proper hand washing and hand hygiene procedures to improve infection control [22]. The example of patients being engaged to ensure hand hygiene emphasizes how patients can be engaged to ensure the accountability of healthcare providers to patients with respect to observing safety checks. Thus, combining the element of patient engagement to improve healthcare provider accountability with a checklist may serve the purpose of assuring that the safety checks are being adhered to by healthcare providers. Furthermore, engaging patients in error prevention and supporting patient participation and contribution could be a method through which the checklist is valued and supported in the clinical environment.
Chapter 2
Study Rationale and Summary

2 Thesis Summary

2.1 Thesis Statement

This study will assess the current state of patients’ and radiation therapists’ perceptions of the safety of radiation therapy treatment. Patient anxiety\(^6\) will be studied to attempt to understand how it changes through the treatment process. Furthermore, this study will gain insight into the culture of patient engagement and its potential as a means of error prevention. Through an iterative design process, a checklist will be designed to allow patient engagement in the clinical setting that is also in line with the radiation therapists’ views of what would work in their current workflow. Finally, a strategy will be outlined that proposes methods for piloting and validating the checklist in the clinical setting.

2.2 Objectives

Objectives (Phase 1): Observe the radiation therapy environment to understand and assess the methods of quality assurance and patient engagement in radiation therapy at Princess Margaret.

Objectives (Phase 2): Design a preliminary checklist according to checklist design principles and current statistics of incidents occurring in radiation therapy.

Objective (Phase 3&4): Conduct focus group meetings with radiation therapists as well as interviews with patients nearing the end of their radiation treatment. The goal will be to

\(^6\) Anxiety: “Characterized by subjective feelings of tension, apprehension, nervousness, and worry, and by activation or arousal of the autonomic nervous system” [57]
understand their perceptions of the safety of radiation therapy as the process currently operates and ask for opinion on preliminary checklist design. Furthermore, these phases will aim to assess the perception of safety and effectiveness of using a checklist to engage patients as well as the usability\(^7\) of integrating the tool into the current workflow.

**Objective (Phase 5):** Redesign the radiation therapy checklist using methods of checklist design and the feedback acquired from Phases 3 and 4.

**Objective (Phase 6):** Evaluate how the anxiety state of prostate cancer and post-operative prostate cancer patients changes over time throughout their radiation treatment.

**Objective (Phase 7):** Conduct focus groups with radiation therapists to assess the redesigned checklist in terms of content, usability and potential to engage patients in the quality and safety aspects of their treatment. Propose a piloting strategy for the checklist.

### 2.3 Research Questions

**Research Question 1:** What are the current perceptions of patients and radiation therapists about the safety of radiation therapy and using patient engagement to improve it?

**Research Question 2:** Is there a role for a patient-centric checklist in changing these perceptions and if so, what types of information and checks should this checklist include?

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\(^7\) Usability: “can be broadly defined as the capacity of a system to allow users to carry out their tasks safely, effectively, efficiently, and enjoyably”. [80]
**Research Question 3:** What is the feasibility of implementing a patient-centric checklist into the radiation therapy workflow, what barriers exist to its successful integration and usability and what is the best way of piloting the checklist?

### 2.4 Project Phases

The project was broken down into multiple phases that focus on understanding the clinical environment and the safety attitudes of staff and patients. This information attained through the literature was used to generate a patient-provider collaborative checklist and recommendations for methods of piloting the checklist in the clinical setting.

#### 2.4.1 Phase 1 – Clinical Observations

The research student conducted observations of the clinical setting by shadowing radiation therapists through every step of the radiation therapy treatment process. Approximately 45 hours were spent shadowing and learning from radiation therapists as they treated many patients. The emphasis of these observations was to observe how the radiation therapist interacts with patients and to understand the radiation therapist workflow as it pertains to interacting with patients and treating them. The intended result of this phase was to generate a summarized workflow diagram that could aid in the design of a preliminary patient-provider collaborative checklist. See Section 3.1 for more detail on the methodology of this phase.

#### 2.4.2 Phase 2 – Checklist Design

A literature review was conducted to examine the types of checklists that are used in health care, aviation and other industries. The literature review focused on studies that specifically outlined checklist design criteria. Another literature review was conducted to describe the types of incidents that occur in the radiation therapy setting. The information from these literature
reviews was used to design a preliminary patient-provider collaborative checklist. See Section 3.2 for a thorough description of the methodology used to carry out this phase of the study.

2.4.3 **Phase 3 – Focus Groups and Interviews**

Focus groups were conducted with radiation therapists to assess their perceptions of the safety of radiation therapy and to understand how they believe patients feel with regards to safety. Questions centered on experiences treating patients and the idea of using patient engagement in the form of a checklist to improve patients’ perceptions of safety. See Section 3.3.1 for methodology used to conduct focus groups.

The research student conducted interviews with patients completing their treatment to understand their perceptions of the safety of radiation therapy and how these perceptions may have changed through their treatment experiences. Furthermore, patients were introduced to the concepts of patient engagement and a patient-provider collaborative checklist to determine their views on implementing such strategies to improve perceptions of patient safety. See Section 3.3.2 for an in-depth discussion of the methodology used to conduct patient interviews.

2.4.4 **Phase 4 – Revising Checklist Design**

Phase 4 involved using the feedback from the focus groups with radiation therapists and interviews with patients to make appropriate changes to the preliminary patient-provider collaborative checklist design. See Section 3.4 for a detailed description of this phase.

2.4.5 **Phase 5 – State-Trait Anxiety Inventory Control Group**

It was important in this study to understand how patients’ anxiety levels change as they progress through treatment to understand if an intervention such as a checklist had the ability to positively
change these trends. A state-trait anxiety inventory (STAI) survey was completed by a group of prostate cancer patients once per week to assess their state anxiety and how it changes as they progress through their treatment. Refer to Section 3.5 for further detail on the methodology used to conduct Phase 5.

2.4.6 Phase 6 – Checklist Assessment Focus Group

Once the checklist was designed, it was important to validate the changes. Two focus groups were conducted with radiation therapists to assess the redesigned checklist and discuss whether they believed it could fit into the clinical setting. Topics such as the usability, content, benefits and drawbacks of the checklist were discussed. See Section 3.6 for further detail on the methodology used to conduct Phase 6.

2.4.7 Phase 7 – Final Checklist Design

Following the final set of focus groups with radiation therapists, a finalized design was created for the checklist. Refer to Section 3.7 for a description of the methodology used to conduct Phase 7.
Chapter 3
Methodology

3 Methodology

3.1 Phase 1: Radiation Therapy Workflow Analysis

This part of the study involved observing the workflow at Princess Margaret Radiation Medicine clinic and using qualitative feedback to understand the way that information is transferred and communicated in the treatment setting. Specific steps in the observation process included spending approximately 45 hours over 3 weeks in the clinical setting, shadowing radiation therapists and taking notes to understand how the treatment process is carried out and the ways in which therapists and patients communicate on a daily basis. This phase of the project also consisted of observing the activities of radiation therapists and patients from the moment a patient signs in for treatment to the moment they leave at the end of their daily routine. Furthermore, an effort was made to observe the safety practices that are intended to ensure the safety of radiation therapy patients and consistent delivery of treatment. All of the above information was used to generate a workflow diagram to aid in understanding the clinical environment as well as identifying important checkpoints where the implementation of a checklist may be feasible.

3.2 Phase 2: Preliminary Checklist Design

This phase of the project was dedicated to designing the preliminary checklist that was presented to radiation therapists during focus groups and patients during individual interviews. The preliminary checklist design incorporated information collected during the study as well as evidence from the literature.
The workflow diagram created in Phase 1 was analyzed to identify checkpoints that would be ideal for using the checklist as well as some checks that could be included based on the observed interaction between radiation therapists and patients.

Literature reviews were conducted on the incidents and errors that occur in radiation therapy as reported by various organizations. This information was used to validate the need for the checklist during the treatment itself as well as to identify any checks that could be included in the preliminary checklist design. An additional literature review was carried out that focused on studies that describe the design of checklists in healthcare and industry. These studies were analyzed in an attempt to summarize important design considerations that should be incorporated into the design of checklists in industry and healthcare. These design considerations were leveraged and applied to the preliminary patient-provider collaborative checklist.

See Section 4 for a thorough description of the checklist research and development.

3.3 Phase 3: Focus Groups and Interviews

3.3.1 Focus Groups with Radiation Therapists

This phase of the study was dedicated to conducting focus groups with radiation therapists. Focus groups are centered on a topic chosen by the researcher and are dedicated to collecting data, using interaction as a source of data and acknowledging that the researcher should be pivotal in guiding the discussion such that data collection is possible [52]. Focus groups were used as they effectively encourage participants to interact with one another. They allow peers,

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8 Focus Group: a form of group interview that capitalizes on communication between research participants in order to generate data [50].
radiation therapists in the case of this study, to compare and discuss their views on a number of important subjects. This aids in discerning the differences in therapists’ views instead of having to discern these differences from two separate dialogues, as in the case of individual interviews [52]. Focus groups were also chosen for this phase, as the interaction between therapists exposed their thoughts and experiences and aided in understanding “not only what people think but how they think and why they think that way” [53].

Two focus groups with a targeted size of 6-8 participants were conducted. Lane et al. stated that, according to Kruegar and Then[54], focus groups should consist of 6-8 individuals in order to allow a thorough and in-depth look at perceptions and behaviors of participants [55][54]. Kitzinger listed the ideal number of participants as 4 to 8 individuals [53]. There is a significant amount of debate within the literature as to the ideal number of focus groups. One study states the ideal number is 4-6 focus groups [52] whereas other studies have indicated that the number of focus groups is at the discretion of the researcher based on the quality of data acquired [55] or the aims of the project [53]. However, according to Kitzinger, most studies only consist of a few focus groups [53]. Due to the homogeneity of participants, the ability to recruit an ideal sample size of participants for each group, and the standardization of questions across groups, it was decided that two focus groups would be adequate for the purposes of this phase of the study.

According to the literature, focus groups should be relaxed and comfortable, and the participants should be encouraged to address their fellow participants as opposed to addressing the researcher directly [53]. Therefore, focus groups were conducted in a casual setting with lunch provided to allow interaction among participants. Furthermore, group discussions were recorded and data analysis consisted of identifying important themes [53]. A moderator was recruited to ensure that
the focus groups are carried out in a professional and effective manner and to steer the direction of the conversation onto topic and allow elaboration on subject matter that was discussed and could be important to the research.

Each focus group was approximately one hour in length and was audio-recorded and transcribed for later analysis. Complementary notes were taken to ensure important statements by participants are captured and highlighted during analysis. Finally, a script was developed in advance (see Radiation Therapist Focus Group Session in Appendix A) to assist the moderator in guiding the sessions and ensuring the important research questions are addressed. The first set of focus groups aimed to outline radiation therapists’ views on the safety of radiation therapy, whether they believe patients feel safe during treatment, and whether they believe that patients can play a more active role in safety aspects of the treatment. The concept of patient engagement was introduced just prior to demonstrating the preliminary design of the patient-provider collaborative checklist to radiation therapists. Therapists were asked to comment on its possible effectiveness in promoting patient engagement and suggest possible changes to the checklist.

3.3.1.1 **Radiation Therapist Recruitment**

Steps were taken in order to recruit and involve as many radiation therapists in the focus groups as possible. A presentation was delivered during Quality Assurance rounds to radiation therapists explaining the study as well as the need for therapists to participate and lend their professional knowledge. One month prior to the estimated focus group dates, an email was sent out to all radiation therapists requesting participation in the focus groups. The focus groups were scheduled during lunch periods in order to permit as much participation as possible and interested parties were able to choose between the two focus group dates based on availability.
Radiation therapists complete the Consent Form prior to the start of the focus groups (See Phase 2: Radiation Therapist Consent in Appendix B).

3.3.2 Interviews with Genitourinary Patients

In order to assess patients’ perceptions towards patient engagement and the safety of radiation therapy, individual interviews were conducted with genitourinary (GU) patients. GU patients were chosen as this group encompassed prostate patients, who were the subjects of the STAI survey. Furthermore, choosing this group allowed for both male and female patients of other cancer types to be interviewed in addition to prostate cancer patients. The patient group was expanded with the goal of having more generalized results on patient perceptions of safety as well as the concept of patient engagement.

Interviews were chosen for patients as they provide an opportunity to explore details and insights related to the experiences of the interviewee and are useful when examining experiences, opinions, attitudes, and processes [56]. Additionally, interviews help the researcher to understand individual behavior and what drives this behavior [57]. Conversely, interviews may be prone to bias; they require careful planning by the interviewer and cannot be as generalized as other qualitative methods [58].

In general, when conducting interviews, specifically semi-structured ones, a general script is followed but divergence from the script may occur based on the participant’s responses [57][56]. This script is based on 6 to 12 well written questions [56] that make up the central aspects of an interview guide [57]. Interview questions are accompanied by prompts to have the interviewee elaborate further on their answers and help promote a discussion [58][56]. These questions are broken down more precisely into main questions that are followed by planned follow-up
questions or probes, in addition to spontaneous follow-up questions based on the participant’s responses [57]. The literature states that interviews should avoid correcting or educating the participant, demonstrating bias, not allowing enough silence or time to allow the participant to elaborate and not listening attentively to the participant’s answers [57]. Furthermore, questions should not be leading, invite “yes” or “no” answers, overly vague or invasive [56]. Patient interviews were the preferred method in this study, as the subject matter involved is personal to each individual and patients may not be as comfortable sharing this information in larger groups such as a focus group.

Interviews with GU patients were carried out until saturation was reached and participants were not presenting new ideas. The interviews were 10-20 minutes in length and discussed topics such as patient perceptions of safety, patient anxiety, and patient engagement. Furthermore, the preliminary checklist was presented to patients who discussed their opinions on potential benefits and drawbacks to its implementation. See Patient Script (Prior to Checklist Design) in Appendix A for a copy of the main script.

3.3.2.1 **Patient Interview Recruitment**

Staff members were consulted and assisted in identifying and recruiting patients that were possible candidates for interviews based on their ability to communicate in English. Candidates were chosen from GU patients that had completed approximately half of their total treatment fractions or more. This was done to ensure that patients who participated in interviews had an adequate amount of experience in treatment to be able to make comments on how they perceive some aspects of it. Patients were presented with a Consent form (see Phase 2: Patient Consent in Appendix B) explaining the study and were asked if they had some preferred times for the
interview. Patients who agreed to participate were interviewed either before or after their treatment depending on what time they were available on the interview day.

3.3.3 Data Analysis

During focus groups and interviews, qualitative data was collected to understand patients’ and radiation therapists’ views on patient engagement and the safety of radiation therapy. In order to attain accurate and thorough analysis of the data, thematic analysis principles were applied.

A 2006 publication by Braun and Clarke described methods for applying thematic analysis to qualitative data [59]. Following the recommendations of Braun and Clarke, interviews and focus groups were audio-recorded and subsequently transcribed into written form while maintaining the context and punctuation of the initial speech. Excerpts of the transcribed text were manually coded for statements and themes that appear interesting or relevant to the research. Once the data had been coded and collated, the codes were analyzed to determine how they could be grouped together to form themes. This was done using tables and hand-drawn flowcharts to visually organize the data. This step resulted in all of the codes having been placed into themes and sub-themes in tabular form.

Further refining of themes was carried out at this point, including removing and combining themes. All extracts were reread carefully to see if they formed a pattern with relation to the theme and overall research. Once the themes were re-organized, the entire data set was re-read to ensure that all themes related to the overall data and to ensure that any additional extracts that were missed the first time through the data were coded.
The codes and data were organized to create a descriptive and detailed narrative from the data for each theme. Each theme was related to the overall research and a detailed analysis was written to indicate the importance of these themes and what story they tell about the data and research. A set of fully worked out themes was used to write up the final analysis on the findings from the interviews and focus groups. Specifically, data extracts were used to support the themes and findings.

3.4 Phase 4: Checklist Design Revision

This phase of the project took the preliminary checklist design and modified it according to responses and themes from focus groups with radiation therapists and interviews with patients. The checklist maintained the fundamentals of checklist design that were researched initially but feedback from patients and radiation therapists was incorporated to improve upon the perceived usability of the design.

3.5 Phase 5: State-Trait Anxiety Inventory Survey Group

The STAI survey was developed in 1983 by Dr. Charles Spielberger to assess state anxiety and trait anxiety. The survey comprises two scales for measuring state and trait anxiety using 20 questions per scale. The state anxiety (S-anxiety) form evaluates how individuals feel at that moment in time, whereas, the trait anxiety (T-anxiety) form assesses how respondents generally feel. The S-anxiety scale was used in this phase of the project to assess anxiety, as the survey is

9 State and Trait Anxiety: “Trait anxiety refers to relatively stable individual differences in anxiety-proneness, that is, to differences between people in the tendency to perceive stressful situations as dangerous or threatening to respond to such situations with elevations in the intensity of their state anxiety reactions.” [57].
useful in assessing anxiety induced by stressful situations such as “imminent surgery, dental treatment, job interviews or important school tests”. The survey is designed to give a total anxiety score between 20 (lowest) and 80 (highest) depending on the responses of individuals to these 20 questions. The STAI survey has defined norm values for different groups of individuals with various backgrounds. In the case of working males, the mean score was 35.72 with a standard deviation of 10.40. For men over the age of 50, this average drops to 34.51 with a standard deviation of 10.34. For general medical and surgical patients, the average score is 42.68 with a standard deviation of 13.76 [60].

The STAI Survey Group phase of the study involved recruiting approximately 20 prostate cancer patients to participate in a survey to assess how their state-level of anxiety changed as they progressed through their treatment. See Section 3.5.2 for STAI survey sample size rationale. At the time of consent, all patients were provided with a demographics survey to fill out to provide background information to complement the STAI. The survey was approximately 7 or 8 weeks in length dependent on whether the patient is undergoing curative treatment or post-operative treatment. This survey intervention did not change the patients’ treatment procedure and was administered by radiation therapists on the treatment units once a week on a Wednesday. This day was chosen to attempt to remove the effects on anxiety that the beginning or end of a treatment week might have and attempt to standardize the day in which the survey was administered. See Pre-Survey form in Appendix A for the demographics form and Phase 3: STAI Patient Consent in Appendix B for patient consent form.

Surveys were collected, calculated and analyzed to determine how prostate cancer patients’ anxiety changed as they progress through their treatment.
3.5.1 **Prostate Patients**

Prostate cancer patients were chosen for this portion of the study for a number of reasons. This phase involved analyzing patient anxiety in the radiation therapy setting and observing the changes in anxiety over time. Since prostate patients are all men and tend to be over the age of 50 [12], the goal was to reduce the number of demographic factors that could affect anxiety levels within the chosen group and therefore increase the ability compare individuals with similar diagnosis. Furthermore, patients being treated for other types of cancers may have more severe side effects and prognosis that could cause them to be reluctant to complete the survey and could cause a lower recruitment rate and a higher withdrawal rate following recruitment. Finally, prostate patients are a relatively common patient group and thus the goal was to improve the likelihood of recruiting the desired number of patients for the STAI survey.

3.5.2 **Sample Size Rationale**

Twenty patients were chosen as a sample size for the STAI survey in order to detect any significant changes in patient anxiety. For working males, the average survey value is 35.72 with a standard deviation of 10.40. The sample size was chosen to detect changes in anxiety that were outside of this standard deviation. Thus, a sample size of 20 achieves a 99% power to detect differences of 10.4 (the standard deviation) from a mean of 35.72. This calculation was performed as a 2-sided t-test with an alpha value of 0.05[61][62].

3.5.3 **State-Trait Anxiety Indicator Patient Recruitment**

Prostate cancer patients were recruited with the help of the patient navigator and radiation therapists at the treatment units. The patient navigator assisted by indicating when patients would be arriving for their CT appointment at CTSim4. The research student approached these patients
in the waiting room and presented them with the consent form and answered any questions that they had. The research student followed up with patients on the first day or two of treatment to determine if patient remained interested in participating. The radiation therapists on the treatment units were notified of the patient’s participation and they assisted by administering the survey to these patients.

3.6 **Phase 6: Checklist Assessment Focus Group**

Following the re-design of the checklist as described in Section 3.4, a second set of focus groups with radiation therapists was conducted to assess the new iteration of the checklist. These focus groups followed the same general methodology and analysis as described in Section 3.3.1. However, the participants chosen for these focus groups will be individuals who did not previously participate in the last round of focus groups. This set of focus groups focused on topics such as the usability, content, benefits and drawbacks of the checklist as currently designed. Therapists were asked to suggest any improvements or modifications to the design of the checklist itself or to the process by which it can be implemented into the clinical setting. See Phase 3: Radiation Therapist (Focus Group Following Checklist Re-design) in Appendix A for a copy of the script that was used to guide these focus groups.

3.7 **Phase 7: Final Checklist Design**

As with Phase 4, themes and suggestions from the data analysis of the previous set of focus groups were used to make final changes to the design of the checklist. This phase signified the end of the iterative process of including prospective users in the design of the checklist. Once a final checklist was designed, a strategy was proposed that outlined potential methods by which the checklist could be introduced, piloted, assessed and validated in the clinical setting.
3.8 Research Ethics Approval

The methodology for this study was conducted with ethics approval from the University Health Network Research Ethics Board and Office of Research Ethics at the University of Toronto. All forms in Appendix A and B received ethics approval.
Chapter 4
Intervention Description

4 Checklist Design

Literature reviews were conducted both in the areas of checklist design and incidents in radiation therapy. This was done to ensure these checklists were designed in an evidence-based manner.

4.1 Literature Review – Incidents in Radiation Therapy

Radiation therapy is considered to be a safe procedure that is employed to treat many types and stages of cancer. However, errors do occur and healthcare organizations are constantly pursuing ways of reducing their frequency and likelihood. Reports have shown that the rate of incidents occurring is low and the consequences from these incidents typically cause no or minimal clinical significance to patients [63]. However, many organizations have begun looking into establishing methods of incident reporting and have broken down these incidents into where they tend to occur during the treatment cycle. A literature review was conducted using scientific databases to try and summarize where errors tend to occur during radiation therapy treatment.

This literature review was important for the design of the patient-provider collaborative checklist. Many of the cited checklist design studies emphasized the importance of evidence-based checklist design. Thus, it is important to identify what stages of the treatment process yield high frequency or critical errors.

Table 3 summarizes the general methodology used to conduct this review, which was based on a similar review of incidents occurring in radiation therapy performed by Alvita Chan [64].
Table 3: Methodology used to conduct literature search of incidents occurring in radiation therapy.

<table>
<thead>
<tr>
<th>Search Date</th>
<th>November 5, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>PubMed, Scopus, Web of Knowledge, PubMed, Google Scholar</td>
</tr>
<tr>
<td>Search Terms for databases</td>
<td>“Radiation Therapy” OR “Radiotherapy” AND “Treatment Incidents” OR “Treatment Errors”</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Study lists the number of incidents that occurred in radiation therapy treatment and breaks them down by category.</td>
</tr>
<tr>
<td></td>
<td>• Describes origin, cause, location or detector of incidents</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No data given for the frequency of errors</td>
</tr>
<tr>
<td></td>
<td>• Does not outline at which point in the treatment cycle the stated errors occurred.</td>
</tr>
</tbody>
</table>

Searches of these databases yielded multiple studies. Studies were included on the basis that they list the number of incidents or errors that occurred in the clinical setting related to radiation therapy. Furthermore, these studies were included if they describe the origin, cause, location or the individual or group that detected the errors. This information is important to understand the types of errors that are occurring in the clinical setting, how they propagate forwards and how they may be caught, corrected or mitigated. Table 4 outlines the number of studies from each database that were initially screened in and finally accepted.
Table 4: Summary of radiation therapy incidents literature review from each searched database.

