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Developing a Presimulation Protocol for Prostate Cancer Patients Undergoing Radiotherapy

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Walden University

College of Nursing

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Jennifer Grace Wieworka

has been found to be complete and satisfactory in all respects,
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Walden University
2021

Abstract

Developing a Presimulation Protocol for Prostate Cancer Patients Undergoing Radiotherapy

by

Jennifer Wieworka

MS, York College of Pennsylvania, 2017

BS, York College of Pennsylvania, 2012

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

February 2021

Abstract

Inadequate preparation of prostate cancer patients undergoing radiation therapy (RT) can damage healthy tissue and cause long-term complications. Proper setup can reduce side effects. Currently, there are no standardized guidelines to help prepare patients for prostate radiation. Guidelines will help nurses coordinate care and manage symptoms for these patients. The purpose of this doctoral project was to address the gap in practice of the lack of a standardized process for implementing presimulation interventions for patients with prostate cancer undergoing RT by developing an evidence-based clinical practice guideline (CPG). The practice question for this project focused on the best practices contributing to a CPG for set up patients with prostate cancer undergoing RT treatment. The model guiding the development of a CPG was the Johns Hopkins nursing evidence-based practice model. Sources of evidence that informed the CPG came from these databases: CINAHL Plus with Full Text, MEDLINE with Full Text, PubMed, Ovid Nursing, Embase, ProQuest Nursing and Allied Health Source, and Google Scholar. The project team used the Appraisal of Guidelines for Research and Evaluation (AGREE) II method to assess for the validity of the CPG. A prostate radiation oncologist, RT director, and prostate nurse analyzed the CPG using the AGREE II instrument and indicated validity in the CPG for guiding nurses to appropriate interventions. The recommendation is to implement a CPG with interventions that address bladder and bowel management, image quality, and patient education. The development of CPGs has a potential impact on social change by addressing others' needs, using trustworthy sources for research, and developing guidelines that address cultural consideration of the target population.

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Section 1: Nature of the Project

Introduction

Radiation therapy for the treatment of cancer can have toxic effects on both cancerous and healthy tissue (Graf, Boehmer, Nadobny, Budach, & Wust, 2012). Particular setup can help reduce toxic exposure of radiation to healthy tissue. An adequate setup that spares noncancerous tissue can reduce lifelong bowel, bladder, and sexual function complications for prostate cancer patients (Tsang & Hoskin, 2017). However, there are no clinical practice guidelines (CPGs) for best practice interventions for prostate radiation setup at the practice site. With this project, I aimed to determine what best practices contribute to a CPG for setting up patients with prostate cancer undergoing radiation therapy treatment. CPGs improve care equity, reduce variations in care, assist in social change, and define best healthcare practices (Kredo et al., 2016). CPGs also allow the nurse to identify barriers and choose more appropriate and achievable interventions (Institute of Medicine [IOM], 2011).

Problem Statement

The practice problem addressed in this project was the inadequate preparation of prostate cancer patients undergoing radiation therapy, starting with the planning of the computerized tomography (CT) scan. This scan is required before beginning the 8-week radiation treatment (Johns Hopkins Medicine, n.d.). This planning session is referred to as a simulation. Patients must understand the importance of adequately preparing for the planning CT because when patients are inadequately prepared for simulation; multiple

CT scans may be required, resulting in increased radiation exposure for the patient and delays in the CT scanner schedule. In the specialty of radiation oncology, proper setup and immobilization for treatment are of utmost importance to reduce prostate motion; reduced prostate motion has been shown to minimize damage to healthy tissue during treatment (Darud, Giddings, Keyes, McGahan, & Tyldesely, 2010). Damaging healthy tissue can contribute to short- and long-term side effects caused by the treatment (Maggio et al., 2017). Treatment for prostate cancer requires that the patient has a full bladder and rectum empty of stool and flatulence (Yaver, 2015). Adequate bowel and bladder setup reduces prostate movement during therapy and has been associated with improved clinical disease-free survival (Darud et al., 2010; Maggio et al., 2017).