<table>
<thead>
<tr>
<th>Source</th>
<th>Total Results</th>
<th>Initial Inclusion</th>
<th>Final Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed</td>
<td>10</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Scopus</td>
<td>44</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Web of Knowledge</td>
<td>50</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Google Scholar</td>
<td>399</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>503</strong></td>
<td><strong>15</strong></td>
<td><strong>7</strong></td>
</tr>
</tbody>
</table>

4.1.1 **Summary of Safety Incidents Occurring in Radiation Therapy**

All of the studies included in this review describe incidents that have occurred in radiation therapy over a fixed period of time defined in the study. Table 5 describes each study, the years in which data were collected and the statistical breakdown of the point where errors occurred in the treatment process.
Table 5: Statistical breakdown of incidents in radiation therapy from various reports and institutions.

<table>
<thead>
<tr>
<th>Source</th>
<th>Location, Years Studied</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>[63]</td>
<td>Princess Margaret Hospital, 2001-2007</td>
<td>Described the cause of incidents from 2001 to 2007. For the purposes of brevity, only the most recent 2 years (2006, 2007) are documented below:</td>
</tr>
<tr>
<td>Incident Cause</td>
<td>2006 Number of Incidents</td>
<td>2006 % of Incidents</td>
</tr>
<tr>
<td>Location</td>
<td>18</td>
<td>13.33 %</td>
</tr>
<tr>
<td>Documentation</td>
<td>28</td>
<td>20.74 %</td>
</tr>
<tr>
<td>Non-Compliance</td>
<td>6</td>
<td>4.44 %</td>
</tr>
<tr>
<td>Laterality</td>
<td>2</td>
<td>1.48 %</td>
</tr>
<tr>
<td>Change</td>
<td>14</td>
<td>10.37 %</td>
</tr>
<tr>
<td>Human Error</td>
<td>16</td>
<td>11.85 %</td>
</tr>
<tr>
<td>Planning/Dos.</td>
<td>24</td>
<td>17.78 %</td>
</tr>
<tr>
<td>Malfunction</td>
<td>8</td>
<td>5.9 %</td>
</tr>
<tr>
<td>Accessory</td>
<td>19</td>
<td>14.07 %</td>
</tr>
</tbody>
</table>

*All figures approximated from histogram.

[65] Multiple Incident Publications, After 2000  100 incidents were broken down into their frequency and cause:
Unintended exposure in radiotherapy: Identification of prominent causes

- Incorrect data for patient dose calculations and incorrect patient dose calculations (22%)
- Incorrect setup/treatment procedures (21%)
- Incorrect calibration of beam output (14%)
- Equipment and software failure/design faults (12%)
- Use of wrong source due to incorrect source identification (7%)
- Improper storage of source or improper disposal or improper decommissioning of leaky sources (7%)
- Incorrect data provided by vendor or supplier (6%)
- Source displacement or dislocation or intentional removal of implant by patient (5%)
- Misidentification of patient or dose administration to ineligible patient (5%)
- Inappropriate or incomplete commissioning of equipment and accessories including TPS (1%)

The management of radiation treatment error through incident learning

The Ottawa Hospital, 2007-2009

In the years 2007-2009, incidents were classified into 4 main categories and their percentages of total incidents based on year.

<table>
<thead>
<tr>
<th>Incident Origin</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>22 %</td>
<td>19 %</td>
<td>8 %</td>
</tr>
<tr>
<td>Booking</td>
<td>8 %</td>
<td>17 %</td>
<td>14 %</td>
</tr>
<tr>
<td>Preparation</td>
<td>55 %</td>
<td>51 %</td>
<td>63 %</td>
</tr>
<tr>
<td>Treatment</td>
<td>15 %</td>
<td>13 %</td>
<td>15 %</td>
</tr>
</tbody>
</table>
Incident Reports (101 Departments), 2003-2008

Examination of first 1074 reported ROSIS incidents showed that the majority of incidents are detected by the radiation therapist at the treatment unit:

<table>
<thead>
<tr>
<th>Who Detected Incident</th>
<th>Percentage of Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapist (treatment unit)</td>
<td>56 %</td>
</tr>
<tr>
<td>Unknown</td>
<td>15 %</td>
</tr>
<tr>
<td>Oncologist</td>
<td>8 %</td>
</tr>
<tr>
<td>Therapist (Sim/CT)</td>
<td>5 %</td>
</tr>
<tr>
<td>Other</td>
<td>22 %</td>
</tr>
</tbody>
</table>

43\% of incidents were found at the time of patient treatment while 33\% were found during a QC process chart check.

Boston Medical Center, 2003-2009

Looked at the cases of 39 patients that had some error in their treatment and classified them according to the type of error:

<table>
<thead>
<tr>
<th>Error</th>
<th>Instances</th>
<th>Percentage of Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect Patient</td>
<td>1</td>
<td>2.56 %</td>
</tr>
<tr>
<td>Incorrect Site</td>
<td>3</td>
<td>7.69 %</td>
</tr>
<tr>
<td>Incorrect Isocenter</td>
<td>5</td>
<td>12.82 %</td>
</tr>
<tr>
<td>Where Incident Occurred</td>
<td>Instances</td>
<td>Percentage of Incidents</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Commissioning</td>
<td>796</td>
<td>25.47 %</td>
</tr>
<tr>
<td>Planning</td>
<td>1702</td>
<td>54.46 %</td>
</tr>
<tr>
<td>Treatment Information Transfer</td>
<td>276</td>
<td>8.83 %</td>
</tr>
<tr>
<td>Treatment Delivery</td>
<td>317</td>
<td>10.14 %</td>
</tr>
<tr>
<td>Multiple Stages</td>
<td>34</td>
<td>1.09 %</td>
</tr>
</tbody>
</table>

Reviewed radiation therapy incidents with adverse patient outcomes occurring in a 30 year span (3125 incidents). These incidents were classified according to where they occurred in treatment:

An international review of patient safety measures in radiotherapy practice

Multiple Incident Publications, 1976-2007

[69]
Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period

Northeastern Ontario Regional Cancer Centre, 1992 – 2002

624 incidents from November 1992-December 2002 were classified according to the source of the error:

<table>
<thead>
<tr>
<th>Origin of Incident</th>
<th>Instances</th>
<th>Percentage of Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation</td>
<td>263</td>
<td>42.15 %</td>
</tr>
<tr>
<td>Absolute Dose</td>
<td>2</td>
<td>0.32 %</td>
</tr>
<tr>
<td>Treatment Planning</td>
<td>81</td>
<td>12.98 %</td>
</tr>
<tr>
<td>Patient Set-up</td>
<td>252</td>
<td>40.38 %</td>
</tr>
<tr>
<td>Patient Data Management</td>
<td>1</td>
<td>0.16 %</td>
</tr>
<tr>
<td>Machine/Accessories Fault</td>
<td>16</td>
<td>2.56 %</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>9</td>
<td>1.44 %</td>
</tr>
</tbody>
</table>
As previously documented in Table 4, the studies listed in Table 5 were included in the literature review as they describe either the source/origin of the incident, note cause of the incident, classify the incidents into categories or identify the individual who noticed or reported the incident.

Some of the studies listed in Table 5 demonstrate that malfunction [63], equipment and software failure [65] and machine fault [70] are often not the primary source of errors that occur during radiation therapy treatment. This theme does not suggest that proper design of technology is not important in preventing incidents, but rather that many errors result due to the human aspect of the treatment process.

In 2007, Bissonnette and Medlam found that human error accounted for 23.16% of radiation therapy incidents occurring at Princess Margaret [63]. Furthermore, of the incidents that arise during radiation therapy, a significant number can be attributed to incorrect patient setup. Boadu and Rehani found that of the incident publications they examined, approximately 21% resulted from incorrect patient setup[65] while Yeung et al. noted that of the incidents occurring at Northeastern Ontario regional Cancer Centre from 1992-2002, approximately 40.38% originated from incorrect patient setup[70]. An Ottawa Hospital based study by Clark et al. highlighted this fact by showing that 55%, 51% and 63% of incidents during the years 2007, 2008 and 2009 respectively, occurred at the treatment preparation stage [66].

A study outlining the first 1074 reported incidents in the ROSIS database from 2003-2008 found that approximately 56% of all reported incidents were detected by the radiation therapist working on the treatment unit [67]. This figure demonstrates that during radiation therapy treatment, the
radiation therapist is the last individual who can prevent or cause an error before it reaches the patient being treated.

Finally, incidents such as delivering treatment to the wrong patient and delivering treatment to the wrong anatomic site occur on occasion [68]. These types of incidents have the potential to be major incidents and thus should be considered when researching ways of preventing errors in radiation therapy.

4.2 Literature Review – Principles of Checklist Design

In order to ensure that the checklist was designed according to established best practices, a comprehensive literature review was carried out using several databases. This literature review encompassed many examples in medicine and industry where a checklist was designed and implemented. Furthermore, inclusion criteria emphasized studies that documented clearly some of the steps or concepts they employed during the design and/or implementation of said checklist. One of the cited studies [71] made reference to the book “The Checklist Manifesto” by Atul Gawande, which describes in detail examples of industries that use checklists and why Gawande believes this validated the creation of the WHO Surgical Safety Checklist [43]. As a well-known and well-received book on the design, benefits and value of checklists in industry and healthcare, “The Checklist Manifesto” was included in the literature review. Table 6 summarizes the methodology used to conduct the literature review.
Table 6: Search criteria used to identify, include and exclude studies that describe important design considerations for creating checklists.

<table>
<thead>
<tr>
<th>Search Date</th>
<th>October 24, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>PubMed, Scopus, Web of Knowledge, Engineering Village, Google Scholar</td>
</tr>
<tr>
<td>Search Terms for databases</td>
<td>“Checklist Design”</td>
</tr>
<tr>
<td></td>
<td>• Paper describes methodology of checklist design used</td>
</tr>
<tr>
<td></td>
<td>• Study suggests checklist design criteria or considerations</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
<td>• Study does not explain in adequate detail how the checklist was designed</td>
</tr>
<tr>
<td></td>
<td>• Study does not include a specific design of a checklist AND/OR its design considerations are based solely on papers that can be independently acquired</td>
</tr>
</tbody>
</table>

In total, database searches yielded many papers that were considered for inclusion. Papers were screened in for review by reading titles and abstracts if necessary and determining the potential relevance of the article. In particular, the studies were only included if they specifically outlined some criteria or considerations for checklist design or a methodology that was used to design a checklist. Papers were also excluded if they did not explain in detail the methodology by which they designed checklists or if the cited sources explained the methodology of checklist design and could be acquired directly. By referring to the reference sections of all initially included papers, additional papers were retrieved. Table 7 describes in detail the process by which these papers were initially screened in and further analyzed to eliminate those that did not fit inclusion criteria.
Table 7: Summary of the studies found using the search criteria in Table 1 and breakdown of the final inclusions by database.

<table>
<thead>
<tr>
<th>Source</th>
<th>Total Results</th>
<th>Initial Inclusion</th>
<th>Final Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed</td>
<td>8</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Scopus</td>
<td>31</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Web of Knowledge</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Engineering Village</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Google Scholar</td>
<td>438</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>References</td>
<td>-</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>485+</strong></td>
<td><strong>26</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

4.2.1 **Results of Checklist Design in the Literature**

The studies chosen from the literature review describe the use, development, design and evaluation of checklists in various industries. Some of the studies outline standard practices applied when developing checklists while others put particular emphasis on the aviation and healthcare applications of checklists. Table 8 summarizes the checklist design studies that were included from this literature review and outlines some of their considerations or suggestions on checklist design, implementation and evaluation.
Table 8: Summary of the included studies and some of their recommendations on the design of checklists for various industries.

<table>
<thead>
<tr>
<th>Source</th>
<th>Checklist Design Considerations</th>
</tr>
</thead>
</table>
| [72] *The Checklist for Formatting Checklists* | Proposes a checklist for formatting checklists prior to final design. This checklist stresses the importance of addressing:  
1. Context: audience, timing, directions, title  
2. Content: complete, precise terms, focuses user, consistent language, items are clear  
3. Structure: similar items grouped, functional order, numbered, visual breaks/white space used, important information and words highlighted or emphasized, textual devices used)  
4. Images: used when needed, explanatory text, oriented for user, obvious purpose  
5. Usability: tested to see if it works as intended, used with members of target audience, tester did not intervene to help during testing, revisions made to checklist |
| [73] *Design Guidance for Emergency and Abnormal Checklists in Aviation* | Suggests numerous aspects that are important in checklist design such as and relate to: physical properties and interface, organization and access, typography and use of symbology, layout, format, display, length, workload, navigation, progression, nomenclature, abbreviations, language, grammar, wording and purpose. |
| [74] *Guidance on the Design, Presentation and Use of Emergency and Abnormal Checklists* | A very detailed review of abnormal emergency checklists in aviation that can broken down into three main categories:  
1. Physical characteristics  
2. Content  
3. Layout and Format |
<table>
<thead>
<tr>
<th><strong>[75]</strong></th>
<th>Cockpit Checklists: Concepts, Design, and Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on human factors findings, 11 design considerations were made for aviation checklists. Some of the points from this list can be applied to checklists designed in healthcare. Some of these considerations were interpreted to be more generalized to areas other than aviation:</td>
<td></td>
</tr>
<tr>
<td>1. A long checklist should be subdivided to smaller task-checklists or chunks…</td>
<td></td>
</tr>
<tr>
<td>2. The most critical items of the task-checklist should be listed as close as possible to the beginning of the task-checklist, in order to increase likelihood of completing the items before interruptions may occur.</td>
<td></td>
</tr>
<tr>
<td>3. Checklists should be designed in such a way that their execution will not be tightly coupled with other tasks.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>[76]</strong></th>
<th>Development and validation of the SURgical Patient Safety System (SURPASS) checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created a surgical patient safety system checklist using the following methodology:</td>
<td></td>
</tr>
<tr>
<td>1. Collected “known surgical safety risk events from the relevant literature” to develop prototype</td>
<td></td>
</tr>
<tr>
<td>2. Checked whether “theoretical safety risk events matched the safety risk events occurring in practice”</td>
<td></td>
</tr>
<tr>
<td>3. Evaluated the clinical use of the instrument.</td>
<td></td>
</tr>
<tr>
<td>Consulted human factors literature to create the ideal format, design, length and graphic layout of the checklist.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>[43]</strong></th>
<th>The Checklist Manifesto: How to Get Things Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Gawande’s explanation of the WHO surgical safety checklist, he emphasizes several key points on the design of good checklists:</td>
<td></td>
</tr>
<tr>
<td>• Efficient, to the point, easy to use in the most difficult situations</td>
<td></td>
</tr>
<tr>
<td>• Provides reminders of the most critical and important steps</td>
<td></td>
</tr>
<tr>
<td>• No more than 60-90 seconds at a pause point</td>
<td></td>
</tr>
<tr>
<td>• 5-9 items per pause point</td>
<td></td>
</tr>
<tr>
<td>• Uses data to establish most critical steps</td>
<td></td>
</tr>
<tr>
<td>• Tested in real world</td>
<td></td>
</tr>
<tr>
<td>• Strikes a balance between brevity and effectiveness</td>
<td></td>
</tr>
</tbody>
</table>
“The Checklist Manifesto” also provides “A Checklist for Checklists” that guides the development, drafting and validation of designed checklists.

<table>
<thead>
<tr>
<th>[36]</th>
<th>Development of medical checklists for improved quality of patient care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outlined considerations for formatting medical checklists:</td>
<td></td>
</tr>
<tr>
<td>1. Context: “Location of checklist should be determined prior to development.”</td>
<td></td>
</tr>
<tr>
<td>2. Content: Should use “peer-reviewed guidelines” and “evidence-based best practices” to “form body of the checklist”. Should reflect the policies and procedures of the institution employing the tool.</td>
<td></td>
</tr>
<tr>
<td>3. Structure: “Checkpoints should be presented in a logical and functional order to reflect sequence or flow of real-time clinician activities and regular patient-care routines”. If “part of standard patient care, it might be important to include a checkpoint at the end where two users can sign off that it was completed”.</td>
<td></td>
</tr>
<tr>
<td>4. Images: “Clear, equally spaced bold fonts”. Commonly used colours matching those used in the checklist’s intended environment.</td>
<td></td>
</tr>
<tr>
<td>5. Usability: “Should not be onerous or time-consuming as to interfere with administration of patient care”. Should cover major checkpoints while allowing clinicians the freedom to use their judgement. “Members of each discipline within a unit should pilot the checklist”. “Validation of the checklist should occur, where possible, within the appropriate simulated clinical environment”.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>[77]</th>
<th>Development and Evaluation of a Checklist for Medication Order Review by Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed checklist for medication order review based on:</td>
<td></td>
</tr>
<tr>
<td>• Results from task analysis of pharmacists conducting medication order review</td>
<td></td>
</tr>
<tr>
<td>• Review of the literature on checklist design</td>
<td></td>
</tr>
<tr>
<td>• Consultations with “pharmacists who perform this type of review”</td>
<td></td>
</tr>
<tr>
<td>Used satisfaction surveys, interviews, focus groups and review of near-miss occurrence reports to evaluate the checklist.</td>
<td></td>
</tr>
</tbody>
</table>

| [78] | Developed a 12 point checklist to aid and guide in the design and implementation of evaluation checklists. This guide is described below: |
### Guidelines for Developing Evaluation Checklists: The Checklists Development Checklist (CDC)

1. Define content and purpose, study literature, consult experts
2. Define potential checkpoints and identify merit of these checkpoints
3. Classify and sort the checkpoints into categories
4. Rationalize each category and review checkpoints
5. Determine the order of categories
6. Create a draft of the checklist and consult potential users on its design
7. Address the questions and concerns and edit the checklist accordingly
8. Consult users to determine if scoring is required on the checklist. Format the checklist accordingly
9. Evaluate the checklist using reviews from potential users. Have the checklist tested in its intended environment and determine if it meets its intended requirements
10. Finalize the checklist based on the findings above
11. Apply and disseminate the checklist
12. Revise and review the checklist periodically based on feedback

### [79]

*Can a structured checklist prevent problems with laparoscopic equipment?*

Developed 28-item checklist based on frequently occurring laparoscopic equipment failures. The following design criteria were considered:

- Checklist designed based on incident analysis
- Guidelines for aviation checklist design taken into account

### [80]

*Requirements for the design and implementation of checklists for surgical processes*

Using recommendations from CAA and FAA guidelines, checklist requirements for surgical processes were summarized. Combined personal experiences in a pilot study with a checklist, some of the most important requirements for checklist design were found to be:

- “Consistency, clarity, straightforwardness”
- “Clearly stated purpose”
- “Used intuitively”
- “Robustness and consistency”
| Number of checks: “Maximum of 7 tasks or checks per page”
Font size: 14pt for heading and 12pt for text
Font type: Helvetica, Arial, Sans Serif |
|---|
| **[71]**
*Perspectives in quality: designing the WHO Surgical Safety Checklist*

The checklist development process can be broken down into five steps:

1. Content and format: focus on most important items that are critical, likely to be overlooked or dangerous if missed
2. Timing: design checklist around workflow patterns and identify natural checkpoints
3. Trial and feedback: trial the checklist in its intended setting and gain feedback
4. Formal testing and evaluation
5. Local modification: allow individuals in specific institutions to modify the checklist to their individual needs

| **[81]**
*Checking it twice: an evaluation of checklists for detecting medication errors at the bedside using a chemotherapy model*

Listed seven steps used for developing a checklist to detect medication errors at bedside:

1. “Determine the errors with high risk or high probability that could reach the bedside”
2. Create specific instructions on procedures to deal with each predictable type of error. “Keep the list short by omitting items with lower risk and lower probability”.
3. “If the possibility of an error is abstract or general, but the error itself has a high severity or probability, break the error down into smaller, more specific steps that can be added to the instructions”.
4. Determine the workflow of those involved by observing them work in their natural environment.
5. Assemble a checklist in such a way as to correspond with their natural workflow and use language that matches their existing tools.
6. “To test and improve the usability of the checklist, recruit a small sample of end users (three to six people) to use the checklist while you observe”.
7. “For each potential error not included on the checklist, develop alternate strategies to prevent it from reaching the bedside. Continue to develop additional strategies for eliminating all possible errors, even those that can be identified with the checklist, since no human checking process is failsafe”.

<table>
<thead>
<tr>
<th></th>
<th>Suggested checklists should be developed using the following considerations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>“Design checklists based on caregivers’ needs and the realities of their work by doing ethnographic studies of the clinical work and involvement of potential users”.</td>
</tr>
<tr>
<td>2.</td>
<td>Major items should be at the beginning of the checklist where possible.</td>
</tr>
<tr>
<td>3.</td>
<td>Avoid making checklists too long and subdivide into smaller sections where possible.</td>
</tr>
<tr>
<td>4.</td>
<td>It is important to take usability into account. This means focusing on “the time it takes to complete the checklist, potential negative effects on caregivers’ work and patient safety, and feedback from potential users”.</td>
</tr>
<tr>
<td>5.</td>
<td>Pilot the checklists and validate before implementation.</td>
</tr>
<tr>
<td>6.</td>
<td>Checklist design team should include “potential users, content experts, and human factors/usability experts”</td>
</tr>
<tr>
<td>7.</td>
<td>“Re-evaluate/update checklists periodically based on new literature and organizational experiences”</td>
</tr>
</tbody>
</table>
The studies listed in Table 8 were reviewed in detail to identify general themes that were common among at least two of the studies listed. Firstly, a well-designed checklist should make use of direct and clear language that is understandable by the user [72][80]. Furthermore, potential checklist users or experts should be consulted to assess the usability of the checklist [77][81][82]. Many of the studies listed in Table 8 noted the importance of using data and incidents from the literature to determine some of the most important checks that should be included in the design [76][43][36][77][79][81] and to evaluate the usability of the checklist clinically [76][43][36][78]. A well-designed checklist should be brief and effective [43][82], it should not interfere with patient care [36], the number of checks should be manageable [80], and it should fit into the workflow of its intended user [81]. Identifying the checkpoints for the checklist is also vital [36]; this means clearly locating points in the workflow where the checklist should be used as well as clearly identifying the task to be completed [78] and the overall purpose of the checklist [80].

The studies outlined in Table 8 make reference to the need to ensure that the checklist fits into the workflow of the users and reflects their specific needs. Thus, observation of the clinical setting is an important way of understanding the workflow and users’ needs [77][81]. Furthermore, the checklist itself can be evaluated through the use of interviews, focus groups and reviews of near-miss occurrences [77].

4.2.2 Summary of Checklist Design Recommendations

From the checklist studies above, several important design, implementation and evaluation considerations were noted:

- Group similar checklist items together
- Use direct/clear language
- Test the checklist for its usability and consult staff/users
- Subdivide long checklists into smaller sections
- Review literature for safety incidents and data
- Evaluate the use of the checklist clinically
- Place most critical steps first
- Keep the checklist brief but effective
- Ensure checklist does not interfere with patient care
- Keep number of checks manageable
- Observe workflow and determine appropriate location and checkpoints for implementation
- Clearly define the task to be completed and the purpose of the checklist

4.3 Preliminary Checklist Design

Literature reviews conducted on incidents occurring in radiation therapy and checklist design, were used in conjunction with the workflow diagram to create the preliminary checklist design (see Figure 4). These design considerations are summarized in Table 9.
Table 9: Summary of checklist design considerations based on literature reviews on incidents in radiation therapy and checklist design. Numbered design considerations are listed demonstrating how they were implemented in the preliminary checklist design.