The first opportunity patients have to experience this setup is during the simulation appointment. Simulation for radiation therapy treatment is a nondiagnostic CT scan for planning purposes where the patient is positioned like the patient is getting radiation treatment (Johns Hopkins Medicine, n.d.). These patients must duplicate this alignment preparation every day, 5 days a week, for 8 weeks (Memorial Sloan Kettering Cancer Center, n.d.). Due to the combination of the difficulty of obtaining a full bladder and an empty rectum and the importance of this setup, patients often do not obtain the correct setup during simulation (Maggio el at., 2017). When patients cannot adequately set up, they need to be resimulated, which consists of an extra CT scan and, therefore, additional radiation to healthy tissues. The waiting period can be uncomfortable for the patient. Additionally, these patients are likely to be rescheduled later in the same day as

their first scan, which requires them to spend a significant amount of time in the clinic awaiting resimulation.

At the project site, there are currently no CPGs for prostate cancer presimulation interventions. In this project, I addressed this gap through the creation of a CPG for use at the clinic. In this setting, nurses are responsible for educating patients regarding radiation treatment and initiating interventions, such as bowel and bladder preparation regimen, for preparing the patient for successful simulation. Developing a CPG can help support nurses to prepare the patient better to implement these interventions.

Purpose Statement

The purpose of this doctoral project was to address the gap in practice related to the lack of a standardized process for implementing presimulation interventions for patients with prostate cancer undergoing radiation therapy by developing an evidence-based CPG. The practice problem addressed in this project was the inadequate preparation of prostate cancer patients undergoing radiation therapy for their planning CT scan. The guiding practice-focused question for this doctoral project was: What best practices contribute to a CPG for preparing patients with prostate cancer undergoing radiation therapy treatment? I intended this doctoral project to address the gap in practice by evaluating the quality of literature currently available on interventions to minimize prostate movement and reduce radiation to healthy surrounding tissue and practically synthesizing the evidence into a CPG.

Nature of the Doctoral Project

CPGs are statements developed to optimize patient care informed by a systematic review of the evidence (Kredo et al., 2016). A panel of experts and key stakeholders should be involved in developing CPGs (IOM, 2011). For this project, I used peer-reviewed articles involving experimental and observational studies and systematic reviews, expert opinion, and publically available patient education materials from National Cancer Institute-designated organizations for the past 5 years. I obtained these resources by searching databases, including CINAHL, MEDLine, Embase, and ProQuest. Additionally, Google Scholar was searched for other resources. I consulted with prostate-specialized radiation oncologists and included them in the project team to obtain expert opinions. The Johns Hopkins nursing evidence-based practice (JHNEBP) model was used to grade the evidence and associated tools to synthesize and organize the evidence. Once the CPG was developed, it was appraised by the project team using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument to verify that the guidelines were methodologically rigorous and free of bias. The project team determined how the guideline needed revision and then presented it to stakeholders. This process enabled the doctoral project to fulfill its purpose and fill the gap in practice involving the lack of clinical guidelines for prostate cancer presimulation interventions.

Significance

The impact of patients being inadequately prepared for simulation reaches across disciplines. Patients can get frustrated by the process when unprepared, undergo multiple

CT scans, and be delayed until later in the day. Nurses are impacted by the lack of standardized presimulation interventions and are searching for different techniques to best help patients with issues involving the need to be frequently reeducated. Radiation therapists must rearrange the machine schedule when patients are delayed due to inadequate preparation. Front desk staff are affected by apologizing and attempting to preserve customer satisfaction for other patients still awaiting their now delayed treatments. Radiation oncologists may face backlash from staff and patients because of the frustration with the process.

Besides having a direct impact on the local clinic, the development of a CPG for patients undergoing prostate radiation can contribute to nursing practice by reinforcing the concept that nurses can practice to their fullest scope by coordinating care and symptom management. Nurses may find this guideline beneficial in acting as the multidisciplinary leader in ensuring patients have various interventions to improve outcomes. Furthermore, the project team's findings in the doctoral project can expand the base of professional nursing knowledge.

The development of this CPG has the potential for transferability to other practices outside of the project site clinic. The guidelines can be locally transferred to other clinics within the health system for patients with prostate cancer. On the Oncology Nursing Society discussion board (https://communities.ons.org/), the topic of bowel and bladder preparation comes up frequently. Within the United States, there are no societal or publicly available guidelines that address presimulation interventions for patients

undergoing prostate radiation therapy, so there is potential for national transferability as well. The Global Cancer Observatory (2018) reported that prostate cancer is the second most common cancer in men globally and is expected to increase in prevalence over the next 2 decades. While the guidelines may recommend interventions or techniques that are not currently available everywhere globally, there is great potential for international transferability for most clinical guidelines. Especially in areas where imaging technology is not as advanced, it is important to reduce prostate motion; reducing prostate motion can spare healthy tissue and improve mortality (den Harder, van Gils, Kotte, van Vulpen, , & Lips, 2014).

Developing CPGs has potential implications for positive social change by establishing evidence-based interventions in an easy-to-use format for use in small, generalized radiation clinics and large, highly specialized academic institutions. Additionally, this project aligns with Walden University's (2017) mission for social change by addressing others' needs, using trustworthy sources for research, and developing inclusive guidelines that address cultural consideration of the target population.

Summary

Undergoing cancer treatment can be frightening and anxiety-producing for patients; therefore, patients must trust the healthcare team to provide the best treatment. However, finding the best evidence-based practices (EBPs) can be time-consuming and often confusing for the healthcare team. CPGs can quickly guide practitioners to

evidence-based interventions for specific situations. In Section 1, I described the gap in practice and project question, the nature of the project, and the significance of the project to stakeholders. In Section 2, I will introduce the model that framed the project, the evidence supporting the project, and my role in the CPG development.

Section 2: Background and Context

Introduction

Preparing patients undergoing radiation oncology to set up the same way every day for treatment is important to ensure they receive the planned radiation to cancerous tissue. This setup can be obtained with special pillows, masks, and surgical interventions (Memorial Sloan Kettering Cancer Center, n.d.). Patients receiving radiation for prostate cancer have a challenging setup; they must have an empty rectum and a full bladder, and often, they struggle with or cannot obtain an appropriate setup for treatment (Maggio et al., 2017).

The practice problem addressed in this project was the inadequate preparation of prostate cancer patients undergoing radiation therapy for the planning session. There are no standardized procedures to guide staff to help prepare the patients for setup. Through this project, I sought to identify evidence to support the development of a CPG for presimulation preparation for patients with prostate cancer undergoing radiation therapy. Identifying the information and developing a CPG addressed the gap in practice involving the lack of a standardized process for implementing presimulation interventions for prostate cancer patients undergoing radiation therapy. In this section, I review the following related to the development of CPGs: guiding theories and models, relevance to nursing practice, the context of implementation, and the role of the DNP student.

Concepts, Models, and Theories

Healthcare providers are tasked with giving patients the best care; unfortunately, providers do not always have quick access to evidence-based guidelines that support that goal. CPGs are evidence-based references for healthcare providers. According to Jeffs et al. (2013), nurses prefer to receive evidence-based information presented in an easy-to-understand and succinct format. Jeffs et al. identified three factors necessary to address when presenting evidence-based interventions to nurses: (a) the information needs to be easy to take in, (b) specific to the population/care provided by the staff, and (c) come from substantial sources.

The model used to guide the development of the CPG for this project was the JHNEBP model. The JHNEBP model is used to evaluate the level and quality of each evidence source, summarize the evidence, and then synthesize the collective evidence for quality and strength (Dearholt & Dang, 2012). One benefit of using the JHNEBP model is the inclusion of internal and external forces (i.e., regulatory and accreditation bodies) when considering the application of identified best practices. The model also supports users through problem identification, gathering evidence, and translating into practice (Dearholt & Dang, 2012). The first 10 steps of the JHNEBP model are applicable to the CPG development process:

1. Recruit interprofessional team.
2. Develop and refine the EBP question.
3. Define the scope of the EBP and identify stakeholders.