<table>
<thead>
<tr>
<th>Summary of Incidents in Radiation Therapy</th>
<th>Summary of Checklist Design Considerations</th>
<th>Numbered Checklist Design Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher Frequency Errors related to Treatment:</td>
<td>Content:</td>
<td>1) Checkpoint Identification</td>
</tr>
<tr>
<td>- Location [63]</td>
<td>- Review of literature[76][43][79][81]</td>
<td>2) Patient Treatment Preparation</td>
</tr>
<tr>
<td>- Accessory[63]</td>
<td>- Driven by organizational procedures and policies[36]</td>
<td>3) Patient Identification</td>
</tr>
<tr>
<td>- Positioning/Setup[65][68]</td>
<td>- Critical steps included[75][78][81]</td>
<td>4) Proper Patient Setup</td>
</tr>
<tr>
<td>Lower Frequency, Noteworthy Errors:</td>
<td>Organization:</td>
<td>5) Treatment Accessories</td>
</tr>
<tr>
<td>- Site/Location/Laterality [63][68]</td>
<td>- Subdivide checks into groups based on checkpoints [75][78][82]</td>
<td>6) Verify Site/Laterality</td>
</tr>
<tr>
<td>- Incorrect Patient[65][68]</td>
<td>- Group similar items [72]</td>
<td>7) Verify Checklist Completion</td>
</tr>
<tr>
<td>- Accessory</td>
<td>- 5-9 checks per checkpoint</td>
<td>9) Title Reflects Objectives</td>
</tr>
<tr>
<td>- Patient Identification</td>
<td>- 60-90 seconds per checkpoint</td>
<td>10) Minimize Number of Checks</td>
</tr>
<tr>
<td>- Treatment Preparation</td>
<td>Formatting/Usability:</td>
<td>11) Proper Formatting/ Usability</td>
</tr>
<tr>
<td></td>
<td>- Direct/Clear language [72]</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4: Preliminary checklist design according to the considerations listed in Table 9
4.3.1 Checklist Design Considerations

Based on the literature reviews conducted on incidents occurring in radiation therapy (see Table 5) and checklist design in industry and healthcare (see Table 8), design considerations were outlined for the preliminary checklist design (see Table 9). These design considerations were numbered and are shown in Figure 4 indicating how they were applied to the preliminary design of the patient-provider collaborative checklist.

4.3.1.1 Checkpoint Identification

According to the literature, larger checkpoints should be divided into sections and subdivided into checkpoints or small meaningful sections [75][82]. This was done by conducting workflow analysis and considering the goal of the checklist. Since the checklist was designed to ensure patient and radiation therapist communication, collaboration and participation, two checkpoints were identified. The first checkpoint occurs when the patient first enters the room; at this point the patient can complete the “Patient” side of the checklist. Following this, the radiation therapists setup the patient according to their notes and prior to leaving the room, the second checkpoint occurs. Checkpoint 2 requires the therapists to complete the “Radiation Therapist” side of the checklist followed by communicating with the patient and verifying patient consent before exiting the room and commencing the treatment. This division of checkpoints is noted by number “1” in Figure 4.

4.3.1.2 Patient Treatment Preparation

Through observation of the radiation therapy workflow, patient treatment preparation was identified as an area for patients to engage and communicate with their therapists. In the case of prostate cancer patients, they are expected to maintain a full bladder and empty rectum prior to
treatment. The patients were asked questions about preparation either on the walk from the waiting room to the treatment room, while inside the treatment room or in certain cases not at all if therapists had developed a relationship with this patient. This item was identified as something that could facilitate communication between staff and patients if asked prior to each treatment. Thus, the “Patient” side of the checklist contains checks about patient preparation. These checks are indicated by the number “2” in Figure 4.

4.3.1.3 Patient Identification

Fewer than 5% of incidents are categorized as “incorrect patient”[65] or “misidentification of the patient or dose administration to ineligible patient”[68]. However, while errors related to patient misidentification or incorrect patient are rare, they are nevertheless serious errors that are preventable. Since patient identification is already an important aspect of treatment procedures, patient identification checks (number “3” in Figure 4) were added to the checklist. These checks include the patient indicating their birthday and therapists verifying name, date of birth and photo prior to treating the patient. Identification checks were added for both the “Patient” side of the checklist as well as the “Radiation Therapist” side of the checklist.

4.3.1.4 Proper Patient Setup

Boadu et al. have stated that 21% of radiation therapy incidents that were caused by “incorrect treatment setup and incorrect treatment procedures” [65]. A check called “Verified proper patient setup and alignment” was added as indicated by the “4” contained in Figure 4; this check was added to the “Radiation Therapist” side of the checklist.
4.3.1.5  **Treatment Accessories**

Bissonnette et al. noted that from 2006 to 2007, accessory-related errors accounted for 14% and 11% of incidents respectively. Accessory\(^{10}\) incidents are defined as “omission, addition, or incorrect use of any treatment accessory” [63]. A check “All necessary accessories included” (labeled “5”) was added to the “Radiation Therapist” side of the checklist.

4.3.1.6  **Verify Site/Location/Laterality**

The checklist seeks to address issues surrounding treatment to the incorrect site, location\(^{11}\) and laterality\(^{12}\). Thus, a check was added on the “Radiation Therapist” side of the checklist where the therapist is meant to verify the site of the treatment with the patient prior to starting the treatment (labeled “6” on Figure 4). Table 5 outlines how errors related to “Site”, “Laterality” and “Location” are notable incidents that range in frequency but have the potential to reach the patient [63][68].

4.3.1.7  **Verify Checklist Completion**

As the goal of the checklist is to promote safety as well as collaboration between the patient and care providers, a check was added to the bottom such that the therapist could obtain final consent from the patient and verify that both parties were satisfied that the checklist was completed successfully (See “7” in Figure 4).

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\(^{10}\) Accessory: “Includes wedges, bolus, electron cones and inserts, or immobilization devices” [58].

\(^{11}\) Location: “Inappropriate isocentre shifts are applied, skin marks are misidentified, junctions are mismanaged, or an inappropriate anatomy is planned or treated” [58].

\(^{12}\) Laterality: “Subclass of location errors, defined by the transposition of left and right” [58].
4.3.1.8 **Follow Current Procedures and Policies**

Under their consideration for formatting medical checklists, Hales et al. stated that the content of the checklist should reflect the policies and procedures of the specific hospital or institution [36]. The checklist was designed with the current practices and policies of Princess Margaret Cancer Centre in mind; the check “Double verification date checked” (See “8” in Figure 4) is an important step that must be carried about by radiation therapists to ensure that two full verifications have been done for the current treatment and that the dates of the verification match with the approval dates for the treatment fields [10]. This step was identified during the radiation therapy workflow observations as an area that should be included. In the treatment room, one therapist would communicate and verify this date with the other therapist (Refer to Section 5.1 Workflow Observations).

4.3.1.9 **Title Reflects Objectives**

In “A Checklist for Checklists” contained within the “Checklist Manifesto” by Gawande, he states that the title of the checklist should reflect its objectives [43]. Number “9” in Figure 4 outlines two titles for the checklist. The first title “Radiation Therapy: Team Checklist” was chosen as it was concise and clear with the purpose of describing that the checklist is to be used during radiation therapy and that it will serve as a team exercise between patients and radiation therapists. In addition to the title, a purpose for the checklist is listed; this title states that the purpose of the checklist is to be “Used on a Daily Basis Prior to Treatment”. This purpose is clear, concise and outlines that the checklist is to be completed each day prior to delivering radiation.
4.3.1.10 **Minimize Number of Checks**

Gawande outlines the design of the checks themselves as important in the design of medical checklists. He states that the checks and checklist should strike a balance between brevity and effectiveness. To this end, the checkpoints should take 60 to 90 seconds to complete. Furthermore, there should not be more than five to nine checks or items per checkpoint [43]. Taking these design considerations into account, the checklist was created to contain only two main pause points. The first pause point where patients complete the checklist contains four checks or items. Similarly, the second checkpoint where radiation therapists complete the checklist was limited to seven checks. These numbers were kept as low as possible to make the checklist brief without omitting any important items.

4.3.1.11 **Proper Formatting/Usability**

Formatting and checklist organization were considered to be vital when designing the checklist. The fonts used were bold, clear, equally spaced, sans serif, made use of upper and lower case text, and appropriately sized to allow patients and staff to be able to read the directions easily [36][43]. Furthermore, dark texts were used on a light background and simple sentence structure and basic language were used to make the checklist accessible and applicable to most patients. An effort was made to ensure that the checklist was as uncluttered as possible and that separate boxes were used to indicate when checkpoints occur and which individuals are responsible for the checks occurring at that time [43]. This is evident with the two text boxes for checkpoint 1 where patients complete the checklist and checkpoint 2 where radiation therapists complete the checklist. These two boxes serve to distinguish the two checkpoints in an intuitive manner.
Chapter 5
Results

5 Results

5.1 Workflow Observations

The goal of the clinical observations was to develop a workflow diagram and use the diagram to identify possible areas where a checklist could be implemented in the clinical setting as well as identifying some critical checks that could be included in the preliminary checklist design. The first draft of the workflow diagram was completed after the first week using notes taken during the observations.

During the following two weeks of observations, further notes were taken and edits were made dynamically to the radiation therapy workflow diagram. Furthermore, final changes to the radiation therapy workflow diagram were made using current Princess Margaret procedures and policies that guide the conduct of radiation therapists as summarized in Table 1 and Table 2. The workflow diagram that was created is shown in Figure 5.
<table>
<thead>
<tr>
<th><strong>Radiation Therapist 1</strong></th>
<th><strong>Radiation Therapist 2</strong></th>
<th><strong>Patient</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Opens patient chart</td>
<td></td>
<td>Patient prepares, enters, signs in</td>
</tr>
<tr>
<td>Goes to get patient from waiting room</td>
<td>Sets up room</td>
<td>In waiting room</td>
</tr>
<tr>
<td>Ask patient about bladder/bowel prep</td>
<td>Enters treatment room</td>
<td>Verifies prep</td>
</tr>
<tr>
<td>Enters treatment room</td>
<td>Enters treatment room</td>
<td>Enters treatment room</td>
</tr>
<tr>
<td></td>
<td></td>
<td>States birthday</td>
</tr>
<tr>
<td>Ask patient DOB</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Flowchart:
- Patient enters the waiting room.
- Radiation Therapist 1 opens the patient chart.
- Patient provides personal details.
- Radiation Therapist 1 reviews the patient's chart.
- Radiation Therapist 2 sets up the treatment room.
- Patient states their birthday.
- Patient education on the day of treatment.
- Patient is positioned on the bed.
- Patient's location is confirmed.
- Patient's information is verified.
- Patient leaves the room.
- Patient is imaged.
A number of observations were made from the workflow observations. Prior to retrieving the patient, one therapist opens the patient chart and looks at the picture of the patient. While one radiation therapist prepares the room, the other therapist calls the patient from the waiting room. During this walk from the waiting room, the therapist may ask the patient about their general side effects, concerns or their perceived preparedness for the treatment that day. They may also discuss these issues once they enter the treatment room. There is variability as to when this discussion between patients and therapists occurs. Once inside the treatment room, the patient is asked to state his/her birthday. There is no specific moment when this question is asked and it can be asked to the patient anytime before the patient is being aligned on the bed. On Day 1 of treatment, patients are given additional information about the treatment prior to starting treatment for that day. On subsequent days, patients are asked generally about any questions or concerns that may have about their treatment, as stated above.
Therapists place the patient on the bed and align them according to their tattoos and setup notes. Following this, therapists confirm the double verification date of the plan to ensure it is up-to-date and leave the treatment room. Patients are then imaged to ensure that they are aligned properly and, in the case of prostate cancer patients that their bladders are full enough. In the case of improper alignment or inadequate preparation, the patient is re-positioned or asked to drink more water until the bladder is full. In the first two days of treatment, therapists verify each beam against the treatment plan before delivering it to the patient. While beams are being delivered, therapists observe the patient on the treatment monitors to verify that everything is fine with the patient. Once the treatment is completed, the radiation therapist enters the room while the other therapist goes to get the next patient from the waiting room. Often there is not a lot of time for the patient and therapist to talk following the treatment.

A few important observations were made with respect to the interactions between patients and therapists. In most of the treatment checks, patients act as passive members of the process and are not engaged by radiation therapists. In certain cases, if the therapists forgot to ask or were late in asking the patient’s birthday, the patient would let the therapist know. This shows a natural inclination on the part of the patient to engage in their treatment. Natural times when patients and therapists interact are: upon entering the treatment room, while being set-up on the treatment bed, just prior to leaving the treatment room and following the treatment. In one instance, just prior to starting the treatment, the therapists paused treatment as the patient was waving to the treatment camera. This patient had forgotten to insert his dental tray. This event highlighted the importance of engaging with patients to ensure that all treatment accessories were included prior to commencing treatment. In other instances, patients had to have their treatment delayed and be re-imaged if they did not have a full bladder at the time of treatment.
These instances indicated the importance of communicating with patients to make sure that they have prepared adequately for treatment to avoid unnecessary re-imaging and unnecessary delays in the delivery of treatment.

In general, radiation therapists take the safety aspects of the treatment very seriously and perform their tasks with precision and consistency. However, patients are often passive members of the treatment process and may be engaged more actively to avoid some of the issues above that were observed.

5.2 Radiation Therapist Focus Groups

Focus groups were conducted with focus groups according to the methodology described in Section 3.3.1. The sessions were carried out during the lunch period of radiation therapists and an experienced moderator was employed to direct the conversations. While the target number of participants was six to eight per focus group according to the literature[53][54][55], the first focus group was composed of seven radiation therapists and the second focus group consisted of nine. This occurred as both focus groups were scheduled to have eight participants, but one individual missed their focus group but was added to the second session as per their request. The focus groups were transcribed and analysis was performed as described in Section 3.3.3.

5.2.1 Thematic Analysis

Three major themes were identified through data analysis of the transcripts acquired from the two focus groups. Each theme had associated sub-themes. The major themes were: (1) differences exists between perceptions of safety among staff and patients, (2) potential for patients to engage actively during treatment process is dependent on multiple factors and (3)
there currently exists therapist independent factors which affect the quality and perceptions of care.

Table 11, Table 12, and Table 13 (see Appendix D) outline all of the existing themes, sub-themes as well as supporting quotes from the transcripts.

Theme 1: differences exist in perceptions of safety among staff and patients

Radiation therapists participating in the focus groups indicated that some patients tend to ask questions that show a general concern or anxiety about the safety of the treatment as well as the amount of radiation their body was being exposed to. Therapists indicated that this concern or anxiety stemmed from a lack of knowledge on the part of the patient about the areas that would be exposed to radiation and sometimes why they were being treated. Very occasionally, this anxiety has caused patients to discontinue their care. Contrarily, therapists trust that the current practices and technologies such as image-guidance and patient identification protocols ensure patient safety. However, time constraints and time pressure can increase the likelihood of mistakes. Furthermore, therapists believe that patients feel safe in the clinical setting due to the relationships and trust they build with their care providers. Therapists develop personalized relationships with the patients they see on a regular basis and alter their approach to patient care according to these relationships. Some therapists believed that when patients develop a rapport with their therapists and trust them, they ask fewer questions about the treatment procedures and are less alarmed by small changes in these procedures. These therapists understood fewer questions from patients to mean that these individuals trusted therapists and were satisfied with the treatment process.
Theme 2: there are multiple factors affecting patient engagement potential

Therapists noted that there exist multiple patient-related factors that may increase or decrease their ability to engage actively in the treatment process. Therapists indicated that patients become very aware of their routines and may demonstrate a natural inclination to engage during treatment. Some patients are apt to indicate when they feel that a certain step was missed or done in a different order than on previous days and have intervened in the past when treatment accessories were missed. Furthermore, patients will communicate to the therapists when they feel that the treatment lasted longer than previous treatments. Many therapists also felt that the ability or inclination for patients to engage in treatment was personality dependent. These therapists believed that some patients are naturally distrustful of the treatment process and tend to ask a lot of questions while other patients tend to be ‘more laid back’. Another important issue related to patient engagement that certain therapists indicated pertained to the wide variance in patient knowledge and understanding of radiation therapy. Some participants stated that many of the patients they see are not technologically savvy and could be rendered anxious by having to take on further responsibilities related to their treatment. This knowledge level is also applicable to the treatment itself and their understanding of what the treatment machine is doing. Finally, therapists indicated that some existing barriers to communication could hinder the ability for patients to engage as active member of treatment. Some patients may display a reluctance to vocalize their anxiety for fear of being considered a nuisance or causing problems with the therapists. Furthermore, there also currently exist demographic barriers to patients being able to engage actively and communicate effectively. Therapists made specific references to the difficulty of communicating with patients who did not have a strong foundation in the English
language in addition to patients having difficulties engaging as active members due to cognitive issues stemming from age in the case of certain patients.

**Theme 3: patient safety, anxiety and perceptions of safety can be affected by therapist independent factors**

The subject of time was one that was brought up consistently by therapists as one of the most pressing issues facing them in their current work environment. Therapists indicated that the proper checks and balances are in place to keep patients safe. However, when the time allotted for treatment becomes limited, the likelihood of human error may increase. Time can become strained for a number of reasons. Stresses related to time affect the quality of patient care, the safety of the treatment and even limit the amount of additional training that therapists can take advantage of. One therapists noted that time has become more of an issue over his/her career as a therapist. Another concern that was communication centered on issues surrounding the status of the treatment machines. The therapists that communicated this issue stated that when machines are out of service, they do not have enough information about the issue to communicate it to patients in the best manner to facilitate patient understanding and mitigate concerns. Furthermore, one participant indicated that while therapists have the ability to assuage fears about radiation and answer treatment-specific questions, explaining the machine itself is outside of their knowledge base and understanding and it cannot always be communicated effectively to patients.

5.2.2 **Checklist Recommendations**

In addition to questions pertaining to patient safety, engagement and anxiety, questions pertaining to the design and usability of the checklist were posed to radiation therapists during the focus groups. While the responses to these questions were not extensive enough to denote
them as themes, there were suggestions pertaining to the design of the checklist and some considerations about its usability. These suggestions are outlined in Table 14 in Appendix D.

Some of the radiation therapists that participated in the focus groups indicated that they believed including technical aspects from the radiation therapists’ workflow in the checklist would be overwhelming for many patients. Furthermore, some therapists felt that their current workflows already contain checklists that they need to follow and, as such a patient-provider collaborative checklist would not be of use to them in their daily activities. Therapists also did not believe that patients would benefit from seeing the radiation therapist checks and that this might in fact cause anxiety in patients who do not understand exactly what these checks mean. Conversely, participants did state that the checklist could include patient-related checks that would engage patients. These checks could be things that the patients could touch, see and engage with such as manual additions to the treatment process (e.g. accessories). Radiation therapists emphasized that in their opinion, the checklist should be simple to use for patients and should be limited to issues that patients could engage with directly and verify. This would allow patients to see the checks that they understand being checked off and put them at ease. Some of the checklist suggestions made by therapists included accessories, information about treatment preparation, and asking about other treatments and medications the patients could be taking. One therapist believed that it was a good idea to allow the patient to comment and consent as they could bring up important information to the therapist regarding side effects or other issues that may need to be addressed.

5.3 Interviews with Patients

As per the methodology outlined in Section 3.3.2, GU cancer patients were recruited with the assistance of radiation therapists working on the treatment units. These therapists assisted in identifying patients that could communicate effectively in an interview setting. Interviews were
conducted until saturation or until no new ideas were being brought forth by patients. This resulted in 12 individuals being interviewed.

5.3.1 **Thematic Analysis**

Through the analysis of the 12 interviews conducted with GU patients who were more than halfway through their treatments, three main themes were identified. The main themes expressed by patients were: 1) patient anxiety is not related to perceptions of the safety of the treatment process, 2) the desire to actively engage in treatment process is personality dependent and 3) through experience, patients envision both benefits and drawbacks to the use of a checklist during radiation therapy. The above stated themes, associated sub-themes and representative quotes are listed in Table 15, Table 16, and Table 17 of Appendix D.

**Theme 1: patient anxiety is not related to perceptions of the safety of the treatment process**

Many of the interviewed patients indicated that their anxiety with respect to radiation therapy was not associated with their worries over safe delivery of the treatment. Some patients stated that they derived comfort from the consistency of the treatment. These patients indicated that the treatment was consistent on each day; they saw the same therapists on a regular basis and noted consistency even when unfamiliar therapists were delivering treatment on a given day. Furthermore, some patients felt that developing a rapport and relationships with the therapists they saw on a regular basis helped to make the treatment a more enjoyable process and helped them to feel empowered. Multiple patients stated that their initial or continued anxiety during treatment resulted from a fear of the radiation itself. These patients voiced concerns over developing further cancers from the radiation and the side effects that may occur as a result of the radiation they were receiving. Some of these fears stemmed from misunderstanding of the
effects that the radiation could have on their bodies, information from outside sources as well as fears about the treatment machines breaking down or malfunctioning. The desire for more information was evident as many patients took the initiative to self-educate. Patients independently sought information from the internet, clinicians and other sources to prepare for the treatment. These patients stressed the importance of self-education and increasing their knowledge level for helping to understand the treatment process better.

**Theme 2: patient engagement is personality dependent**

Opinions on the value to engage actively and the desire to do so varied among the patients interviewed. A sub-group of patients believed that the patient had an important role to play in the treatment process and could carry some responsibility. Patients indicated that as the subject of the intervention, they were responsible for being active as much as possible. One way in which engagement was identified was in the mental and physical preparation prior to the treatment each day. Some patients indicated that being engaged as active members of the process could be empowering. These patients alluded to the fact that being engaged using a tool such as a checklist would allow them to know what the therapists were doing to ensure safety and would help other patients to know why preparation is important and how to mitigate some of the associated side effects of radiation. Other patients believed that the patient’s role was to be a more passive member of the treatment process. These patients believed that a lack of technical understanding of the treatment process on the part of the patient limited just how much a patient could actually contribute to the process. Some patients felt that younger patients would tend to want more information about the treatment processes and technology whereas older patients may struggle with having to read and interact with a tool such as a checklist. Furthermore, some
patients felt that those who did not a fluid understanding of the English language would be at a disadvantage with respect to being able to communicate and engage with staff.

**Theme 3: obvious benefits and drawbacks from the use of a patient engagement checklist**

Patients were introduced to the concept of a patient-provider collaborative checklist during the interviews and were able to identify benefits and drawbacks to its potential use in the clinical setting. Patients indicated that the checklist could act as reassurance that both the therapists had done what they were supposed to do and that the patient had completed his/her role successfully. Some patients also stated that the checklist could be useful to those that desired more information about the treatment process. These patients showed a desire to know what the therapists were doing, what the treatment machines were doing and what problems could exist so they could deal with them. Furthermore, the checklist could act as a way of facilitating communication between the radiation therapists and the patients. Patients stated that they would be more comfortable bringing forth questions and concerns related to bladder and bowel preparation if prompted to do so. Patients also indicated that over the course of their treatments, they could forget to do some of the preparation and the checklist could act as a reminder of how to be fully prepared for the treatment. Patients were also able to identify some barriers to successful implementation of a patient-provider collaborative checklist in the clinical setting. One of the main issues that patients identified was the use of a paper form of the checklist. These individuals believed that some patients would not want to fill out the checklist and radiation therapists could view it as additional work.

Some patients stated that the checklist would result in more paperwork and would require someone to organize it and make use of it for the endeavor to be worthwhile. Another important
aspect is the amount of time the checklist would take to complete. Patients noted that adding any time to current treatments could postpone the treatments that follow and this was especially important to patients that required a full bladder for the safe administering of their treatment.