4. Determine responsibility for project leadership.
5. Schedule team meetings.
6. Conduct internal and external searches for evidence.
7. Appraise the level and quality of each piece of evidence.
8. Summarize the individual evidence.
9. Synthesize overall strength and quality of evidence.
10. Develop recommendations for change based on evidence synthesis (Dearholt & Dang, 2012, p. 226).

Steps 11–18 focus on the translation of evidence into practice and dissemination of findings (Dearholt & Dang, 2012).

Relevance to Nursing Practice

While large professional organizations like the American Society for Radiation Oncology have not developed CPGs for bowel and bladder regimens for prostate cancer patients, there is evidence in the literature for independent interventions for simulation preparation. Waddle et al. (2018) presented bladder regimen filling recommendations that focused on the importance of extra counseling for patients older than 70 years old. Yahya et al. (2013) compared dietary guidelines, microenemas, and no preparation and found microenemas were significantly ($p < 0.001$) superior to reduce prostate motion during treatment. Darud et al. (2010) found no significance in prostate motion between a full bladder with an empty rectum protocol and a full bladder with no specified rectum protocol. Graf et al, 2012) presented data on patient instructions for bladder filling and

the placement of fiducials (i.e., invasively placed gold markers that are used to indicate the location of the prostate on imaging scans) compared to skin marks for reducing prostate movement. Additional sources of evidence include expert recommendations found in patient education materials from large cancer centers, such as Memorial Sloan Kettering Comprehensive Cancer Center (n.d.), which recommended using psyllium 7 days before simulation and a Fleet enema 3 hours before simulation. Additionally, Rogel Cancer Center (2017) recommended bladder filling by voiding 1 hour before the simulation appointment and drinking two and a half cups of water. The amount and variation of evidence indicate that radiation oncology specialists continue to search for presimulation interventions for patients undergoing radiation treatment for prostate cancer.

Medves et al. (2010) identified that CPGs are a way to improve overall care as evidenced by improved patient outcomes, patient care, staff satisfaction, and cost-effectiveness. The IOM (2011) reported that CPGs are useful in specialized areas as recommendations but not as rules. Currently, there are no published guidelines on interventions to help patients with prostate cancer prepare for simulation. Because the providers do not write orders for the bladder and bowel protocol, nurses are left to attempt trial and error to help patients prepare based on experience.. Boehmer et al. (2006) were unable to reach a consensus on best practices to help set patients up for treatment.

Nurses in radiation therapy maintain responsibility for helping patients prepare for treatment. For patients with prostate cancer, the nurse provides presimulation interventions to help reduce prostate movement and, therefore, toxicity during and after treatment. Boehmer et al. (2006) identified several dosimetric guidelines to reduce the irradiation of healthy tissue but could not provide guidelines on bowel and bladder regimens to reduce toxicity. Since Boehmer et al.'s guidelines were published, more studies have been conducted to identify the appropriateness of individual interventions. For example, there are several studies assessing bladder filling protocol. Most of the studies are aimed at identifying the appropriate volume of fluid to consume to obtain a full bladder (e.g., Braide et al., 2019; Maggio et al., 2017; Nathoo et al., 2018), but Tsang and Hoskin (2017) identified that there was no statistically significant difference for acute and intermediate toxicities in terms of empty and full bladders for prostate radiation. To develop a CPG for this project, I collated these individual recommendations into one easy-to-navigate document for radiation oncology nurses.

Local Background and Context

Evidence from the project site that supports the relevance of the problem at the local level manifests as delays in schedules due to inappropriate preparation for simulation, patient-reported qualitative comments obtained from the online patient satisfaction survey, and nurse displeasure at the situation taken from the employee engagement survey and clarified during a nurse-only meeting on results. Nurses viewed

the lack of standardized guidelines for prepping patients for prostate radiation therapy as evidence of not having the tools required to complete the job.

The identified setting for this project site was the radiation oncology department of a large academic health system in a sizeable metropolitan area in the northeast United States. This department encompasses six clinics, including four hospital-based and two satellite campuses. This project was completed in one of the hospital-based clinics that manages the majority of the patients with prostate cancer. This clinic supports a hospital that meets the local urban community's needs and is a destination hospital for national and international patients.

There was support for this project from departmental leadership, prostate radiation oncology specialists, and the primary nursing team that supports these patients. Stakeholders consisted of prostate radiation oncologists, RNs, a clinical coordinator, a clinical nurse specialist, radiation therapists, clinic administration, and patients. Between the two full-time prostate care providers at the project site, approximately 32 patients are consulted for treatment per month, with about 25 patients actively receiving treatment at any given time. Current practice for how patients are educated to prepare for simulation varies depending on the radiation oncologist and the nurse consulting the patient. For example, one provider recommends that the patient voids 1 hour before simulation then sips 32 ounces of water, and another provider tells the patient to void and then drink until his bladder is comfortably full. Another variation is the recommended bowel regimen: One provider suggests taking sennoside-docusate, while the other recommends

psyllium. Practice varies between nursing staff with one of the primary prostate care nurses calling patients either the Monday or Wednesday before simulation to review the bowel and bladder protocols, while the other hands the protocols to the patient, on a sheet of paper, at the time of consultation.

Role of the DNP Student

I have been employed by the project site for 3.5 years as the clinical nurse specialist in radiation oncology. In my role, I monitor metrics such as patient satisfaction, clinic productivity numbers, and safety metrics. I work across all six clinical sites to standardize processes, policies, and procedures to improve patient safety and quality of care. I am consulted to help with complex patient cases and have been asked by the multidisciplinary team to identify best presimulation practices to improve the ability of patients with prostate cancer to complete their treatment planning on the first attempt. With my training on EBP and project management, I led the project to identify best practices and applicability to the project site. I worked with the multidisciplinary team to better understand CPG implementation barriers to address these barriers during the CPG development process.

My motivation for this doctoral project came from several factors. First, I was concerned about nurse job satisfaction. Our nurses reported in the employee engagement survey that they do not have the tools they need to do their job. The primary prostate care team nurses have also verbalized dissatisfaction with informing prostate patients on how to prepare for simulation. Providers have different expectations for patient preparation,

and the nurses are keenly aware that the interventions they are instituting are not evidence based. Another motivation for this project was the patients' quality of life. Patients anecdotally report how uncomfortable and challenging it is to maintain a full bladder and empty rectum. Patients have even more difficulty maintaining the full bladder when there is a delay in the treatment schedule. Delays as short as 15 minutes have resulted in episodes of incontinence. Being incontinent can be a mortifying experience for patients and further delay that patient's treatment while the patient's bladder refills. Finally, I am driven by clinic efficiencies. When one patient with prostate cancer is delayed, it creates what staff calls a domino effect, and all of the other patients with prostate cancer are delayed. When the prostate patients are delayed, they have challenges holding a full bladder, often void, and then restart the bladder filling process. My wide-ranging motivations led me to want to create the CPG and combat any bias I may have contributed to the project, and to mitigate this bias, I selected expert project team members to evaluate the CPG using the AGREE II instrument.

Role of the Project Team

The project team was an interdisciplinary team consisting of me, the radiation therapy director, a radiation oncology nurse specializing in prostate cancer, and a prostate radiation oncologist. I contacted the various team members in person, and they agreed to participate in the project. Before the first meeting most of the literature was collected and the grading process had started. The team first met to review the literature and grading of evidence based on the JHNEBP model. At the start of the project, the plan was for the

team to meet weekly, either in person or virtually, to review progress on grading and evaluating the literature for recommendations. The group was not able to meet as frequently as planned due to the COVID pandemic. At the start of project implementation, the team debriefed on the practice problem and current practice at the practicum site and were educated on the AGREE II instrument for CPG evaluation. The individuals in the group also shared their experiences with the practice problem. They provided contextual insight into the challenges surrounding the problem and helped identify potential barriers to implementing interventions recommended by the literature.