5.3.2 **Checklist Re-design**

Following focus groups with radiation therapists and interviews with patients, modifications were made to the checklist. These modifications were made based on the clinical experience shared by radiation therapists as well as the perspectives of patients. Furthermore, the checklist maintained the important elements learned from the literature reviews done on incidents that occur in radiation therapy and the current standards of checklist design as well as the workflow observations and analysis that were performed. The numbers marked on Figure 6 correspond to design changes that were made to the checklist in response to the findings from focus groups and interviews.
Figure 6: Checklist re-design based on feedback from focus groups with radiation therapists and interviews with patients.
5.3.2.1 **Checkpoints and Instructions**

The first version of the checklist (Figure 4) was based on identifying two main checkpoints: when the patient enters the room and before the radiation therapist leaves the room to treat the patient. This version of the checklist did not properly leverage the natural checkpoints that occur in the process as identified in the workflow analysis as the times when therapists and patients interacted with one another. The times when patients interact with the therapist include upon being called from the waiting room, upon entering the treatment room, just prior to leaving the treatment room and immediately following completion of the daily treatment.

This version of the checklist stipulates that the checklist be completed during these main checkpoints. The first part of the checklist, denoted by “1)” in Figure 6, should be completed by the therapists prior to and as they call the patient. The second part of the checklist, denoted by “2)”, should be completed just after entering the treatment room with the patient. The third part of the checklist, denoted by “3)”, should be checked off just prior to leaving the treatment room. The fourth and final section of the checklist, denoted by “4)”, should be checked off immediately following the completion of the treatment for that day.

5.3.2.2 **Radiation Therapist Checks**

In the previous version of the checklist, some checks related to specific radiation therapist checks were included. In focus groups with radiation therapists, they indicated that their current system of checks was more extensive than the checklist itself and thus this aspect of the checklist may not be useful to therapists. Furthermore, therapists indicated that they believed that if the goal of the checklist was to engage patients, the checks contained in the checklist should be things that patients could understand and verify themselves. Patients also indicated that while it could help
to verify the checks the therapists are doing, they believe that many of the patients would have difficulty understanding what these checks meant.

Thus, the checklist was modified to limit radiation therapist checks to simple tasks that both addressed safety concerns outlined in the literature as well as limiting the number of checks that may confuse patients. The radiation therapist checks (denoted by the red “1” on Figure 6) were limited to verifying patient name, patient photo and the site of treatment; these checks were included to address issues relating to identifying the correct patient as well as the correct site for treatment.

5.3.2.3 Patient Checks

Patient checks remained relatively consistent with the previous design of the checklist. As denoted by “2” in Figure 6, patients will be tasked with verifying that their birthday was checked, that their treatment preparation is complete and that all of their questions and concerns are addressed. In patient interviews, many patients outlined the importance that these checks had on their treatment and understood the significance of ensuring they were done properly. Furthermore, as described in the workflow observations in Section 5.1, if GU patients do not prepare adequately for the treatment, the scan prior to treatment will indicate this and this might cause a delay in the treatment while the individual drinks water. This means that the patient must endure additional scans needlessly. Finally, treatment preparation is important in mitigating symptoms the patients may receive as a result of the radiation.

Some patients indicated that the checklist could serve to facilitate patient-provider communication; this advantage was leveraged to allow patients the opportunity to address all questions and concerns with their therapists in a formalized manner. The goal of this check is to
create a window through which patients will feel comfortable describing any questions or concerns that they may have.

5.3.2.4 **Situational awareness and concerns**

In the focus groups and interviews, both therapists and patients indicated that over the course of the treatments, patients tend to develop a high situational awareness and notice discrepancies or differences from one treatment day to the next. Some therapists indicated that patients have actually intervened in certain cases to bring one of these discrepancies to light to remind therapists of things they may have forgotten. Thus, two checks were added to the checklist as denoted by “3” in Figure 6. The first check occurs just before radiation therapists leave the treatment room; patients are asked if the setup or anything related to their treatment feels different from previous days. This allows patients to express any concerns or issues to the therapist before they exit the treatment room. The second check occurs just after treatment when the radiation therapist re-enters the treatment room; at this point, the patient is asked if anything in the treatment felt different as opposed to other treatment days. This facilitates a discussion with the patient and allows them to have their questions or concerns addressed or followed-up on.

5.4 **State-Trait Anxiety Inventory Survey**

The methodology for the STAI state-anxiety survey was carried out as per the description in Section 3.5. Although the intended number of patients was 20 as outlined in Section 3.5.2, the total number of patients who were recruited to take part in the STAI survey was 18. These patients completed the survey within the first few days of starting treatment as well as once per week (Wednesday) in an attempt to standardize the day in which the survey was administered.
5.4.1 **Patient Demographics**

While being consented for the survey, prostate patients were presented with a demographics form to provide some background information. This information is summarized in Figure 7. All patients exceeded the age of 50 and a large proportion of the patient sample was over the age of 70 years old.
Figure 7: Demographics summary of prostate patients who participated in STAI survey (n=18)
5.4.2 Missing Values

Although the vast majority of surveys were filled out completely by patients, in certain instances, questions were missed. Figure 8 illustrates a breakdown of the number of participants who missed each question on the survey.

![Figure 8: The 20 STAI questions broken down by the number of participants who missed each one.](image)

In certain cases, individuals showed a reluctance to answer certain questions on a regular basis whereas in many cases, questions were only missed once or not at all by most individuals. To accommodate for missing values, the scoring guide advises survey administrators to prorate the scores based on answered questions to calculate an approximation of a completed survey. In the case that two questions or less were missing on the survey, the score was prorated over the full 20 questions to correct for these omissions. In the case that three or more questions were missing, the score was omitted since the validity of the prorated score could be called into question [60]. A list of adjusted patient scores is shown in Table 10.
Table 10: STAI scores adjusted for missing values.

<table>
<thead>
<tr>
<th>Participant Number</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>Week 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAI 1</td>
<td>29</td>
<td>52*</td>
<td>23*</td>
<td>26</td>
<td>32</td>
<td>24</td>
<td>20</td>
<td>20</td>
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<td>STAI 2</td>
<td>45</td>
<td>31</td>
<td>50</td>
<td>54</td>
<td>52</td>
<td>45</td>
<td>49*</td>
<td>-</td>
</tr>
<tr>
<td>STAI 3</td>
<td>41</td>
<td>40*</td>
<td>38*</td>
<td>46*</td>
<td>45*</td>
<td>47*</td>
<td>44</td>
<td>44*</td>
</tr>
<tr>
<td>STAI 4**</td>
<td>29</td>
<td>33</td>
<td>45</td>
<td>47*</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>STAI 5</td>
<td>37</td>
<td>47</td>
<td>51</td>
<td>38</td>
<td>41</td>
<td>42*</td>
<td>41</td>
<td>40</td>
</tr>
<tr>
<td>STAI 6</td>
<td>51</td>
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<td>STAI 7</td>
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<td>STAI 8**</td>
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<td>STAI 9</td>
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<td>STAI 18</td>
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* Score adjusted for one or two missing questions
x Score omitted if 3 or more questions missing
**Patient discontinued the survey.

5.4.3 State-Trait Anxiety Inventory Mean Values

The scores of all individuals were averaged by week in order to determine if there was any trend in the anxiety levels of all participants over time. These mean values over 8 weeks of treatment are summarized in Figure 9. Some scores were missing if individuals did not continue the survey past a certain week or if treatment was shorter than 8 weeks based on the type of prostate treatment the patient was receiving (see Section 1.1.4).
Figure 9: Adjusted mean scores for anxiety for STAI participants over 8 weeks of treatment (*Bars represent standard error calculated for each week).

Figure 9 appears to display that the mean anxiety levels of patients tend to change over time. However, using methods of null hypothesis testing, this cannot be stated with statistical significance. Since the goal is to examine whether anxiety changes over time, the means for Week 1 of treatment and Week 8 were compared. The p-value for a two-tailed t-test was approximately 0.23; therefore, it cannot be concluded with statistical significance that the means from Week 1 and Week 8 of treatment are different.

As previously stated, the mean score for working males was 35.72 with a standard deviation of 10.40. This average drops to 34.51 with a standard deviation of 10.34 for men over the age of 50. Thus, the means calculated for participants in this study are roughly the same and slightly lower than these standard norms for the STAI survey. The STAI survey has also defined norms for
general medical and surgical patients; these individuals have mean anxiety scores of 42.68 with standard deviations 13.76. The patients observed in this study showed scores that were lower than the mean for general medical and surgical patients.

5.4.4 **State-Trait Anxiety Inventory Box Plots**

The data was further displayed graphically using box plots to extract any trends in the responses of participants over the course of 8 weeks of treatment. These plots, shown in Figure 10, display the total range of STAI scores, as well as the median and the 25th and 75th percentile of total scores as described by the legend. The median is the 50th percentile, the line that divides the two quartiles shown in Figure 10.
Figure 10: Box plot representation of STAI scores of prostate patients over 8 weeks of treatment (Bars represent total range of STAI scores for that week).

Analysis of the plots shows that the range of scores was constant between 20 and 54 throughout the course of treatment with the exception of a large change in week 8. However, many participants did not have 8 weeks of treatment since there was a mix of curative and post-operative prostate treatments. Thus, this apparent drop in anxiety scores at week 8 may not be reflective of any obvious change in anxiety levels since the sample size is lower at week 8. The median score dropped noticeably in the first 3 weeks of treatment before stabilizing and remaining constant for the next few weeks. This indicates an increase in the number of lower
STAI scores. This result appears to signify that anxiety scores tend to drop in the first few weeks of treatment and remain consistent until the end of treatment.

5.5 **Follow-up Focus Groups**

Follow-up focus groups were conducted with focus groups according to the methodology described in Section 3.6. Once again, the focus groups occurred during the lunch period of radiation therapists and employed the same moderator to direct the discussions. Each focus group consisted of six radiation therapists which matched the intended target of 6-8 participants per focus group. The focus groups were transcribed and analysis was performed as described in Section 3.3.3.

5.5.1 **Thematic Analysis**

Four major themes were identified through data analysis of the transcripts acquired from the second set of focus groups with radiation therapists; each theme had associated sub-themes. The major themes were: (1) designing patient engagement tools could be rendered difficult due to differences in users’ personalities, (2) patients have heightened awareness during treatment that could help or hinder engagement, (3) radiation therapists are concerned about compromising trust with patients and (4) patient engagement using a checklist will have unknown effects on multiple clinical factors. Table 18, Table 19, Table 20, and Table 21 in Appendix D outline all of the existing themes, sub-themes as well as supporting quotes from the transcripts.

*Theme 1: designing patient engagement tools could be rendered difficult due to differences in users’ personalities*

Radiation therapists participating in the focus groups indicated that they believe some of the patients they treat show a natural aptitude and desire to engage in their treatment. Conversely,
other patients feel that the radiation therapists are solely responsible for the treatment process and therefore these patients will not engage. Some participants believed that the latter group would question why the therapists were engaging them in the process. Furthermore, some participants listed a number of barriers that can prevent a patient from or limit the extent to which they can engage. These barriers included their knowledge of the technical aspects of the treatment process, their ability to communicate in English, the patient’s ability to read due to age or the effects of their ailment. Radiation therapists noted that from their experiences as clinicians, patients have varying levels of anxiety. Some patients feel nervous and overwhelmed about the treatment process. These individuals may become more comfortable and less anxious over the course of their treatment whereas other individuals may not. Patients may also naturally seek more knowledge and information about their treatment by engaging with the therapists or independently through sources such as the internet. However, some patients want to be treated and leave, and do not want to be given any additional information about their treatment.

**Theme 2: patients have heightened awareness during treatment that may help or hinder engagement in safety aspects of treatment**

Radiation therapists discussed how patients have intervened in the past to indicate when errors or discrepancies have occurred in their treatment. The errors that patients have noticed include when bolus was forgotten, the radiation therapist forgot to ask the patient’s birthday, the patient was setup incorrectly on the chest board or the blocks were not put in. In one instance, a pediatric patient’s mother noticed that the child’s bed was set up for another patient. In all cases, these patients were aware of important physical aspects of treatment that they interact with from prior experience. Participants also gave examples of instances where patients stated to their therapists that they perceived that their treatment was different on a particular day. In these cases, the
claims made by patients were not proven to be true or significant. Thus, outlining the fact that perceived differences may not reflect the actual situation. The responses from radiation therapists also indicated that patients are focused on the consistency and continuity of their treatment. Some patients do not feel comfortable if they are moved to a different treatment machine or being treated by different staff. These patients may not understand that their treatment information is being transferred with them. In certain cases, the anxiety that patients feel as a result of the above mentioned circumstances may not be communicated by the patients. Radiation therapists described how some patients may mask their concerns or anxiety by asking the question in a joking manner and not explicitly stating their concerns. Radiation therapists felt that in some cases, patients were too nervous to actually express their concerns to therapists and that therapists assume that these patients are okay with their treatment.

**Theme 3: radiation therapists are concerned about affecting trust with patients**

Throughout the focus groups with radiation therapists, they made reference to the importance that they place on developing a rapport and trust with patients. These therapists felt that since many patients feel nervous or anxious, it is important to build this rapport and allow the patients to develop trust in therapists. Some therapists voiced concerns about any interventions that might affect the trust of patients in therapists. Radiation therapists indicated that they believe that they are solely responsible for maintaining the safety of treatment and they would not want to inadvertently place this onus or responsibility on patients. Participants discussed that while engaging patients is important, this should be done as a backup to the procedures that they currently carry out in the case that something is forgotten. Two therapists noted that when a patient notices a discrepancy or error in the treatment, however minor it may be, it causes the therapists to feel embarrassment or momentarily panic. Some participants also demonstrated a
reluctance to interventions that might have patients score their care as it would make therapists feel nervous or feel that they were being graded by patients.

**Theme 4: patient engagement using a checklist will have unknown effects on multiple clinical factors**

With respect to the patient-provider collaborative checklist, therapist responses show an uncertainty about the effects that such an intervention could have on multiple clinical factors. Therapists feel that with the high volume of patients and treatment in a day, adding an intervention such as a checklist might disrupt their workflow and add time to treatments, it may be difficult to accommodate for any required flexibility in the scheduling of patients. Therapists believe that a tool such as a patient-provider checklist could assist in emphasizing the importance of certain safety checks and treatment preparation. Some patients do not understand the importance of adequately preparing for their treatment and including this preparation on the checklist could emphasize its importance and, by extension, increase conformity to these aspects of the treatment. In addition, a patient-provider collaborative checklist may facilitate the communication process between radiation therapists and patients. Some therapists felt that patients may be more apt to ask questions at the time of treatment instead of waiting for their appointments with their doctor. This communication could improve the quality of treatment as patients may bring up concerns related to issues that are not directly related to safety but may be causing them discomfort or preoccupying their thoughts. Participants also suggested that the use of an intervention such as a checklist may have different effects on patient anxiety. These participants believe that while a checklist may not make individuals feel safer, it may make them feel more at ease. Conversely, asking patients questions about safety or the consistency of their treatment could cause them to consider adverse possibilities that they were not concerned about...
previously. These patients could be stressed following treatment if they do not remember whether or not a certain check was done or whether everything went according to the checklist. Furthermore, patients with high anxiety levels could have those feelings compounded by being prompted to express their concerns on a daily basis to their therapists.
Chapter 6
Discussion and Implementation Strategy

6 Discussion

This goal of this study was to assess the current state of patients’ and radiation therapists’ perceptions of safety during treatment as well as patient anxiety and how it changes through treatment. Furthermore, this study aimed to gain insight into the culture of patient engagement and its potential to serve as a source of error prevention in radiation therapy. The goal was to design a checklist that would allow patients to engage in the clinical setting and conform to radiation therapists’ views of what would work in their current workflow. The final goal was to design an implementation strategy for the checklist based on the findings of the study.

6.1 Patient Engagement and Perceptions of Safety in Radiation Therapy

6.1.1 Perceptions of Safety and Anxiety

One of the research questions of this study was: What are the current perceptions of patients and radiation therapists about the safety of radiation therapy and using patient engagement to improve it? This question was posed to answer how the perceptions of the safety of radiation therapy compared between patients and radiation therapists. This question was answered through focus groups with radiation therapists and individual interviews with patients undergoing radiation therapy treatment. This question has been posed previously in the domain of chemotherapy [24][25] but the attitudes of patients and radiation therapists have not been formally assessed in the same manner.
Radiation therapists that participated in focus groups expressed the idea that many patients tend to show anxiety and concerns related to the safety of the treatment and the amount of radiation that their body is exposed to. They believed that this anxiety stemmed from a misunderstanding or lack of knowledge on the part of the patient. However, radiation therapists themselves believe that the current methods of treatment are safe due to the technologies that are used to monitor this safety and the protocols that are in place to ensure that patients are safe. These protocols include proper patient identification, and confirming correct treatment location. They also expressed the idea that by developing relationships and trust with patients, many of these concerns can be addressed and calmed.

Many of the patients that were interviewed indicated that their anxiety did indeed stem from a fear of the effects of the radiation on their bodies but not necessarily from fears about safe delivery of the treatment. Some of this anxiety was caused by a lack of knowledge or misinformation about the treatment itself, as also stated by radiation therapists. Patients’ attitudes also agreed with radiation therapists’ in that they drew a lot of their comfort and feelings of safety from the consistency of the treatment process. Some of these consistencies include the continuity of therapists and the manner in which the treatment is conducted on a daily basis. When aspects of the treatment appear to be inconsistent, patients begin to develop anxiety. Both patients and radiation therapists cited examples of patient anxiety stemming from being treated on recently repaired treatment machines.

Radiation therapists and patients agreed on many points relating to the fact that perceptions of safety and associated anxiety varied from person to person. Both groups stated the important role that developing patient-provider trust and communication plays in allowing patients to feel comfortable and at ease during their treatment.
6.1.2 **Patient Engagement and Safety**

Radiation therapists shared stories of incidents involving patients where a patient intervened to indicate differences that they perceived in their treatment or some step that was missed related to treatment accessories or setup. One radiation therapist in particular lamented about the fact that this was often done after the fact and thus did not prevent the error that was noticed. This was a similar finding to nurses who felt frustration if an error resulted during treatment that could have been avoided if a patient had communicated it earlier [25]. It is important to note that in the short time spent observing clinical workflows, an incident was observed where a patient forgot to insert their dental tray prior to treatment and was able to get the therapists attention just prior to starting treatment by waving to the in-room camera. This incident was not serious in nature but outlines the reality of errors in radiation therapy and how patient engagement and participation can be used to prevent them.

Radiation therapists indicated that patient engagement could be personality dependent. Some patients are constantly nervous or anxious and unwilling to participate actively in their treatment, whereas others are very eager and keen to ask questions of therapists and engage on a regular basis. Many patients indicated that they tried and were willing to be active in any capacity they could. This engagement includes taking an active role in the treatment process, treatment preparation, and/or mentally preparing for treatment on a daily basis. Similar to chemotherapy patients [24], these radiation therapy patients felt that their roles could include engaging more actively in their treatment and some felt that their roles should include participating more actively in safety aspects of their treatment. This attitude stemmed from the fact that these patients are the target of the intervention and thus they felt it their responsibility to take as active a role as possible in their care. Some patients that were interviewed also expressed the view that
they would feel empowered by the engagement process. These patients wanted to know that all safety steps were being followed and that all necessary information was being communicated to them. One patient acknowledged that therapists were human and thus were expected to err from time to time and believed that engagement from both parties could compensate for lapses or errors by one of the parties. This statement reflects the themes of de Vries et al. and Wilson et al. that humans should be expected to err and thus systems should be designed in such a way as to catch, prevent and minimize the harm deriving from these errors [19][20].

Conversely, some patients indicated that by definition of the clinical roles, they as patients are forced to some degree to take a passive role in their treatment. These patients cited lack of technical knowledge and expertise as the main barriers to engaging in the safety aspects of treatment.

6.2 Patient Engagement using a Checklist

The second research question posed in this study was: Is there a role for a patient-centric checklist in changing these perceptions and if so, what types of information and checks should this checklist include? Thus, it was important to assess what radiation therapist and patient attitudes were towards the checklist and how it might help or hinder patient engagement or safety in the clinical setting. In order for checklist development and implementation to be successful, it is important to understand the attitudes and needs of these users and how the tool should be designed to accommodate for these attitudes and needs.

6.2.1 Potential Benefits of Patient-Provider Collaborative Checklist

The results of this study denote opportunities in the clinical setting where a patient-provider collaborative checklist could benefit patient safety and patient engagement. In the literature, it
was stated that checklists have proven to be effective in preventing errors and improving performance in high-stress and fast-paced environments [36]. In the focus groups and interviews, radiation therapists and patients often stated how time was one of the most pressing issues that they faced. These individuals highlighted that any delays in time or treatment would have an impact on their ability to conduct treatment in a timely manner. However, focus groups and interviews highlighted the fact the checklist could assist in facilitating communication between staff and patients. Moreover, standardizing the time and location at which patients are engaged through checkpoint identification, as noted in the workflow observations in Section 5.1, may actually be able to render the treatment process more time efficient.

As noted in the interviews and focus groups, patients have a high awareness of their surroundings and are tuned in to small changes in their environment as they progress through treatment. This was evident in the literature; chemotherapy patients became more aware of safety and the possibility of errors as treatment progressed [24]. By empowering patients with a tool such as a checklist, and facilitating communication between staff and patients, this heightened situational awareness on the part of patients could be leveraged to prevent certain errors from occurring. This could prove especially true for incidents regarding physical aspects of treatment. Therapists noted that patients have intervened in the past to prevent errors related to setup and treatment accessories. Provisioning patients with a checklist and encouraging them to actively participate may serve the purpose of leveraging this awareness as well as creating an environment where patients who are naturally less inclined to engage may be able to contribute on a more consistent basis. This would effectively encourage and promote the potential to engage in a larger number of individuals.
As stated by Rabol et al, many incidents in medicine related to patient safety can be attributed to errors in communication [21]. Given the feedback from patients and radiation therapists, a checklist may be able to facilitate this communication. Standardizing communication by identifying engagement checkpoints may be able to assist in improving safety. Facilitating communication may also assist in empowering patients that may not naturally choose to engage for fear of affecting their relationship with radiation therapists. Some radiation therapists indicated that patients may hide or mask their fears or anxiety. As stated by Coulter et al, patients may be able to play a significant role in the quality and safety of treatment only if their involvement is supported and valued [22]; provisioning patients with a checklist that facilitates their ability to ask questions and voice their concerns can allow patients to feel valued and supported.

During focus groups and interviews with radiation therapists and patients, many participants indicated that they believed it was important to include information about treatment preparation in a checklist or patient engagement endeavor. Radiation therapists communicated that many patients do not realize how important treatment preparation is and may try to rush to be treated rather than waiting for their bladder to be completely full. Treatment preparation minimizes the side effects that patients feel during their treatment, and for this reason, therapists want to impart the importance of treatment preparation to patients. Many of the patients interviewed felt that a reminder about treatment preparation would be important for patients as they felt that they personally understood the importance of this preparation but other individuals may not. Thus, based on the findings of this study, implementing a checklist in the clinical setting could emphasize the importance of treatment preparation and by extension increase patient compliance to these checks. This idea is reflected in the literature where Coulter et al stated interventions to
improve care processes can lead to better interactions between clinicians and patients, and greater patient satisfaction that may lead to better treatment adherence and health outcomes [23].

6.2.2 Checklist Information and Checks

For this study, a checklist was designed specifically with prostate cancer patients in mind. However, the findings can be extended to multiple types of treatments and patients. Based on the findings in the literature, many of the incidents that occur in radiation therapy can be classified as location, laterality, human error, malfunction, and accessory-based [63]. The first iteration of the checklist (see Figure 4), accounted for these issues and included checks about accessories, patient setup, wrong patient and wrong location. However, in interviews with patients, many did not fully understand specific radiation therapist checks and therefore were more focused on the checks that related directly to them. Radiation therapists also validated this point by stating that checks should not include aspects of treatment that patients cannot understand or engage with. Thus, based on these findings and the literature, it is important to strike a balance between checks that address where statistically errors occur in radiation therapy intersects with the abilities of the patient to engage.

From these considerations and the potential checklist benefits listed in Section 6.2.1, a number of checks that can be included on a patient-provider collaborative checklist were identified. The first main consideration, as stated above, is the fact that if the checklist is to be collaborative, all checks on the checklist must be actively engaging patients. To this end, the first set of checks should center on patient self-identification; that is, checks can include patient identifying themselves, their site of treatment and ensuring that they were asked to state their birthday.
The next set of checks should focus on ensuring that the patient has adequately prepared for treatment. In the case of Figure 4, these treatment preparation checks focus on prostate cancer patients. Furthermore, to ensure that the patient is prepared for treatment, the radiation therapist should verify with the patients that all of their questions and concerns have been addressed. This provides the patient an opportunity to express any issues with their treatment that may need to be addressed and provides an invitation for patients to ask questions. This check is important as some radiation therapists felt that some patients may hide their anxiety and concerns; therefore, it is important to invite patients to share these concerns without fear of affecting their relationship with radiation therapists.

As expressed in Section 6.1.2, patients have shown a high-level of situational awareness with respect to changes and differences in their treatment on a daily basis. This fact should be leveraged with checks that give the patient the opportunity to communicate these differences to radiation therapists. The first check should have radiation therapists ask patients if they are ready to proceed with treatment or voice any last concerns before the therapists leaves the treatment room. The therapists indicated that in most cases, they naturally perform this check with patients prior to leaving the room. The next check that should be included is checking with the patient to ensure that the treatment itself went well or whether they were concerned about any differences they noticed that day. This check would once again leverage this situational awareness to address any actual differences in the treatment or assuage any fears the patient may have if the differences are easily explainable as normal treatment phenomena.

Other checks that could be included in patient-provider collaborative checklists for other treatment types could include items that a patient would interface with on a regular basis. Many therapists brought up accessories such as bolus as items that a patient could engage with on a
daily basis since it is physically added to treatment. Furthermore, for treatments where laterality is a concern, the checklist should include checks that verify laterality. These two checks also align with the literature in terms of the types of errors that occur in treatment; namely, accessory-related errors and laterality-related errors [63].

Although concurrent treatments may not be as prevalent for prostate cancer treatment, the checklist could serve as a communication tool whereby patients communicate to therapists about their other treatments. That is, checks can be included that allow patients to communicate the status of a clinical trial that they may be participating in or communicate the days and time in which they are receiving chemotherapy treatment. Moreover, checks can be included if the patient is required to take any medications that are related to their radiation treatment such as anti-emetics. This information would be more pertinent if the checklist was being designed for other patient groups other than prostate cancer patients.

### 6.3 Checklist Feasibility and Barriers to Implementation

The third research question posed in this study was: *What is the feasibility of implementing a patient-centric checklist into the radiation therapy workflow, what barriers exist to its successful integration and usability and what is the best way of piloting the checklist?* The feasibility was described by first identifying the possible barriers, drawbacks, and challenges to implementing a checklist into the clinical setting. Through the various forms of data collected in this study, some challenges and barriers became evident. These challenges are important, as the majority of these challenges should be addressed during the implementation of the checklist to maximize the likelihood of success.
6.3.1 **Potential Barriers and Challenges to Checklist Success**

As stated by Schwappach et al, nurses recognized the engagement potential for patients in the clinical setting but identified some barriers to successful patient engagement. Some of these barriers included in certain cases when an error was noticed, the patient involved lost trust in the nurse and the nurse perceived that trust had been affected [25]. Similarly, radiation therapists feared that trust with patients may be affected if they were to involve them in the safety aspects of treatment and error prevention using a checklist. However, these cases do not address the fact that a checklist intervention could reduce the likelihood of error and therefore reduce the frequency of incidents occurring in the clinical setting.

Other barriers and challenges to checklist implementation and patient engagement were identified by patients and radiation therapists as well. Radiation therapists felt that patient engagement was personality dependant. Specifically, they felt that certain individuals would be more capable of engaging than others while certain patients would be more likely to want to engage than other patients. This attitude was shared by patients who were interviewed; some patients expressed the desire to be engaged with a tool such as a checklist whereas others did not see the benefit.

Responses from radiation therapists indicate that demographic barriers could be hindrance on the success of the checklist. These demographic barriers could include therapists attempting to communicate and engage using a checklist with patients who do not speak English as well as patients who may have issues reading the checklist due to age. Once again, patient attitudes on this subject reflected those of radiation therapists. Of the patients interviewed, many indicated that they believed older patients may struggle with reading and interacting with a checklist, as well as patients who cannot communicate effectively in English. These demographic factors
were evident during the recruitment phase for the STAI survey and patient interviews; many patients could not be approached or recruited due to their understanding of the English language and this could hinder their ability to communicate using the patient-provider collaborative checklist.

Patients identified that the process of filling out a paper checklist could be tedious on a daily basis and could become a nuisance for certain individuals. Furthermore, patients felt that the additional paperwork could become extra work for therapists on a daily basis. One major concern for both therapists and patients was the idea of a checklist adding more time to the actual treatment process. Radiation therapists were concerned about adding time to individual treatments as this could cause a delay for the next patient. Similarly, patients did not want to add additional time to their treatment or in the time that they had to wait for their treatment. This was especially true for patients who had to prepare a full bladder for their treatment; any delay could result in discomfort for these patients. The theme of time constraints was also noted to be a factor in the literature; Schwappach et al. found that chemotherapy nurses stated time constraints could be an issue for patient engagement [25].

Although time constraints are a definite factor for patients and radiation therapists, clinical validation is required to determine whether or not time would actually be added to the treatment process through the use of the checklist. By standardizing and facilitating communication with patients, over the course of treatment, the likelihood of time straining events may actually decrease. The above mentioned barriers and challenges reflect actual barriers that may exist but may highlight the fact that the largest barrier to implementation could be user adoption. The comments by radiation therapists and patients show some apprehension about a checklist
intervention that may stem from a reluctance to adopt such an intervention in the clinical setting for fear of these challenges and barriers.

6.4 **Implementation strategy**

Following workflow analysis, literature reviews on checklist design and incidents in radiation therapy, focus groups with radiation therapists and interviews with patients, a third and final checklist design was developed, as seen in Figure 11. Furthermore, recommendations for piloting the checklist in the clinical setting were made. These recommendations include suggestions for methods of piloting the checklist, measuring its effects on patient anxiety, monitoring the rate of incidents being reported during the time of implementation, and gathering further qualitative data from patients and radiation therapists on its perceived usefulness in engaging patients in the clinical setting.

6.4.1 **Final checklist design**

As stated in Section 5.3.2.1, checkpoints were identified for when the checklist should be completed. However, these checkpoints stated that there were checks that should be completed by the therapists and checks that should be completed by the patients. This final version of the checklist suggests that users go through all checks together in order to emphasize the collaborative aspects of the activity and to ensure that the patient is present to engage in all safety checks. Thus, checkpoint “1)” should be completed between the two radiation therapists and the patient upon entering the treatment room. Checkpoint “2)” should be completed just prior to and upon setting the patient up on the bed. Checkpoint “3)” should be completed just prior to the radiation therapists leaving the treatment room and commencing treatment. Finally, checkpoint “4)” should be completed immediately following treatment.
Figure 11: Final checklist design based on all results and findings from the study.
6.4.1.1 **Checkpoint 1: Patient Identification**

Based on findings from the literature, workflow analysis, and organizational policies and guidelines, patient identification was identified as an important safety step in the radiation therapy process [65][68] (Table 2). Thus, the first checkpoint addresses this by having the radiation therapists work with patients to collaboratively confirm the patient’s name, photo, site of treatment and birthday. As stated in Section 6.2.2, the checklist could be expanded to include checks relating to laterality. Thus, as part of the patient identification process, site of treatment could be expanded to include laterality of treatment. This checkpoint could also be expanded to include information pertaining to concurrent treatments or medications that a patient may be taking. This information was important for radiation therapists to know when treating patients and this checkpoint could serve to communicate this information to the therapists.

6.4.1.2 **Checkpoint 2: Treatment Preparation**

The treatment preparation checks are designed to be completed upon entering the treatment room but could also include checks that occur as the patient is being setup or just prior to the patient being setup. Since radiation therapists expressed that a checklist could be a good way of emphasizing treatment preparation, these checks were maintained in the final design of the checklist. Furthermore, patients are afforded an opportunity to voice any questions or concerns that they may have prior to treatment. The goal of this check is to facilitate communication with patients. Some therapists indicated that some patients may be shy or reluctant to voice concerns about their treatment for fear of questioning the therapists. Thus, it is important to include a check that allows these types of individuals to be invited to voice their concerns.
Depending on the type of treatment, other checks can be included at this checkpoint. Some of these checks include checks pertaining to the proper setup of manual treatment additions such as treatment masks, patient positioning and accessories such as bolus.

### 6.4.1.3 Checkpoint 3: Patient Readiness Confirmation

As initially stated in Section 5.3.2.4, the checkpoint “3)” is designed to verify that the patient is prepared to begin the treatment for that day. This check is designed to accommodate for patient situational awareness and their ability to notice discrepancies in treatment. Furthermore, this check allows these patients that opportunity to voice any concerns that may or may not be related to the safety of their treatment for that day. This check will ideally serve to catch any errors that a patient could potentially have noticed right up to the point where treatment is set to begin.

### 6.4.1.4 Checkpoint 4: Post-Treatment Check

As initially stated in Section 5.3.2.4, checkpoint “4)” is also designed to leverage an individual’s situational awareness. In this case, the check is asking patients an open-ended question of whether or not they were “OK” with today’s treatment. The goal of the wording of this check is to allow patients to describe any concerns they may have relating to treatment in general. Furthermore, this check will ideally open a discussion about any particular discrepancies or observations they may have noted during today’s treatment that troubled them. This check provides the therapist the opportunity to explain anything that the patient may not understand and alleviate their concerns. Moreover, should any of the patient’s concerns point to real issues or errors, this could allow the radiation therapist to document and act upon the patient’s concerns. Some therapists voiced concerns that asking this type of open-ended question may cause patients to ask questions that are not related to the actual treatment that could add time to the procedure. From focus groups, interviews and examining the literature, the time following a treatment may
be when a patient chooses to state any differences that they perceived during their treatment and therefore this check was maintained in the final checklist design.

6.4.2 Piloting strategy

This project has emphasized a significant amount of critical information pertaining to the attitudes of patients and radiation therapists on the subjects of patient engagement, patient safety and patient anxiety that have culminated in the design of the patient-provider collaborative checklist. The checklist should be piloted in the clinical setting to gain feedback on its effectiveness and usability. In the literature review on checklist design, it was noted that checklist should undergo rigorous pilot testing and validation before full implementation [82]. It is important to evaluate the clinical use of the instrument [76]. The checklist can also be tested for usability using a small number of end users in a simulated environment and note any confusions or difficulties they may have [81].

To validate the use of the checklist, users should be recruited to use the checklist. To accomplish this, all units treating prostate cancer patients should adopt the checklist for these patients as a quality initiative for 2 or 3 months and have therapists work with patients to complete the checklist. The checklist should be introduced to these radiation therapists during a quality assurance meeting so that they understand how they are supposed to work with patients to complete it. That is, radiation therapists should work directly with patients through each check to complete the checklist. Furthermore, radiation therapists should explain the checklist to patients during Day 1 education so that they understand that they are to complete the checklist at each treatment. Furthermore, these patients should complete an STAI survey in the manner explained in Section 3.5 to monitor anxiety levels through treatment.
For the piloting stage, the checklist should be a paper copy that is collected to record statistics on checklist compliance rates as measured in the WHO Surgery Checklist [48][47][45]. Furthermore, a number of treatments should be observed by a third party observer to document how the checklist fits into the workflow of radiation therapists. Prior to checklist piloting, this user should document the average time taken per prostate treatment and compare this with timed observations from treatments that use the checklist. This will address user concerns that some patients and therapists may not use the checklist. Moreover, these observations will address the concerns that a checklist will add time to the overall treatment process. This piloting exercise can also document any difficulties that may occur due to language or demographic issues since this was a potential challenge that was brought up by both patients and radiation therapists.

6.4.2.1 Measuring affect on anxiety and comparing to State-Trait Anxiety Inventory results

An STAI survey should be administered to all users using the checklist in the manner explained in Section 3.5. Patients should complete a demographics form to ensure that the data sample is roughly representative of the sample taken in this study. This summary of demographics information will allow the comparison of STAI results from this study with those performed on patients who use the checklist. Thus, it will be possible to ascertain whether or not a checklist intervention causes a significant gain or reduction in anxiety with respect to the results found for the baselines group. If the checklist is modified for other patient groups as well, the STAI survey can be delivered to a group that does not use the checklist (as described in Section 3.5) as well as a group that uses the checklist to compare the anxiety levels of individuals who use the checklist and those that do not. This will serve to address concerns by some radiation therapists that a checklist intervention could contribute to patient anxiety. The STAI survey of a baseline group
of prostate patients showed that mean anxiety did not change substantially from week to week. Median scores showed a drop in the first three weeks of treatment before stabilizing at approximately the same value. This additional surveying can also be used to validate whether the anxiety trends observed in this study are representative of this population group.

6.4.2.2 Measuring Safety Incidents

In the Radiation Medicine Program, there is a mechanism known as the Radiation Therapy Treatment Incident Reporting system that explains what constitutes an error or a near miss. Staff members are encouraged to report incidents and near misses. This error reporting system should be monitored during any checklist piloting endeavor to identify whether any errors or incidents were reported due to checklist intervention. Furthermore, the rate of incidents should be monitored to see if the checklist results in a higher or lower rate of incident reporting. This data should be analyzed to determine how the checklist affects the rate of incidents and the reporting of incidents; it may be difficult to discern the differences between these two categories.

6.4.2.3 Follow-up interviews with staff and patients

Staff and radiation therapists should be recruited in a similar manner to this study to discuss their experiences using the patient-provider collaborative checklist in the clinical setting. This information will complement the findings from STAI surveys and observations to assess how the checklist is fitting into the clinical setting, as well as its perceived usability and benefits from staff and patients. See Appendix C for the proposed script of questions for these interviews.

6.5 Future Directions

The future directions of the checklist intervention should focus on methods of implementing the checklist as outlined in Section 6.4. In addition to this implementation, there are some central
ideas and themes that must be addressed in future work surrounding this topic. These themes became evident as this study progressed. Specifically, future directions of this project should seek to generate results that can be generalized to multiple patient groups, characterize the relationship between patient engagement, anxiety, and safety, and improve the effectiveness of a checklist intervention by integrating it with more effective stages on the Hierarchy of Intervention Effectiveness. Finally, the checklist created in this study looks at daily treatment activities and maintaining consistency of treatment. More time should be spent finding ways to address episodic events that occur in the treatment setting that may not be addressed in the daily checklist proposed in this study.

6.5.1 Generalizing the Results to Patient Groups and Institutions

This study focused mostly on gaining qualitative and quantitative feedback from GU and prostate cancer patients. Future work should expand the scope to involve other patient groups and generalize the results to a wider base of patients. Specifically, this expansion should involve focusing workflow observations on specific site groups and customizing a checklist based on the needs of these groups. This checklist should be introduced to individuals of the site group in question in interviews similar to those conducted in this study. This method would yield results more specific to these groups. STAI surveys should also be conducted on these same population groups to identify any trends in anxiety levels and see how they compare to other patient groups. Furthermore, results could be generalized to more patient groups by conducting interviews with a larger and wider base of participants instead of focusing on specific groups. By including multiple patient groups with various prognoses and demographic factors, the results generated may be less specific but could be richer and more able to be generalized.
Further work could also include conducting focus groups with radiation therapists and clinicians working in different sized radiation therapy institutions. This checklist was more focused to a larger centre such as Princess Margaret Cancer Centre. However, the needs of smaller, community-based institutions could be significantly different. Conducting focus groups and workflow observations in smaller institutions could characterize the differences in these institutions and identify how the intervention design could be altered to meet the needs of different institutions.

6.5.2 Characterizing anxiety, patient engagement, safety

This study outlines themes centering on patient engagement, patient anxiety and patient safety: future work is required to characterize the precise relationship that exists between these concepts in the clinical environment. Specifically, any future work should look to characterize baseline anxiety levels and how they compare to anxiety levels for patients that are asked to participate as more active members of the treatment process using a patient-provider collaborative checklist. The reason this relationship is so important to the future success of this checklist is the fact that patient engagement should be used as a tool to improve the quality of the treatment and ideally the safety as well. Increasing safety should not be accompanied by a significant increase in patient anxiety as this would negatively affect the quality of the treatment; this is not the desired outcome for interventions to increase patient engagement. Ideally, any graph that plots engagement versus anxiety should show that as patient engagement increases, anxiety levels should decrease or remain constant at the very least when compared to baseline anxiety with no engagement. As previously stated, potential ways of measuring and characterizing this relationship involve comparing STAI data over the course of treatment for a baseline group of patients and those that are using the patient-provider checklist intervention. The most difficult
aspect of this relationship to measure would be the affect on patient safety. As stated in Section 6.4.2.2, future work should focus on performing analysis on reported incidents in the clinical setting in an attempt to characterize whether the checklist has an effect on the prevalence or rate or reporting for clinical incidents and errors.

6.5.3 **Improving checklist effectiveness**

As stated in Section 1.2.3.2, the checklist finds itself ranked fourth on the Hierarchy of Intervention Effectiveness [49][50]. Undoubtedly, any paper form of a checklist could suffer from some of the drawbacks that have been identified as weaknesses for checklist interventions. As such, future work related to implementing a checklist should seek methods to push the checklist into higher tiers of the Hierarchy of Intervention Effectiveness. With respect to radiation therapy, there may be an opportunity to integrate checklist use with the highest level of the hierarchy, “forcing functions and constraints”. Specifically, an electronic form of the checklist can be integrated into the electronic medical record of the institution implementing the checklist. The checklist should be connected to the patient chart and the treatment software. One way of forcing constraints is to program the software in such a way that the treatment cannot proceed unless the checklist has been completed electronically by the therapists/patient and submitted electronically. This step could ensure checklist compliance as well as tracking the completion of the checklist in the patient’s chart. The checklist could also be integrated with mobile or tablet technology to improve its portability while removing some of the drawbacks identified with paper checklists.

6.5.4 **Accounting for Episodic Events in Radiation Therapy**

The current iteration of the checklist focuses on attempting to address the daily routine of treatment and attempting to maintain continuity and consistency in these routines. However,
some issues being faced by therapists in the clinical setting around episodic events such as trying to coordinate patients’ radiation treatment with other concurrent treatments, trying to track patients’ medications or communicating information such as whether or not the patient has recently been to see their doctor to provide updates on their treatment or associated side effects. These types of events may not occur on a daily basis but represent issues that could be addressed with a checklist. Thus, further work on a checklist intervention should look at ways to address concerns surrounding these types of events and how they can be integrated into a checklist intervention.

6.6 Study Limitations

6.6.1 Checklist Design
Focus groups and interviews were used to complement the literature in the design of the checklist and assist in identifying the general usability of the device for clinical purposes. However, this study did not pilot the use of the checklist in a real or simulated clinical environment. Thus, is it possible that the results do not capture the full scope of issues that a user could encounter while using the tool in the clinical setting. Moreover, some of the issues brought up by patients and radiation therapists could be overstated in their significance. Thus, validation in a real or simulated clinical setting may be necessary to fully confirm or reject these considerations.

6.6.2 Patient Interviews and Data Analysis
This study was limited due to the possibility of selection bias during the patient interview section. Since these patients were recruited with the help of radiation therapists on the unit, as per research ethics protocol. There is the possibility that the sample of patients interviewed was
not representative of the overall population of GU patients. Furthermore, patients who decided to participate in interviews could have personality traits that differentiate them from those that did not wish to participate. Thus, it is possible that the responses from these patients may not be generalized to the attitudes of average users. It is conceivable that patients with varying anxiety levels may participate less or more actively in interviews or research endeavors and this could be reflected in the data.

The thematic analysis for focus groups and interviews in this study were carried out according to the procedures laid out by Braun and Clarke (see Section 3.3.3). However, a second individual may have been recruited as a second observer for this analysis. This additional person would have served to read the transcripts and perform coding of themes. This would have allowed for a more rigorous identification and validation of the themes that were identified in this study. Furthermore, this independent insight may have resulted in a more extensive discussion of themes that may have changed how they were organized and ordered.

6.6.3 **Survey Sample Size**

At the outset, the desired number of participants for the STAI survey was 20 individuals to detect a change of 10.4 from the standard mean value of the survey. However, 18 individuals were recruited and some of these individuals did not complete the survey fully for each week. Thus, the overall results could not state with statistical significance whether the mean values from Week 1 to Week 8 of treatment were different and therefore no distinct trend could be confirmed. The anticipated change in anxiety was overestimated and therefore, the initial estimate for sample size could have been increased to allow for smaller changes in anxiety to be detected as was the case in this study.
6.6.4 State-Trait Anxiety Inventory Survey Group

During recruitment for the STAI surveys, many individuals were screened out due to their ability to communicate in English and thus the sample may not be indicative of the overall population of users. Furthermore, many participants when approached did not want to participate in the survey and a few of these individuals had specific concerns about feeling overwhelmed about the situation they were in. Thus, the anxiety levels of those chosen for the survey may not be representative of the general population of prostate patients. The STAI survey itself is designed for individuals up to the age of 69; however, many of the participants were over the age of 70. This means that the results from this survey could not necessarily be compared to the established average for the survey as stated by the authors.

6.6.5 Application to Different Patient Groups

As stated in Section 3.5.1, prostate patients were chosen as the survey group for this study due to the relatively large number of prostate patients. Furthermore, there was the worry of recruiting patients being treated for other types of cancers that have more severe side effects and prognosis. This could cause these individuals to be reluctant to complete the survey and could cause a lower recruitment rate and a higher withdrawal rate following recruitment. Additionally, the goal was to ensure that all individuals surveyed were within the same patient group to reduce the number of factors that could affect anxiety. Since the patient group was selected in this manner, the anxiety score results may not be generalized to other patient groups or the larger population of patients. Other patients may have very different prognosis, side effects, demographic factors, and experiences related to their specific treatment and subsequently their anxiety scores may be different than the chosen patient group. Therefore, choosing a different patient population may have resulted in different STAI anxiety scores over time.
The information collected in focus groups may have been biased by the checklist that was introduced to radiation therapists. Since the checklist introduced to radiation therapists focused primarily on checks relating to prostate cancer patients, radiation therapists may not have suggested checks or information that was relevant to all patient groups. For example, complementary treatments may be important an important check for some patient groups but not a prominent check for prostate cancer patients. Responses may have been biased by the information that was already contained on the checklist that was presented to individuals. Future directions for addressing this issue are stated in Section 6.5.1.
Chapter 7
Conclusions

7 Conclusions

This study extensively examined the attitudes of radiation therapists and patients with respect to their perceptions of safety during radiation therapy. Patients and radiation therapists agreed that for the most part, patients feel that their treatment is safe and draw this feeling of safety from the staff that they interact with on a daily basis. This study also highlighted how radiation therapists and patients are both perceptive of the fact that a number of patients experience anxiety during treatment, that this anxiety varies greatly from individual to individual and that it may be caused by factors that are outside of the control of radiation therapists such as a patient’s knowledge understanding of the treatment or fear of the treatment machine itself. State-trait anxiety inventory surveys demonstrated how with a group of prostate patients, anxiety levels tend to remain constant through the weeks of treatment but the median of scores may drop within the first few weeks of treatment. With respect to patient engagement, this study highlighted the fact that while both patients and radiation therapists support and value the patient playing an active role in treatment, there are a number of challenges and barriers that exist in reality that render engagement potentially difficult. These challenges and barriers reflect many of the challenges and barriers previously described in the literature for other types of treatment. Finally, using proven methods of checklist design and feedback from potential users, a patient-provider collaborative was designed. The checklist combined aspects of workflow analysis and feedback from potential end users to yield its final design. Potential end users showed some concerns those related to the potential time strain that the checklist could create. However, many of these concerns cannot be validated or disproven without adequate piloting and validation of the
checklist. Thus, while this study has addressed clinical attitudes and evidence-based design of the checklist, the implementation strategy suggested should be followed to validate the tool. Finally, comments from radiation therapists and patients indicate that user adoption may be the biggest challenge a potential clinical checklist could face. Therefore, proper design that is validated by clinical piloting is essential to its future success.
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Appendix A: Focus Group and Interview Scripts

Patient Script (Prior to Checklist Design):

Phase 2

- Prior to treatment, how did you perceive the safety of radiation therapy?

- How did your perceptions of the safety of radiation therapy change as you progressed through treatment?

- Did you ever come across any situation where you think a mistake was made over the course of your treatment? If so, could you explain further (i.e. what happened, how did that make you feel, how did the health providers respond, etc.)?

- Can you think of any factors that would make you feel unsafe during treatment? Others factors that would make you feel safer?

- What do you think is the role of patients in improving the safety of radiation therapy?

- What do you think is the role of a checklist in improving safety for treatment delivery? What types of checks do you think patients can be engaged in?

- Do you believe that being able to participate actively using a checklist would make you feel safer about the treatment or feel more empowered when it comes to your treatment? Why or why not?

- What barriers do you see in trying to involve patients using a checklist prior to treatment?
Radiation Therapist Focus Group Session

Phase 2

- Did you ever experience a patient who noticed an error or close call in radiation therapy administration? What happened and how did the patient intervene?

- How did you feel, or would you feel, if a patient pointed you to an error or intervened to intercept an error?

- Do you believe that the current methods of administering radiation therapy in terms of setup, information verification and patient identification are safe?

- Do you believe that patients feel safe during their radiation treatment? Do patients ask questions related to safety throughout the course of treatment? What types of questions would they be?

- Would you see patients as partners in identifying and preventing errors in radiation therapy? Why or why not?

- Do you believe that as a radiation therapist, your role could include engaging patients in safety and error prevention?

- Do you believe that patients would feel more empowered or safer as a result of being more involved in the safety and error prevention aspect of their treatment? Why or why not?

- Could the implementation of a patient-centric checklist into the workflow be an effective way of engaging patients to assist in verifying important information along with the therapists? How?

- What problems and or barriers do you believe could exist in engaging patients both from a therapist side as well as a patient side?

- What barriers could affect the proper use and implementation of a checklist? What would facilitate the use of such tool?

- What types of checks do you think are important to be included in a checklist? What should not be included?

- What are some of the considerations that should be made when designing a checklist? Implementing a checklist?
Phase 3: Radiation Therapist (Focus Group Following Checklist Re-design)

- Do you think this checklist would be useful to engage patients in the clinical environment? Why or why not? What changes would you make?

- What should be included or excluded from this checklist?

- Do you think the use of a checklist will improve patient safety in radiation therapy treatment? Why or why not?

- Do you think this checklist, or some form of a checklist (either on paper or electronic) can be used in the current radiation therapy environment? Why or why not?

- What barriers will prevent this type of checklist from being successfully implemented into the treatment setting? What do you think are potential solutions to these barriers?

- Do you think this checklist would help or hinder developing relationships with patients? If so, how?

- Do you think patients would want to be engaged using a checklist such as this? Why or why not?

- Do you believe that patients would feel more empowered or safer as a result of being more involved in the safety and error prevention aspect of their treatment? Why or why not?

- Do you believe that as a radiation therapist, your role could include engaging patients in safety and error prevention using a tool such as a checklist?

- If you were a patient, would you want to be engaged actively in the treatment using a tool such as a checklist?
Appendix B: Consent Forms

INFORMED CONSENT for Participation in a Research Study

Phase 2: Patient Consent

Title of Study: Assessing Patients’ and Radiation Therapists Perceptions of Safety in Radiation Therapy and Using Patient-Centric Checklist to Engage Patients in Error Prevention

Principal Investigator: Dr Michael Milosevic

Co-Investigator: Michael Crupi, Catarina Lam, Dr David Jaffray, Dr. David Wiljer

You are being asked to take part in a research study because you are a current radiation therapy patient at Princess Margaret Hospital. Before agreeing to participate, it is important that you read and understand this explanation of the study.

The information below describes the purpose, methods, benefits and potential risks of our research. It also describes your right to refuse participation or withdraw from the study at any time. We want you to have enough information to be able to make an informed decision. We will be asking for your consent to participate so if there are any words you do not understand, please ask the study staff to explain them to you before signing. Make sure you are satisfied that all of your questions have been answered. If you do not wish to take part, simply return the form unsigned without consequence. Participation in this study is voluntary.

Background and Purpose

The purpose of this study is to learn more about patient’s views when it comes to the safety of radiation therapy. As part of this study we hope to engage patients to participate in providing feedback on some ways in which they can become more active members of their treatment process. We would also like to talk to radiation therapy staff and ask them their views on the patient’s role in safety and error prevention and determine any barriers that could potentially exist in successfully engaging patients. Furthermore, this study will examine the benefits and barriers surrounding implementing a checklist into the clinical setting that focuses on allowing patients to become more involved in the treatment preparation process.

Procedure
We would like to conduct individual in person interviews with 10-15 radiation therapy patients. These interviews will be approximately 45-60 minutes in length and will be audio-recorded to ensure all data is captured. These interviews will be audio recorded and converted to written form on the computer. Both the audio recording and written forms will be de-identified so that the participant is only identified by a case number. If you are interested in being involved, you will be sent an email invitation that will suggest a date, time, and location for your interview with the Researcher. The interview includes questions about your experiences during your treatment, your views of your personal safety throughout the treatment as well as your views on engaging with therapists on methods of improving patient safety.

Risks Related to Being in the Study

To the best of our knowledge, there are no known risks to participating in this study.

Benefits to Being in the Study

This study may have no direct benefits for you; however, the information gained from this research may help improve safety in radiation therapy in the future.

Confidentiality

If you agree to join this study, we may collect some demographic information from you during the card-sorting exercise that is needed for the study. We will not record any personal identifying information that can identify you as an individual, such as your name or date of birth. You will be identified by a study case number only. All information collected during this study will be kept strictly confidential and will not be shared with anyone outside the study unless required by law.

The information that is collected for the study will be kept in a locked and secure area in PMH by the study team for 5 years. Audio-tapes will be erased once the information is transcribed. Only the study team will be allowed to look at your records.

Representatives of the University Health Network Research Ethics Board may come to the hospital to look at the study records to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

You will not be named in any reports, publications, or presentations that come from this study.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in this study now, and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer.

Questions
If you have any questions about this study, please contact the Principal Investigator, Dr. Michael Milosevic at [contact information]. You can also reach the Co-Investigator, Michael Crupi, at [contact information].

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

**Consent**

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

______________________________  ________________________________
Print Study Participant’s Name        Signature                       Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

______________________________  ________________________________
Print Name of Person Obtaining Consent  Signature                      Date

Was the participant assisted during the consent process? ☐ YES ☐ NO

If YES, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

______________________________  ________________________________
Print Name of Translator        Signature                       Date
The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness   Signature   Date

Relationship to Participant
Consent to Participate in a Research Study

Phase 2: Radiation Therapist Consent

Title of Study: Assessing Patients’ and Radiation Therapists Perceptions of Safety in Radiation Therapy and Using Patient-Centric Checklist to Engage Patients in Error Prevention

Principal Investigator: Dr Michael Milosevic

Co-Investigator: Michael Crupi, Catarina Lam, Dr David Jaffray, Dr. David Wiljer

You are being asked to take part in a research study because you are a current radiation therapist at Princess Margaret Hospital. Before agreeing to participate, it is important that you read and understand this explanation of the study.

The information below describes the purpose, methods, benefits and potential risks of our research. It also describes your right to refuse participation or withdraw from the study at any time. We want you to have enough information to be able to make an informed decision. We will be asking for your consent to participate so if there are any words you do not understand, please ask the study staff to explain them to you before signing. Make sure you are satisfied that all of your questions have been answered. If you do not wish to take part, simply return the form unsigned without consequence.

Background and Purpose

The purpose of this study is to learn more about patient’s perceptions when it comes to the safety of radiation therapy. As part of this study we hope to engage patients to actively participate in quality assurance and error prevention. We would also like to engage radiation therapy staff and solicit their views on the patient’s role in safety and error prevention and determine any barriers that could potentially exist in successfully engaging patients. Furthermore, this study will examine the use usability and feasibility of implementing a patient-centric checklist into the clinical setting.

Procedure
We would like to conduct a focus group with 10-15 radiation therapists. If you are interested in being involved, you will be sent an email invitation that will suggest a date, time, and location for your focus group meeting with the Researcher. The interview includes questions about your experiences interacting with patients during treatment, with emphasis on the benefits and barriers that could exist with engaging patients in the treatment process as a method of improving quality of care and mitigating the likelihood of errors. This focus group will take approximately 1 hour and will be audio-recorded.

**Risks Related to Being in the Study**

There are no anticipated risks with this study.

**Benefits to Being in the Study**

This study may have no direct benefits for you; however, the information gained from this research may help improve the safety of radiation therapy delivery in the future.

**Confidentiality**

If you agree to join this study, we may collect some demographic information from you during the interview that is needed for the study. We will not record any personal identifying information that can identify you as an individual, such as your name or date of birth. You will be identified by a study case number only. All information collected during this study will be kept strictly confidential and will not be shared with anyone outside the study unless required by law.

The information that is collected for the study will be kept in a locked and secure area in PMH by the study team for 5 years. Audio-tapes will be erased once the information is transcribed. Only the study team will be allowed to look at your records.

Representatives of the University Health Network Research Ethics Board may come to the hospital to look at the study records to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines. You will not be named in any reports, publications, or presentations that come from this study.

We cannot guarantee your anonymity, because you are sharing your opinions and experiences in a group. However, we strongly encourage you to consider things that you might hear in the group as confidential. Please don’t discuss the private opinions and experiences of other group members outside of the group.

**Voluntary Participation**

Your participation in this study is voluntary. You may decide not to be in this study, or to be in this study now, and then change your mind later. You may leave the study at any time without
affecting your employment. You may refuse to answer any question you do not want to answer.

Questions

If you have any questions about this study, please contact the Principal Investigator, Dr. Michael Milosevic at 416-946-2932. You can also reach the Co-Investigator, Michael Crupi, at 647-607-1138.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

_________________________  ________________  ____________
Print Study Participant’s Name  Signature  Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________  ________________  ____________
Print Name of Person Obtaining Consent  Signature  Date

Was the participant assisted during the consent process?  □ YES  □ NO

If YES, please check the relevant box and complete the signature space below:

□ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered..
The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.
INFORMED CONSENT for Participation in a Research Study

Phase 3: STAI Patient Consent

Title of Study: Assessing Patients’ and Radiation Therapists’ Perceptions of Safety in Radiation Therapy and Using Patient-Centric Checklist to Engage Patients in Error Prevention

Principal Investigator: Dr Michael Milosevic

Co-Investigator: Michael Crupi, Catarina Lam, Dr David Jaffray, Dr. David Wiljer

You are being asked to take part in a research study because you are a current radiation therapy patient at Princess Margaret Hospital. Before agreeing to participate, it is important that you read and understand this explanation of the study.

The information below describes the purpose, methods, benefits and potential risks of our research. It also describes your right to refuse participation or withdraw from the study at any time. We want you to have enough information to be able to make an informed decision. We will be asking for your consent to participate so if there are any words you do not understand, please ask the study staff to explain them to you before signing. Make sure you are satisfied that all of your questions have been answered. If you do not wish to take part, simply return the form unsigned without consequence. Participation in this study is voluntary.

Background and Purpose

The purpose of this study is to learn more about patient’s perceptions when it comes to the safety of radiation therapy. As part of this study we hope to engage patients to participate in providing feedback on some ways in which they can become more active members of the treatment process. We would also like to engage radiation therapy staff and ask them their views on the patient’s role in safety and error prevention and determine any barriers that could potentially exist in successfully engaging patients. Furthermore, this study will examine the benefits and barriers of engaging patients to become more involved in the treatment preparation process.

Procedure

You will be asked to complete a survey prior to start of treatment as well as once a week, throughout your treatment (approximately 7-8 times). The survey itself will only take 5-10 minutes to complete.
Risks Related to Being in the Study

To the best of our knowledge, there are no known risks to participating in this study.

Benefits to Being in the Study

This study may have no direct benefits for you; however, the information gained from this research may help improve safety in radiation therapy in the future.

Confidentiality

If you agree to join this study, we may collect some demographic information from you during the interview that is needed for the study. We will not record any personal identifying information that can identify you as an individual, such as your name or date of birth. You will be identified by a study case number only. All information collected during this study will be kept strictly confidential and will not be shared with anyone outside the study unless required by law.

The information that is collected for the study will be kept in a locked and secure area in PMH by the study team for 5 years. Only the study team will be allowed to look at your records.

Representatives of the University Health Network Research Ethics Board may come to the hospital to look at the study records to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

You will not be named in any reports, publications, or presentations that come from this study.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in this study now, and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer.

Questions

If you have any questions about this study, please contact the Principal Investigator, Dr. Michael Milosevic at [contact information]. You can also reach the Co-Investigator, Michael Crupi, at [contact information].

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.
Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

_________________________  __________________  ___________________________
Print Study Participant’s Name  Signature  Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________  __________________  ___________________________
Print Name of Person Obtaining Consent  Signature  Date

Was the participant assisted during the consent process?    [ ] YES    [ ] NO

If YES, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

_________________________  __________________  ___________________________
Print Name of Translator  Signature  Date

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_________________________  __________________  ___________________________
Print Name of Witness  Signature  Date

Relationship to Participant  Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_________________________  __________________  ___________________________
Print Name of Witness  Signature  Date

Relationship to Participant
Consent to Participate in a Research Study

Phase 3: Radiation Therapist Focus Group Consent

**Title of Study:** Assessing Patients’ and Radiation Therapists Perceptions of Safety in Radiation Therapy and Using Patient-Centric Checklist to Engage Patients in Error Prevention

**Principal Investigator:** Dr. Michael Milosevic

**Co-Investigator:** Michael Crupi, Catarina Lam, Dr. David Jaffray, Dr. David Wiljer

You are being asked to take part in a research study because you are a current radiation therapist at Princess Margaret Hospital. Before agreeing to participate, it is important that you read and understand this explanation of the study.

The information below describes the purpose, methods, benefits and potential risks of our research. It also describes your right to refuse participation or withdraw from the study at any time. We want you to have enough information to be able to make an informed decision. We will be asking for your consent to participate so if there are any words you do not understand, please ask the study staff to explain them to you before signing. Make sure you are satisfied that all of your questions have been answered. If you do not wish to take part, simply return the form unsigned without consequence.

**Background and Purpose**

The purpose of this study is to learn more about patient’s perceptions when it comes to the safety of radiation therapy. As part of this study we hope to engage patients to actively participate in quality assurance and error prevention. We would also like to engage radiation therapy staff and solicit their views on the patient’s role in safety and error prevention and determine any barriers that could potentially exist in successfully engaging patients. Furthermore, this study will examine the use usability and feasibility of implementing a patient-centric checklist into the clinical setting.
Procedure

We would like to conduct a focus group with 10-16 radiation therapists. If you are interested in being involved, you will be sent an email invitation that will suggest a date, time, and location for your focus group meeting with the Researcher. The focus group includes questions about your experiences interacting with patients during treatment, with emphasis on the benefits and barriers that could exist with engaging patients in the treatment process as a method of improving quality of care and mitigating the likelihood of errors. The concept of a checklist will be discussed and how its design could be optimized to improve quality of care and patient-provider collaboration. This focus group will take approximately 1 hour and will be audio-recorded.

Risks Related to Being in the Study

There are no anticipated risks with this study.

Benefits to Being in the Study

This study may have no direct benefits for you; however, the information gained from this research may help improve the safety of radiation therapy delivery in the future.

Confidentiality

If you agree to join this study, we may collect some demographic information from you during the focus group that is needed for the study. We will not record any personal identifying information that can identify you as an individual, such as your name or date of birth. You will be identified by a study case number only. All information collected during this study will be kept strictly confidential and will not be shared with anyone outside the study unless required by law.

The information that is collected for the study will be kept in a locked and secure area in PMH by the study team for 5 years. Audio-tapes will be erased once the information is transcribed. Only the study team will be allowed to look at your records.

Representatives of the University Health Network Research Ethics Board may come to the hospital to look at the study records to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines. You will not be named in any reports, publications, or presentations that come from this study.

We cannot guarantee your anonymity, because you are sharing your opinions and experiences in a group. However, we strongly encourage you to consider things that you might hear in the group as confidential. Please don’t discuss the private opinions and experiences of other group members outside of the group.

Voluntary Participation
Your participation in this study is voluntary. You may decide not to be in this study, or to be in this study now, and then change your mind later. You may leave the study at any time without affecting your employment. You may refuse to answer any question you do not want to answer.

Questions

If you have any questions about this study, please contact the Principal Investigator, Dr. Michael Milosevic at [contact information]. You can also reach the Co-Investigator, Michael Crupi, at [contact information].

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

_________________________   _______________   ____________

Print Study Participant’s Name   Signature   Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________   _______________   ____________

Print Name of Person Obtaining Consent   Signature   Date

Was the participant assisted during the consent process?  □ YES  □ NO

If YES, please check the relevant box and complete the signature space below:
The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

_________________________________________  ____________  __________
Print Name of Translator          Signature          Date

_________________________________________
Relationship to Participant

_________________________________________
Language

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_________________________________________  ____________  __________
Print Name of Witness          Signature          Date

_________________________________________
Relationship to Participant
Appendix C: Proposed Scripts

**Patient Script (After Checklist Implementation):**

- Before the start of treatment, how did you perceive the safety of radiation therapy?
- How did your perceptions of the safety of radiation therapy change as you progressed through treatment? How do you think the checklist has affected that change in perception (if any)?
- Can you think of any factors that make you feel unsafe during treatment? Do you think using the checklist will make you feel safer even if those factors were still present?
- Did you perceive the checklist to be simple and usable in practice? Why or why not?
- What changes to the checklist would you suggest to improve the checklist and render it more user friendly in the future?
- Did you feel comfortable working with the radiation therapist to complete the safety checks listed on the checklist? Why or why not?
- What types of barriers or issues do you believe presented themselves during the implementation of the checklist?
- How did using the checklist and being actively involved in the safety verification process change your perceptions of safety in radiation therapy?
- Did you feel that you benefitted from being included in the patient verification process? Why or why not?
- Would you want a patient-centric checklist to be part of your treatment?
Radiation Therapist (Interviews following checklist implementation)

- When using the checklist in the clinical setting, do you feel that the tool was easy and quick to use? Why or why not? What changes would you make?

- Do you think the use of a checklist will improve patient safety in radiation therapy treatment? Why or why not?

- Do you think this checklist, or some form of a checklist (either on paper or electronic) can be used in the current radiation therapy environment? Why or why not?

- What barriers will prevent this type of checklist from being successfully implemented into the treatment setting? What do you think are potential solutions to these barriers?

- Did the checklist help or hinder you to develop a rapport with the patient? If so, how?

- Did the patients seem comfortable to engage in completing the safety checks included on the checklist?

- Do you think that patients were pleased to be included and engaged more in the treatment process from a quality assurance perspective?

- Do you believe that patients felt more empowered or safer as a result of being more involved in the safety and error prevention aspect of their treatment? Why or why not?

- Did your opinions on engaging patients as partners in preventing errors and quality assurance change as a result of the checklist study? Why or why not?

- Do you believe that as a radiation therapist, your role could include engaging patients in safety and error prevention using a tool such as a checklist?

- If you were a patient, would you want to be engaged actively in the treatment using a tool such as a checklist?
Appendix D: Focus Group and Interview Quote Tables

Table 11: Theme 1 (wide variability exists in perceptions of safety among staff and patients) identified from thematic analysis of radiation therapists focus groups with accompanying quotations.

<table>
<thead>
<tr>
<th>Subject and Code</th>
<th>Quotation</th>
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</thead>
<tbody>
<tr>
<td><strong>Table 11a: General Patient Anxiety and Concern Related to Treatment</strong></td>
<td></td>
</tr>
<tr>
<td>FG1PG15 – RT4</td>
<td>I’ve had patients ask, “Is this treatment safe? Is this machine safe?” And, you know, “Is the rest of me, how much radiation is the rest of me getting?”</td>
</tr>
<tr>
<td>FG1PG5 – RT5</td>
<td>A lot of times it happens right on day one. “I don’t even know why I’m doing this?” Like that’s the first thing that comes out. “I don’t even know why I’m doing this. Isn’t radiation supposed to cause cancer?”</td>
</tr>
<tr>
<td>FG2PG6 – RT8</td>
<td>I had a patient who was 4-field box, and she was concerned that her hips were receiving radiation dose and that was her concern. I wish I could have explained her more in detail, like I told her “things are coming, this and this way” but I had to refer to her oncologist to have the discussion more. So patients do have concerns thinking, “Is this going to affect my body?” but we do address it at the end.</td>
</tr>
<tr>
<td>FG2PG7 – RT16</td>
<td>In this last week alone there were two breast patients that we reviewed that one of whom stopped her treatment because of concerns about the radiation and her lungs and no matter what was explained to her. And another one whose treatment was totally, it was changed by the oncologist because of the concerns about the radiation etc.</td>
</tr>
<tr>
<td><strong>Table 11b: Radiation Therapists Believe in Safety of Current Practices</strong></td>
<td></td>
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<tr>
<td>FG1PG2 – RT5</td>
<td>I think we go through a process to identify that making sure that the patient is correct. That’s straight from the get go. Treating the right patient partly first is the first thing. Secondly I think we do have checks and balances prior to the treatment, the patient starting their treatment, to ensure that from, you know, a dosimetric point of view, therapy and medical point of view, things are being looked at.</td>
</tr>
<tr>
<td>FG1PG2 – RT6</td>
<td>I also think with image guidance we’re confirming our location of treatment so that’s an extra, that’s a big check that we do.</td>
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<tr>
<td>FG2PG2 – RT14</td>
<td>I think in theory the programs we have in place are safe because we have multiple levels of checking, QA room, the pre-treatment QA process, like, as long as it’s done like independently, by the book, it should be safe. But I think, like in practice, like, as we all know, sometimes there’s a time constraint when people feel rushed, like, you know the history shows, like, if you are rushed or pressured then mistakes can happen. But I think that the programs we have in place, like, in theory, they are, they should, like, guarantee a level of safety.</td>
</tr>
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</table>
| FG1PG4 – RT7 | I think as much we have improved safety there is so many things that are, like, being added to that list as well. I’ve noticed, I float a lot, so I go on a Unit and there’s like certain
things that are broken and not functioning well and we are still putting a patient on a chest board that is half broken and people are aware of it.

<table>
<thead>
<tr>
<th>Table 11c: Patient-Provider Relationships and Trust</th>
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<tbody>
<tr>
<td>FG1PG9 – RT6</td>
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<tr>
<td>FG1PG10 – RT7</td>
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<tr>
<td>FG1PG11 – RT5</td>
</tr>
<tr>
<td>FG2PG6 – RT14</td>
</tr>
<tr>
<td>FG2PG9 –RT?</td>
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</tbody>
</table>

Table 12: Theme 2 (there are multiple factors affecting patient engagement potential) identified from thematic analysis of radiation therapists focus groups with accompanying quotations.

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<thead>
<tr>
<th>Subject and Code</th>
<th>Quotation</th>
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</thead>
<tbody>
<tr>
<td>Table 12a: Routine and Situational</td>
<td>FG1PG8 –RT4</td>
</tr>
</tbody>
</table>
I think that just brings up the fact they are very conscious of what’s going on when they’re on the bed. Most do not just lie there. Most are, some will say, you know, “I was counting and it’s not on for the same amount of time”. Then you have to explain to them that aspect. Or you know, it’s a different person at the controls and they go on a different orientation. “Well you usually don’t go all the way around. Usually end with this on the top.” So you are very conscious of what’s going on which is good as long as you can answer all their questions. I think that puts them at rest.

I know that patients have actually helped on occasion because they’ll say, “oh, but that depth was all along and now it’s different”, because they listen to their numbers, “My number was different”, and they’ll remember, “oh, but where is that piece of stuff that you put on me?”.

Like sixteen, twenty-five, thirty five, whatever fractions they’re getting, they get familiar with how the machine moves, and when they’re in there, and the (gantry) starts moving the wrong way, or, I mean, maybe less so with cone beam that is started at a particular angle.

<table>
<thead>
<tr>
<th>Table 12b: Personality Dependent</th>
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<tbody>
<tr>
<td>FG2PG6 – RT16</td>
</tr>
<tr>
<td>FG2PG7 – RT9</td>
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<tr>
<td>FG2PG17 – RT10</td>
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<tr>
<th>Table 12c: Patient knowledge and Understanding Varies</th>
</tr>
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<tbody>
<tr>
<td>FG1PG20 – RT5</td>
</tr>
<tr>
<td>FG2PG14 – RT10</td>
</tr>
<tr>
<td>FG2PG5 – RT5</td>
</tr>
</tbody>
</table>
beginning of their treatment or it’s, you know, close, in their last week of treatment, having those termination falls or one, you know, the CTs, when the XVI crashes we have to re-do it again it causes them, like some will actually ver… “everything OK? like. And that’s when we’ll stop and we’ll go inside. So that’s the one that’s verbalized it. But I’m sure that’s going on in everyone’s mind when that happens.

Table 12d: Barriers to Communication

| FG1PG20 – RT2 | Um because of a machine problem … and you say to them, “Oh we are just having a machine problem”, and that in itself, I think, causes a lot of anxiety (general agreement) but they don’t always verbalize it because they don’t want to be a pain or they don’t want to cause problems. |
| FG1PG13 – RT7 | You can’t engage patients who don’t speak English and don’t fully understand what's going on. Some patients really don’t care, they want to get in and out and their biggest concern is being on time- “Get me in get me out”, and I think and some people want to be engaged and you know, the more information you that give them, where you sit down, showing them the plan, they’re really thankful and feel a little bit more at ease. |
| FG1PG20 - RT3 | You see this is too formal for our patients because most of the cancer patients are in the patient population of over fifty and sixty or about and they, just having this, is more, it’s more like baby boomer and they’ll be OK and I can just imagine the patient population that would respond positively to this. But most of our patients that are seventy or about well, they probably don’t read English anyway. |

Table 13: Theme 3 (patient safety, anxiety and perceptions of safety can be affected by therapist independent factors) identified from thematic analysis of radiation therapists focus groups with accompanying quotations.

<table>
<thead>
<tr>
<th>Subject and Code</th>
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<tbody>
<tr>
<td><strong>Table 13a: Time Affects Quality of Care</strong></td>
<td></td>
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<tr>
<td>FG1PG3 – RT5</td>
<td>I think all the checks and balances are there if everything goes through smoothly. It’s when things try to get rushed through, that’s where, although when checks and balances are there, there’s still the potential for human error because things are coming down, you know, the patient is actually an hour away and we still haven’t received a plan, things are still outstanding. So when things are running smoothly I think everything is there to make sure everything is safe. However, when things come down real quickly and those timelines aren’t adhered to, that’s where the potential for error, human error actually comes into play because of the time factor.</td>
</tr>
<tr>
<td>FG1PG10 – RT7</td>
<td>When a machine breaks down, we lose time. You know, we fall behind, we’re more stressed out, more likely to rush, to catch up, more likely to make mistakes in that aspect. You know, I’ve been in situations say were stressed out at work, first day education I’m talking and it’s like robotic. I’m saying it without any emotion or feeling and not really reading the patient, just in and out kind of thing. And I think we’ve all done it right and it’s that aspect of can we give them more time and we don’t actually do it with everyone but</td>
</tr>
</tbody>
</table>
with those people that you do we can’t get it because you and your partner and you need to keep on going, keep on treating. So time I think is the really big issue in this whole, you know, even for training, we can’t even organize training sessions because it’s so hard because we don’t have time.

FG2PG4- RT14 I think personally, I think so, cause over just over the last nine years, I can see, for me, from a treatment unit perspective the amount of time that we have on average to do the pre-treatment work up for a plan, from the time of final approvals preceding this. For example for example PDQA and lateralties from that time to the time that the patient is to arrive, it seems like that, that’s a lot shorter.

FG2PG5 – RT8 Sometimes you’re so rushed in time, even if there’s all these checks, it’s easy to miss something. So, you can never be too careful. That’s what I’ve noticed.

Table 13b: Treatment Machine Status

| FG1PG6 – RT6 | The two because a backup form was being used the machine was going down so often, the machine was often delayed, so the patients knew there was a problem with the machine. So I think there’s a difference between, like quality and safety, perceived quality and safety when, in terms of trusting the machine and then trusting that you are being treated to the right area. |
| FG1PG6 – RT1 | It’s sometimes hard to communicate with them too because we, we’re trying to get updates on how long it’s going to be down for but then we may not have that information. So we say well it’s going to be ten minutes, well it’s going to be fifteen minutes, OK half an hour. |
| FG1PG6 – RT4 | And that’s a big part of it I think. Because with the plan, like, if a patient asks, “oh how do you know that you’re treating the right area?” we have, we can describe that and explain it thoroughly to them so they’re confident. When it comes to the safety of the machine, we can’t really explain it. |

Table 14: Radiation Therapists’ comments relating to the design or usability of a patient-provider collaborative checklist.

<table>
<thead>
<tr>
<th>Subject and Code</th>
<th>Quotation</th>
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<tbody>
<tr>
<td>FG1PG11-RT1</td>
<td>But that’s where it would be useful too from those manual things like placing bolus ...............or if it’s like a manual shielding or something like that where it would be useful. A lot happens within the machine that they don’t understand and they’re not going to see whether the MLC is in the correct position. They don’t know what that means. But the stuff that they can feel and see that that’s where it would be useful or also for laterality, team 2 they ask patients “which side are we’re treating?”, that’s useful.</td>
</tr>
<tr>
<td>FG1PG12-RT2</td>
<td>I don’t see yet, but we may well, how we can engage them in the technical parts of our job. Like, ya, other than like things that we manually add to their treatments that aren’t protected by some sort of interlock, I don’t see what other parts we could but maybe there will be check lists.</td>
</tr>
</tbody>
</table>
| FG1PG18-RT2      | I can think of things under the patient one maybe but I would have a hard time thinking of a radiation therapist checklist because we already have a very technical checklist that the
| FG1PG18 –RT1 | And this, as it’s written: all necessary accessories included is so vague compared to what we’re already using that this is of no use to the therapist. |
| FG1PG19- RT2 | So we could probably think of like, like bolus, that’s a big thing. So, I can see bolus on this list and it doesn’t have to say where the bolus should go and how thick but don’t let us leave the room without the bolus; that’s on the checklist. I can’t think of too many else right but, I have to be pretty simple. |
| FG1PG19 – RT4 | I could think of pacemakers cause some of the patients have to go weekly to have their pacemakers checked. That should be something that could be something that we could engage the patients in. And most of them are aware that they have to go weekly, they’re not going to skip it. The other thing would be, you know, are you pregnant? |
| FG1PG19 - RT5 | And I also see this as, I mean, the more checks you put on the radiation therapist’s side, it looks like this sheet is being handed to the patient so there’s that many more things potentially for the patient to worry about. They’re not just going to think about what’s on their side, they’re going to be checking the radiation therapists’ side… |
| FG1PG22 – various therapists | Birthday, bolus, pregnancy, pacemaker, eyes open, antiemetics, full bladder, pre-meds, treatment prep, full bladder, clinical trial information, mostly chemo. |
| FG2PG11 – RT16 | I was just going to say, I like the fact that the patient has a chance to comment and one way that I can see this being used too is actually a section for the patient to state consents. It might not be, if things are really rushed and, or the patient gets thinking about other things, that may not bring it up but when he’s sitting there ahead of treatment, there’s a time they think, “oh you know, this occurred......i had some side-effects in this area or there’s something weird happened” and write it down so it can be addressed. It just might just safe time and also be a heads up to staff on the unit too. |
| FG2PG14 – RT16 | Maybe day one and day seven, day whatever- a long treatment, like once a week then. Would that work on the unit just as sort of a check or is that too time consuming? It depends on what’s on the list too, right, and the patient compliance. It depends on a lot of things. That it might even be good for day one if they come in with, like _______ was alluding to, like information like: What is your understanding of why you’re coming? What area are you coming to be treated for? So you can check their understanding of why they’re coming even and what it’s for and also, “Have you had treatment before?”. At least a heads up there in case it was missed somewhere along the line. So day one could be a bit different than the other check lists if you’re going to do it periodically, like once a week through treatment. So somebody who’s a palliative patient will only fill in the day one. But somebody who is on four or five weeks of treatment may do four or five of them. |
| FG1RT1 – PG22 | Umm, I guess maybe on the patient side of the check list, are there any things, simple or not, that a patient might, like you said they ask some questions, or things that are very simple that they can check off, or even things from a radiation therapist’s point of view, that, if they saw that checked off, even if it’s not something very technical it might kind of put them at ease as far a kind of checks that could be included? |
Table 15: Theme 1 (patient anxiety not related to perceptions of the safety of the treatment process) identified from individual interviews with radiation therapists patients with accompanying quotations.

<table>
<thead>
<tr>
<th>Subject and Code</th>
<th>Quotation</th>
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<tbody>
<tr>
<td><strong>Table 15a: Treatment is consistent</strong></td>
<td></td>
</tr>
<tr>
<td>P1PG1</td>
<td>So it doesn’t vary in-between treatment units. Even if it’s different people administrating, it’s pretty much the same regardless of who’s doing it.</td>
</tr>
<tr>
<td>P11PG3</td>
<td>No because I think there is a set, usually when I dealt with them there was a set of 2 to 4 people, ok. So, they are always doing the same thing no matter who was there.</td>
</tr>
<tr>
<td>P6PG2</td>
<td>To this day, it’s the same thing, I lie there, I take my treatment and I move on.</td>
</tr>
<tr>
<td><strong>Table 15b: Develop Relationships with Therapists</strong></td>
<td></td>
</tr>
<tr>
<td>P3PG3</td>
<td>I usually ask them where they went to school and, have they had anyone with long johns yet, that kind of thing. I like to make things a little more enjoyable whenever I can.</td>
</tr>
<tr>
<td>P9PG2</td>
<td>But I found that I could ask questions here, the nursing staff at the radiology check-in were excellent! They would answer and send you home with different creams to try and I was well looked after once I started peeling. (person’s name) really worked on the skin and made sure I knew what to do and how to do it and checked me the next time I came to make sure I was doing it.</td>
</tr>
<tr>
<td>P10PG2</td>
<td>I think the way that the technicians speak to you every day helps you to feel empowered in your treatment anyways so I don’t know that a checklist on paper would change your empowerment honestly; they’re very good about what they do.</td>
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<tr>
<td><strong>Table 15c: Patient Anxiety Related to Machines and Effects of Radiation</strong></td>
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<tr>
<td>P4PG1</td>
<td>A little bit, I was worried about, you know, developing more cancer from the radiation.</td>
</tr>
<tr>
<td>P5PG1</td>
<td>Well I mean there are side effects related to...bleeding, or damage to the rectum or intestines...</td>
</tr>
<tr>
<td>P6PG1</td>
<td>I did initially because learning about having to take radiation through the doctor’s prognosis, I then had to get myself up to speed on what that meant because I was really concerned about not just the side effects but what happens during it, you’re exposed to radiation, what are the health issues and do I have to be concerned about it. And you often hear about burning sensations, things, what causes that and so those are the kinds of questions you ask and you try to educate yourself through the internet, through papers from the hospital and the one on one with the doctor and some of the technicians.</td>
</tr>
<tr>
<td>P7PG1</td>
<td>Yeah just the fact that I know what radiation is. I think you think about your eyes, that’s what I think about. I think that, you know,”This thing, it’s not going to hurt my eyes is it?”</td>
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</table>
You know, I mean, especially because I’m deaf, I only have 5% of my hearing, so, I’m a skin specialist, everything is about my eyes, so it crosses your mind.

P10PG1  
Ummm, I think the first time you lay on the table, yeah, you go “Huhhh, what have I got myself into? What is this thing going to do? What sort of are the side effects? What is going to happen to me?” Definitely, those things go through your mind. But, yeah, I mean, it still feels like a safe environment that you’re in but you do... once you’re laying on that table, everything changes.

P8PG2  
Yes, I have heard that from time to time the machines break down and, for whatever reason. And sometimes, I think yesterday the computer software was not working or responding. There was another time, I think a light bulb went, something like that. So my only concern would be that these are powerful machines radiating very high levels, that if there was a computer software malfunction of any sort, would it do unnecessary damage to not just me but any other human being.

<table>
<thead>
<tr>
<th>Table 15d: Patients Self-Educate</th>
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<tbody>
<tr>
<td>P1PG3</td>
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<td>P5PG1</td>
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<tr>
<td>P6PG8</td>
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<tr>
<td>P8PG4</td>
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<td>P12PG2</td>
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Table 16: Theme 2 (*patient engagement is personality dependent*) identified from individual interviews with radiation therapists patients with accompanying quotations.

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<thead>
<tr>
<th>Subject and Code</th>
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<tr>
<td><strong>Table 16a: Some Patients Prefer Active Role</strong></td>
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<tr>
<td>P1PG3</td>
<td>Yes. I think I am just as much accountable for my care as they are and if I don’t have an active role how is it going to be positive at the end if I am a passive participant and it’s my body.</td>
</tr>
<tr>
<td>P5PG2</td>
<td>It’s always good to be active in anything that concerns a patient right because they’re the ones who are the object of the intervention, right? So if they can have an active participation and make things better for them and others, why not?</td>
</tr>
<tr>
<td>P8PG2</td>
<td>I think in general, as far as the treatment goes, the physical side of it, I have no option but to be passive because whatever is being, the treatment is determined by the oncologist and the therapists and so on. However, I think from an emotional point of view, attitude is important and I think that is where I can be positive, which I am, but I can stay positive. And, so that is my contribution to this. And then basically things like, they’ve asked me, you know, for example, you need to have a certain level of water, you need to have a certain level of preparedness and I make sure that I can meet that every day so that we’re working jointly on that.</td>
</tr>
<tr>
<td>P12PG3</td>
<td>It’s up to the individual. If you really care about your cancer and your treatments, you want to make sure you do all these things because it’s your fault if you don’t. It’s not their fault because I have been well-versed on this.</td>
</tr>
<tr>
<td><strong>Table 16b: Some Patients Prefer Passive Role</strong></td>
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<tr>
<td>P4PG2</td>
<td>Probably more passive I would guess. Because, you know, we’re not technical and we don’t know how to use the computers and basically it’s all computers anyway.</td>
</tr>
<tr>
<td>P6PG5</td>
<td>Yeah. I don’t know what all of this really means at the end of the day, so whether a regular patient would care. I think 90% or probably better of the patients going in there probably don’t really understand much more than that they’re going in there to make themselves better. I believe that. It’s that 10% or maybe better or less, like myself, who have an interest in knowing “How am I doing?”, “Where have I been?”, “Where am I going?”, “What’s it all about?”, “Is this the right thing?”, “Is this the wrong thing?”. A lot of people just say, just hear their doctor say they got to do it and they go. That’s why the doctor’s take the time to really pound at you to make sure you understand it.</td>
</tr>
<tr>
<td>P7PG2</td>
<td>I want the radiotherapists and the radiation people to take care of that. I mean, I don’t know anything other than the little bit I know about radiation so I don’t, I’m not for lay people getting involved too much.</td>
</tr>
<tr>
<td>P8PG2</td>
<td>I think in general, as far as the treatment goes, the physical side of it, I have no option but to be passive because whatever is being, the treatment is determined by the oncologist and the therapists and so on.</td>
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### Table 16c: Patient Demographics Affect Engagement Potential

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<thead>
<tr>
<th>Patient</th>
<th>Comment</th>
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<tbody>
<tr>
<td>P1PG3</td>
<td>Definitely. I wanna see, I actually want to see the CT, I want to see the MRI, I want to see what are you lining up when you move that bed every time, I wanna know those pieces. And I think the younger generations will more and more, I may want that, but the people who are in their 20’s or their teens now, they’re going to want it even more than I will.</td>
</tr>
<tr>
<td>P3PG4</td>
<td>Well you obviously you can’t print these in 20 languages...ummm...and...again older people, already nervous, already frightened maybe, feeling threatened, probably not going to help what English knowledge they have. Somebody would have to be there to explain and interpret the answer...I dunno, you have a complicated problem.</td>
</tr>
<tr>
<td>P6PG6</td>
<td>Some of the demographics of the people give them some limitations because they're not fully English speaking or educated in it to understand it so they don't know where to go so they get frustrated. So it’s really just the demographics of the individual as opposed to me, you know, who, I have taken time to understand it. I would fill it, if I had to fill it I would fill it out.</td>
</tr>
<tr>
<td>P10PG3</td>
<td>I do see elderly people out in that waiting room who might have issues sort of more so with sight or reading and that sort of thing but the size that you have the font I think would not impede too many people really, right? Because...I don’t mean to sound ageist or anything, but I am one of the youngest people that I see around here; cancer affects, it seems to be older people more so than younger, right? So those would be the factors that? I think could maybe affect a thing like this.</td>
</tr>
<tr>
<td>P12PG3</td>
<td>Maybe language barrier. Elderly patients might have a problem if they don't understand.</td>
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### Table 16d: Patients May be Empowered by Engagement

<table>
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<tr>
<th>Patient</th>
<th>Comment</th>
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<tr>
<td>P1PG5</td>
<td>For me it would. Especially looking at it, “Did you line me up properly?” “Is there anything going on?” “Is there anything that I need to know about?”. Your equipment is not working and it hasn’t been working for the last 3 days and it’s hit and miss. The very first day that I came in, their computer system went down mid-treatment and I was thinking “What the hell is going on? Really? Your computer goes down in the middle of my treatment?”</td>
</tr>
<tr>
<td>P4PG3</td>
<td>I guess it would make you feel more empowered, making sure everything is being followed to the letter. You know everything, like I say, you’re not always having a good day so sometimes they may not have a good day and not check everything properly so you, know. It would be a good thing, just a lot of trees being killed for it, but other than that...it’s paperwork right. I think it’s a good idea.</td>
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<tr>
<td>P5PG3</td>
<td>I certainly think it would. I think it would. I mean if patients understand why it is important to have a full bladder and a empty rectum, not only in terms of the consistency of the service but it would minimize the side effects that they can experience as well, then they would do their best to....</td>
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<td>...to meet these requirements or these pre-requisites as I was saying for each treatment.</td>
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Table 17: Theme 3 (obvious benefits and drawbacks from the use of a patient engagement checklist) identified from individual interviews with radiation therapists patients with accompanying quotations

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<thead>
<tr>
<th>Subject and Code</th>
<th>Quotation</th>
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<tbody>
<tr>
<td><strong>Table 17a: Checklist Could Provide Reassurance to Patients</strong></td>
<td></td>
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<tr>
<td>P3PG3</td>
<td>Yeah it might. Just a little more verification that....that somebody was in charge and knew what they were doing. Reassurance.</td>
</tr>
<tr>
<td>P7PG4</td>
<td>I think it’s good because it tells me that they’re really trying to do their job. Like this first one “verify proper patient setup and alignment”, they’re telling you “Don’t move”. I mean, sometimes you need to be reminded of those things, your nose gets itchy or your…you feel like moving. And sometimes with us, we don’t just want to know when our bladder is not full or our rectum…we want to know, we would just like them to say something, I don’t know. I know they told me today they had to do another scan or something, I don’t know what that was all about. So that was kind of like a negative. But you wouldn’t mind somebody just, if you trained these girls to say “That was really good today ______, I mean, you were nice and still”, like a few positive things.</td>
</tr>
<tr>
<td>P9PG5</td>
<td>Well, you’d be sure that they had done their job in asking and you’d filled out those questions.</td>
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<tr>
<td><strong>Table 17b: Patients Have Inherent Desire for More Knowledge</strong></td>
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<tr>
<td>P1PG2</td>
<td>Yeah, the things...they obviously have a checklist that they’re going through and as a patient I don’t see that checklist, I don’t know what it is. But it would be great in information when you walk in that they tell you “ok, this is what’s going to happen”, “this is what’s going to happen everytime”. So I know what those steps are, what those procedures are. (general agreement from interviewer) That same “We’re keeping you safe by doing X”. You know, your date of birth, I know that they’re gonna ask me, that’s one of the safety precautions “Do I have the right patient?”. But when they’re actually going in and they’re doing the measurements against your tattoos and understanding, “ok, how is that actually a safety precaution to make sure that you’re lining me up right, that you’re actually going to do what you need to do.”</td>
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<tr>
<td>P2PG1</td>
<td>I would say that I wish I knew more of what they were doing. I wish I could see their screens, I wish I could see what areas they were radiating and I also wish that I would also know....any....results isn’t the correct word cause we’re not through it all yet but I would like to know if there’s been any changes, or any notifications, or any noticings of anything that’s working or not working.</td>
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<tr>
<td>P2PG2</td>
<td>Well I don’t know, it’s just that I go in there, I sit on the machine, they do it and I go home. So I don’t know, like I said, I don’t know specifically which areas they’re targeting , which ones they’re not, I don’t know which areas, I don’t know....if it’s working, if it’s...I mean, I just don’t know. Kinda, I’m just, I’m like the guinea pig sitting there.</td>
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</table>
For me it would. A lot of people don’t like to know that but basically I was always interested in sciences, I liked to know if there is a problem so I can be prepared for it. You know, and once I am ok, deal with it but other people maybe would be really put off with having to find out more, I guess everybody is different.

**Table 17c: Checklist Could Facilitate Patient-Provider Communication**

| P1PG4 | Because these are things that sometimes you need to talk about. Like the full bladder, well if you’re on radiation and you have problems with the bowels, full bladder is going to be a problem all the time. So it actually opens a door that you might talk about with your technician that you’re maybe not comfortable just bringing up out of the blue as you’re walking into the room. |
| P6PG5 | Yeah I think so, and this would engage the patient more. Cause then they get a chance to see...not see but they get a better chance of throwing things out than they already do. It should give them time to think about it. |
| P7PG3 | No, I think it’s good to have a checklist because someone like me, I’m getting 39 treatments and you get a little rusty with some of these things. Sometimes you need someone to say “Is your bladder full? Is your rectum empty?” and sometimes we don’t know! I mean that’s the problem. So, for us sometimes you say “I’m not sure, I think it is but I’m not sure” because a lot of time in this society you have to go to the bathroom but you’re right in the middle of seeing 40 patients, you just don’t go! And so maybe there’s something...I think it’s a good thing to say, but it might, you might want to say, the empty rectum, you might want to say “100% certain” or “50% certain”, like you’re not sure. |

**Table 17d: Paperwork May be a Nuisance**

| P1PG5 | The one, I could the patient, especially if it’s a paper form, they don’t want to fill it out, and they don’t want to be bothered with it, “Don’t bug me about it. I just want to go in, get my treatment and get out”. The second would be the radiation therapists themselves; they’ll view it as “This is more of a workload on me. I don’t want to get involved with this, I have enough checklists, I have enough papers”. It would be getting them both on board to say why they would be doing it that contributes to a better outcome. I think that would be what I would see as a challenge. |
| P2PG3 | I think that a paper based, what you’re talking about, isn’t the way to go. I mean it’s done verbally and orally now, and I just think that you’re just creating more waste, wasted time, wasted paper, wasted efforts, wasted everything, It’s like asking me, “How are you today?” and then asking me “Hey, would you write that down for me please?” |
| P3PG3 | Well.....more paperwork. Somebody has to produce it, somebody has to make sure that it’s distributed and administered properly. Someone has to collect them, collate them. To make them of value they have to be reviewed. |
| P8PG4 | I hear they have 400 treatments here a day, right, approximately. Not necessarily in my unit but in general. So if a lot of people, if there is a form like this for a lot of people with different kinds of treatment, that is a lot of paper to collect. |
Well it’s more paperwork, right, and I don’t know about you…but I think most people hate paperwork, right. And then where are you going to keep this? Is it going to go into the garbage again?

Do you put all this into the computer or do you throw the paperwork out or does it pile up in boxes? You know, there’s got to be thousands and thousands eventually.

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<thead>
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<th>Table 17e: Time Factor is Important</th>
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<tbody>
<tr>
<td>P4PG3</td>
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<td>P9PG5</td>
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<tr>
<td>P11PG4</td>
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<td>P12PG3</td>
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<th>Table 18: Theme 1 (designing patient engagement tools could be rendered difficult due to differences in users’ personalities) as identified through the follow-up focus groups with radiation therapists</th>
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<tbody>
<tr>
<td>Participant</td>
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<tr>
<td>FG3P4 – PG6</td>
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<td>FG3P3 – PG7</td>
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</table>
| FG3P3 – PG8 | And they choose themselves. I don’t think we can choose who those patients will be apart from perhaps the language barrier or cultural things or things like that. But I think the patients tend to choose themselves, like for example, I’m the patient. I’m
going to make sure you have me up there, nobody else. That’s my choice, but maybe somebody else might not feel that way, so, they choose themselves I think.

FG3P4 – PG15

Ya, like ask them do you, what are the things that you would like to... some patients just don’t want to know anything. Some patients just want to go in and just get it over with, you know? And some patients do, um but you know want to learn certain aspects of...

FG4P5 – PG6

Not all patients. Some patients we get, they don’t want to know what kind of side effects they might get, we try to tell them. They don’t want to know anything, they just want to get in and get treated. And they pray they don’t have any side-effects.

FG4P6 – PG6

So gauging on those patients, they can be very involve in their QA and the safety and accuracy of their delivery because I think that they know a lot. And I know, like, for some Breast patients, they know where their surgical scar is. They know what should be boosted, or, especially for laterality, definitely patients can be a part of their QA I think. And that too is personality and patient dependent. Like you said, some patients are like, “just do what you’ve gotta don’t, I don’t want to know” but then there’s those patients who are very engaged. And I think those are the ones you want to target. That you can use to be involved in the process.

FG4P2 – PG21

I definitely think there will be some patients who might like it, but I don’t know what percentage that would be, or how to figure out who that is. Because you’re actually talking to them about all this stuff instead of having them fill out a lot of paper.

Table 18b: Barriers potentially limit the extent to which individuals can engage

| FG3P3 – PG6 | I think it depends on what it is that the patient is involved in. The birthday thing yes, that’s a pretty simple thing. But as Participant 2 said, they don’t have enough knowledge to be involved in the QA process. It’s part of treatment delivery itself. |
| FG3P5 – PG7 | uh, I agree totally. Especially some patients, depending on the culture, the language barrier, they just can’t voice out what’s wrong, right? They just follow whatever you tell them. So, I mean... |
| FG3P2 – PG7 | Like even aside from their comfort level their ability to understand what should or shouldn’t be happening, right? There can be all kinds of other, well, great, so if part of your QA process is to have the patient remind you of something, great, well what do you do for patients that don’t speak English? |
| FG3P2 – PG8 | So when you’re talking about something like, you know, are we delivering the right number of monitor units, um, even if the patient is sort of in a partnership with the clinicians, they don’t have anything to contribute to that per say, right? Um, and, their lack of knowledge is a problem in the sense that, you know, I heard 15 beeps today and yesterday it was 17, that someone brought up earlier. |
| FG3P5 – PG15 | Ya, language. If the patient doesn’t read English, it doesn’t really help them. |
| FG3P1 – PG15 | It could also be the patient’s condition. Perhaps at the beginning of the treatment they’re really eager and happy to do this but 4th week they’re not too pleased to have |
I think it’s very difficult for patients to be involved in, at least because it’s, it’s such a technical job that takes years of training to actually understand what’s going on, so, how can they, when they know nothing about the process, really contribute to that.

For us, patients would comment, this doesn’t feel quite, you know, the way it normally felt, or something. And so that’s how they contribute. Through what they know, through their senses, and also what we use as far as accessories. So, that’s one way to contribute. We often ask “does this feel normal, does this feel neutral?” (16:06) because we use, you know, we use masks and it does make a difference in how they’re placed on the neck rest.

Ya. Or if you have a language barrier they might not know how to express it, right? So, ya, you do have to be careful that they might not say something.

Participant 6: If it’s written, then like language for sure is going is going to be an issue.

Participant 1: Or like elderly people who can’t read it very well.

Participant 2: Then again, what you said the buy-in from the staff. You know, not everybody’s going to do it. I mean, we know that not every staff does it, but, so.

Table 18c: Patients have varying anxiety levels

| FG3P2 – PG2 | At least after a few. And I think sometimes, there’s a difference between being nervous general and anxious about it and feeling unsafe, right? So, we have people that I think they’re claustrophobic or they’re just really nervous and they’re overwhelmed, or its really emotional or whatever. It’s difficult for them. But they trust us and they don’t have concerns about, you know, the equipment, or they don’t have safety concerns, uh, so I think in general. |
| FG3P4 – PG22 | Some people are just anxious people. Some people have the best, you know, case scenario |
| FG4P2 – PG3 | I think some patients are predisposed to be more anxious. And some, like, even though you think, the first couple of days, I’m going to get them through this hurdle then they’re going to relax into it, some don’t. Some just, the whole way through. You know, how many (?) Shems 6:33) how many ? (6:36) down there? You know 3, right? Or how many was it yesterday? |

Table 18d: Some patients seek additional knowledge related to treatment

| FG3P6 – PG14 | I’ve shown patients their plan in Pinnacle. If they’re interested enough to ask those types of questions I’ve take them to a station and I’ve shown them what we’re treating and where we’re treating, how we do and I think that that’s great for those people but that’s not the majority of our patients. That’s like one patient in a very long time that I’ve had that, so |
| FG3P6 – PG15 | That’s true. And plus the internet, so many of our patients, especially, they’re very knowledgeable. Where they even come to us, where they’ve googled radiation and |
how it works and they ask us about how much dose they’re getting and all of that stuff cuz they’re basically knowledgeable.

And knew everything. And the doctor was like, this man speaks at the level of doctors. So it’s like for patients like that, they know everything about their surgery, they know everything about the doses, they know the studies, they know everything. So gauging on those patients, they can be very involve in their QA and the safety and accuracy of their delivery because I think that they know a lot. And I know, like, for some Breast patients, they know where their surgical scar is. They know what should be boosted, or, especially for laterality, definitely patients can be a part of their QA I think. And that too is personality and patient dependent.

Table 19: Theme 2(patients have heightened awareness during treatment that could help or hinder engagement) as identified from follow-up focus groups with radiation therapists.

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<th>Participant Quote</th>
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<td><strong>Table 19a: Patients notice errors or discrepancies related to physical aspects of treatment</strong></td>
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| FG3P3 – PG3 | Participant 3: With Bolus usually.  
Participant 3: “How come you didn’t put the sticky stuff on?”  
Participant 3: Um, or “You didn’t ask me for my birthdate.” “Oh you didn’t ask me for my birthday today” |
| FG3P6 – PG6 | Not so much of a, you asking them but you telling them. Like, “We’re putting the Bolus on today” and they’re like “Oh, okay”. If they noticed they had it yesterday and they know that it’s every other day, then that’s when they would say something. Or, for example we’ve had the chest board arm position incorrectly set for the vertical, and the patient goes “this feels different today, something doesn’t feel right” Somebody just didn’t lift up the wrist cuff or didn’t life up the arm cuff. They’re very minor but you know, you kind of just like, Oh ya. Sorry about that. Just adjust it back and “Does that feel better?” and great... |
| FG4P4 – PG5 | I think recently one of the float therapists accidentally set up the bed wrong. It was for another child and the mom noticed. When she came in she said “that’s not his blanket”. Then we checked it. And that was a major, it’s not a major thing but I guess it does affect their trust. They’re like, “you said it was ready for my kid and it’s not” |
| FG3P4 – PG5 | And we’ve have patients who’ve noticed the blocks not put in, as you’re taking them down. It’s happened before. |
| **Table 19b: Patients may perceive discrepancies in treatment accurately or inaccurately** |
| FG3P2 – PG4 | I, we had a patient once uh, he was a prostate IMRT patient who one day, I don’t know, ¾’s of the way through treatment he absolutely insisted that we missed a beam. He always counts the beams, he knows how long each beam is, he’s been through it, and we missed a beam. And...we checked the record, we SHOWED him...
the tracking, um, and uh, and it was very strange because we were really like, you know, you can’t walk away feeling that we didn’t treat a beam, we treated the beam, you know, and we’re trying to reassure him of that, and he walked away more with the attitude of, now, “that’s okay. I know that you missed a beam and you’re never going to convince me otherwise, but that’s okay, its fine” which was very very strange…

| FG3P6 – PG4 | They’ll say things about the timing of it. “Oh, but it only buzzed this many times today, sometimes I count 20 buzzes, but today I only counted like, 15, so why’s it different?” |

**Table 19c: Patients focus on the consistency and continuity of treatment**

| FG3P2 – P3 | But if it’s a brand new patient, or they’ve been moved to a new unit, and then there’s a breakdown on that unit and they don’t know the staff there they don’t feel as comfortable. And if they don’t feel comfortable, they’re more apt to think about, oh, “how do I know this is being handled properly?” right? |

| FG3 – PG4 | Participant 2: Its different staff  
Participant 4: My dose was different today  
Participant 3: Different staff is a big one  
Participant 2: Or they didn’t do that yesterday |

| FG4P3 – PG3 | Participant 3: Well, you also get comments. Like, “I haven’t seen the therapist back to back days since I started treatment”. So I think that makes them a little concerned.  
Participant 3: That there’s no continuity of care. Cause, we have, it’s quite a few people have mentioned, I haven’t seen you in 3 weeks or, I’ve been treated by different people every day. And that makes them nervous. They don’t know we’re transferring our information. |

| FG4P4 – PG3 | When patients are sent over to our unit because there’s an overflow on the other unit’s sometimes we get comments like “is this going to be the same plan? And, you know, we reassure them that the data has been transferred over and it’s the same plan. And usually that’s good enough. |

**Table 19d: Patients may hide or mask anxiety**

| FG3 – PG3 | Participant 3: Sometimes after a machine is broken down, then I mean, you’ll get a patient all settled and they’ll  
Participant 4: is it safe?  
Participant 3: Ya, they’ll say in a kind of a half joking fashion, you know, um, “oh, it’s safe to come in now?” |

| FG3P4 – PG21 | They don’t verbalize it, right? A lot of the times they don’t say anything and there just kind of quiet, they just assume that they’re okay. |
The majority ya. I think they have to trust you to a certain extent in order to put themselves and their body on the bed. But, I mean, you do get the questions or concerns, especially if you have breakdowns and things like that and ? (3:45) afterwards, sometimes they make jokes that aren’t really jokes, you know. “So, is everything working okay?” So, that kind of stuff.

But lots of people are too nervous to say anything because they put all their trust in us, right?

Table 20: Theme 3(*radiation therapists are concerned about affecting trust with patients*) as identified through follow-up focus groups with radiation therapists.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Quote</th>
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</thead>
<tbody>
<tr>
<td><strong>Table 20a: Do not want to inadvertently place onus or responsibility for safety on patients</strong></td>
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<tr>
<td>FG3P2 – PG6</td>
<td>I think where I get uncomfortable is when there comes to be some actual responsibility on the part of the patient, I don’t like that, so, the point about say the Bolus day on and off, if you can, a lot of what we do, the patients do not have the knowledge to understand or critique or raise concerns, but if we can explain to them, this is why you’re having this, this is why its alternating days, um, because we place it on your skin, the machine doesn’t know if it’s there or not. We need to check with that every day so you’re going to hear us talking to you about that. If they understand what you doing and why you’re doing, then there’s a better chance that if we do miss it they’ll know. The other piece of that is for them to be confident enough to actually say “Hey, shouldn’t you be putting that on today? Did you forget the …” you know? And actually point it out.</td>
</tr>
<tr>
<td>FG3P3 – PG7</td>
<td>Right. When you’re saying to a patient “I’m going to ask you for your birthday every day because I want to make sure I’ve got the right person and the right chart. If I was a patient I would say “I want to make sure you’ve got the right chart.” You know, and so a lot of them will come into the room and will automatically say their birthday. So I think it sounds kind of minor but that I think that perhaps is a patient’s responsibility maybe a little bit, but I do feel the responsibility is ours. It’s our responsibility</td>
</tr>
<tr>
<td>FG3P3 – PG14</td>
<td>If anything I think it’s giving out some of the responsibility which is what we talked about earlier, that we don’t actually want to do.</td>
</tr>
<tr>
<td>FG4P2 – PG11</td>
<td>I um, I would be very concerned about the feasibility of doing this for the majority of our patients. I would hazard a guess that maybe 10% of people would be able to do this on a daily basis and not interrupt, I mean not take 15 minutes to do this. And not have this cause a negative effect, rather than…you know the positive effect is to include them in the QA process so they feel more supported. Um, so I’d be concerned about the other 90% where it may cause negative effects. Them starting to feel that they’re responsible for things they never thought they’d be responsible for.</td>
</tr>
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</table>
### Table 20b: Radiation Therapists feel guilt and embarrassment over safety incidents

<table>
<thead>
<tr>
<th>FG3P1 – PG5</th>
<th>With the patients calling us out on forgetting to ask for birthdays I find that feels very embarrassing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FG4P2 – PG5</td>
<td>Well any time a patient tries to say, you know, this was different or something, your heart sinks for a minute. As you’re going through all the things, it’s just to make sure in your mind that you checked everything. So, I think it does give you a little momentary panic.</td>
</tr>
</tbody>
</table>

### Table 20c: Therapists do not want to feel scored or graded by patients

| FG3 – PG13 | Participant 4: Ya but I don’t want them to be scoring me  
Participant 6: Exactly.  
Participant 4: on, like, whether I’m a bit  
Participant 6: No  
Participant 4: Nervous or not.  
Participant 2: I don’t know. If we told all of our patients that I don’t think I’ve missed anything on those notes we’d be  
Participant 4: Ya I know but I don’t want to feel that pressure (Laughter) whether I missed something on the  
Participant 6: Ya |
| FG3 – PG17 | Participant 3: But then you’re grading them  
Participant 2: But then they’re grading us, and it feels more like...  
Participant 4: But then we’re not necessarily engaging them that way I think. It’s just like |

### Table 20d: Trust with patients is an important theme for radiation therapists

| FG4P3 – PG8 | But lots of people are too nervous to say anything because they put all their trust in us, right? |
| FG4P3 – PG2 | And also, day one, more patients, day one, depending on their experience, one, they’re obviously nervous. Once you build a rapport with them they probably trust you a bit more. And also their experiences. If they experienced a machine breakdown or you’re sending them to another unit, then there’s case where they probably don’t trust you and they ask a lot more questions. |
| FG4P6 – PG2 | I think patients that are being transferred sometimes have the most anxiety or, like, you’re not going to drop me? Or they’re really tense when you’re trying to transfer them over. And recently last week we had to transfer quite a few patients, like into |
Paraspinal bodyfix bags, so we actually had to lift them. Or when you’re using (ware? 4:28) lifts, I think, you know, you’re in a more awkward position. So I think patients are a little more wary about do you know what you’re doing, make sure, you know, and they want to reach out and kind of grab you or grab something, um, so we have to remind the always just keep their hands on their chests and just trust us.

Table 21: Theme 4 (patient engagement using a checklist will have unknown effects on multiple clinical factors) as identified through follow-up focus groups with radiation therapists.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Quote</th>
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<tbody>
<tr>
<td>Table 21a: Radiation therapists concerned about affect of checklist on treatment times</td>
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<tr>
<td>FG3P4 – PG9</td>
<td>I think it would be difficult to do this. I really do, with the amount of patients we treat in a day? Every day? I think this would be extremely difficult to keep the flow in the way we work. I think that the idea of some components of it are good. Like, this kind of, if you give this information to someone, then they might realize the importance of it. So sometimes now I think patients don’t realize the importance of certain things in correlation to how good their treatment could be delivered.</td>
</tr>
<tr>
<td>FG4P4 – PG9</td>
<td>And also we have very short booking times.</td>
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<tr>
<td>FG4P3 – PG13</td>
<td>Well, section 2, if you go give them to check this as you’re in the room and they check no then you obviously need to call the doctor to get them seen or someone in the nursing clinic, so you’ve already wasted so much time. And then you’ve got to call new patients. It’s going to take 5 minutes just to walk into the room. Then you’ve got another 5 minutes walking them out, and then, again, you have to fit them in again into your schedule. There definitely is a time crunch but…</td>
</tr>
<tr>
<td>FG4P6 – PG18</td>
<td>That’s what I was going to ask, like, it’s, I’m sure obviously, there are other areas in medicine that use checklists and I’ve heard of, I think, surgery maybe using them. So, but the surgery is a one time thing and you can sit there for 10 minutes and check check check. Okay, put the patient under and do your procedure. But we’re doing 30 procedures a day within 15 minutes, so how are we really going to be, I, I personally don’t think this is feasible, because in the time frame we have, and now with VMat, like, process even 10 minutes, like to shorten the time even more. Like, it’s just another thing for us to fill out on top of all the other things we already fill out</td>
</tr>
<tr>
<td>Table 21b: Checklist could assist in emphasizing safety checks and treatment preparation</td>
<td></td>
</tr>
<tr>
<td>FG3P4 – PG9</td>
<td>I think that the idea of some components of it are good. Like, this kind of, if you give this information to someone, then they might realize the importance of it. So</td>
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sometimes now I think patients don’t realize the importance of certain things in correlation to how good their treatment could be delivered.

But it emphasizes the importance of it though. Some patients just don’t realize it’s that important, like they’ll listen to the spiel, like, when we give them first day education but they don’t, they sometimes, if they don’t actually see it on a piece of paper or they don’t see it on a like, if you say, does your bladder feel full? Then, sometimes they’ll stop and be, oh, I can wait another 10 minutes.

Yes for full bladder empty rectal I don’t know what it’s useful but for but then just in and out. That’s a good reminder to have just before you take them to the treatment room...

Participant 3: You have 2 therapists so hopefully you will remind each other. I don’t think it’s the patient’s responsibility at all. Maybe like as Participant 4 said a little hard to say, make sure your bladder is full and your rectum’s empty. That’s all it takes

Participant 4: Because a daily, almost reinforcement, and daily visual reinforcement, like a mantra to their treatments (Laughter)

If they check now they get a break. If I targeted patients that have preparation guidelines, ‘cause those patients never follow their guidelines. And they don’t understand the repercussions of it, that it is important to their treatment. I mean, I haven’t treated on Team 3 that much, but these patients never care if their bladder is full or not because they don’t realize the long-term effects of this. And by having this, if you targeted this, on ? (stomach? 32:16) patients and prostate patients first, or, whatever, Gynae, I think that would be a good group for. Because they need to be, I think those people of all don’t realize their interaction in treatment is quite important.

Table 21c: Checklist could facilitate communication between patients and radiation therapists

Well I think they’d be more engaged because of that though. They would be more apt to ask a question later on, so “oh, that was a little bit different today. What was that about? And it might not even be accusatory. It might be a genuine question. “I noticed something was a little bit different” and they may feel a little more comfortable stating that because we’ve offered up, you know? We know what we’re doing. We checked these things. Do you want to know more about it? Even just asking them might make them more... apt to, bring up topics.

They might wait to see the doctor next week. They may not mention it. They cross their fingers that it’s okay but they worry about it. But if they feel comfortable they’ll say “I heard that sometimes people have a boost. Should I be having a boost? What’s that all about?” and then you can address it. That’s what you want, right?

Or when you move the mask when you notice that the person’s wriggling around or something and they’ll sit up and drink some water, or whatever it is they need for that moment until they’re ready. And so this question at the end so patient comfortable with today’s treatment, I mean, is that also an interpretation so that you could open up the conversation? Let’s say the patient said “Well, maybe, you
know, I feel as though my back is a little sore” and stuff. That’s when you address it. Okay, if we put a pad under there, tomorrow why don’t we try that? And then, is that, like, sort of going with that question? (42:04)

FG4P2 – PG22

You know, we’re going to be asking you your birthdate every day, we’re going to ask you your prep, you know, make sure you’re comfortable. If you notice anything’s different let us know, um, and, you know, we could have a poster on the wall, if you ever need a refresher and you know what to do. If you need to be reminded what’s on the checklist any day, and then do that twice during the treatment and that’s, then, a physical checking off and breaking it down.

Table 21d: Checklist could affect patient anxiety levels positively or negatively

FG3P3 – PG17

You know what I mean? Look at it from the other side and say alright. I mean, let’s be honest, we do forget to ask questions, like the birthdate. So they’ll say “They didn’t ask me that today. ”What if I got somebody else’s treatment?” So, I think for the patient it might to suddenly start to raise some issues that might, “Oh, they didn’t’ ask me that, or did they, and I don’t remember?” Because they do have problems with thinking and remembering stuff when

FG3P6 – PG19

I don’t think they feel unsafe. I just think that it might make them feel more at ease.

FG3 – PG22

Participant 3: As long as it doesn’t add to their anxiety. Because I think it’s a very fine line between the two. You want patients to ask appropriate questions. Do they really want to know or is it just going to add to their, which I think we talked about already. Is it going to add to their anxiety, “oh my god, I never thought about that. What if they don’t ask me the right birthday? Like what if they don’t put the jelly on, what if they don’t that?” So, you know, it depends on the patient but is it going to create this monster, it’s going to be very difficult to allay those fears. Whether there’s, you know, I don’t know if it’s right sort of thing, if you don’t think about it, is it really an issue, is it really an issue for you if you don’t think about it? Like I, maybe that’s not the right way to word it.

Participant 4: No I know what you’re saying.

Participant 3: You know what I mean? By putting ideas into people’s heads can sometimes can make things worse for them. Especially with people who are dealing with a cancer diagnosis, perhaps not a good prognosis

Participant 4: Some people are just anxious people. Some people have the best, you know, case scenario

FG4P4 – PG11

But also the ones who have a higher anxiety level need to say “I’m uncomfortable today regarding my treatment”, only because they were never able to really cope with it to that level. So, if there’s side-effects, then it becomes, then they’ll ask you, is there a choice? (Laughter. People talking over one another.) Does that mean I have a say in this?