Summary

Previous research on presimulation intervention focuses on individual interventions, but there is no evidence in the literature about attempts to combine best practices into CPGs for presimulation interventions for patients undergoing radiation therapy for prostate cancer. In Section 2, I described how the JHNEBP model can guide project teams to collect and synthesize evidence for the development of CPGs. In this section, literature was reviewed to highlight the importance of this project to nursing practice and the role of the DNP scholar and the project team were described. In Section 3, I will discuss how evidence was collected, analyzed, and how the team validated the CPGs.

Section 3: Collection and Analysis of Evidence

Introduction

The purpose of this doctoral project was to address the gap in practice of the lack of a standardized process for implementing presimulation interventions for patients with prostate cancer undergoing radiation therapy by developing an evidence-based CPG. Kredo et al. (2016) described CPGs as a way to present concise information to improve efficiencies and close the gap in practice with available scientific evidence. In the last 5 years, researchers have identified best practices for individual interventions to improve patient setup for simulation for radiation therapy (Tsang & Hoskin, 2017), but no guidelines have been developed to recommend a collection of best practices. In this section, I review the practice-focused question and the process involved with collecting and analyzing evidence sources.

Practice-Focused Question

There are no societal or publicly available CPGs for setup for treatments to help nurses prepare patients with prostate cancer undergoing radiation therapy. At the practicum site, nurses have verbalized frustration at the lack of standardization and absence of guidelines for helping patients prepare for prostate radiation therapy. The practice question for this project was: What best practices contribute to a CPG for preparing patients with prostate cancer undergoing radiation therapy treatment? Moore-Higgs et al. (2003) reported that since the early 1990s, the radiation oncology nurse's role consisted of independently managing symptoms through nonpharmaceutical means as

well as work in close collaboration with the radiation oncologist for pharmaceutical/interventional symptom prevention and management. Without standard CPGs for presimulation interventions, nurses are challenged to provide consistent, evidence-based interventions for these patients.

Sources of Evidence

To address the practice-focused question, I collected evidence published within the last 5 years. Evidence from expert opinion is not sufficient alone to address the gap in practice of the lack of a standardized process for implementing presimulation interventions by developing an evidence-based CPG. For this project, I followed the guidelines in the Walden University (2019) *Manual for Clinical Practice Guideline Development*. The sources of evidence used included primary sources (i.e., original works of evidence obtained through research), translational literature (i.e., CPGs), and evidence summaries like systematic reviews (see Dearholt & Dang, 2012).

I conducted a literature review using databases accessible through the Walden University Library, including CINAHL Plus with Full Text, MEDLINE with Full Text, PubMed, Ovid Nursing, Embase, ProQuest Nursing and Allied Health Source, and Google Scholar. The following terms were used in the literature search: *prostate*, *prostate cancer*, *radiation therapy*, *radiotherapy*, *simulation*, *bladder filling*, *bladder regimen*, *bladder protocol*, *bowel emptying*, *bowel regimen*, *bowel protocol*, *fiducials*, *prostate motion*, *clinical practice guideline*, *AGREE II*, *implanted rectal spacer*, and *hydrogel*. Additionally, the Boolean strings *and/or* were used to carry out a more

comprehensive search. From the results, I completed citation chaining to ensure a thorough search and identify historical research. Publication years were initially limited to 2014–2019, but I also conducted an additional search to update any articles added in 2020 to include all up-to-date articles. Sources of evidence were not be limited to those published in the United States, so spelling variation was included to account for international studies.

The evidence found in the literature review helped meet the purpose of this doctoral project by addressing the gap in practice of no standardized process for implementing presimulation interventions for patients with prostate cancer undergoing radiation therapy. This doctoral project addresses the gap in practice by evaluating the quality of literature currently available on interventions to minimize prostate movement and reduce radiation to healthy surrounding tissue. I used the tools provided by the JHNEBP model to organize and guide the analysis of the evidence. The grading and scoring of the evidence in the literature review using the JHNEBP model is located in Appendix A. After evaluating the quality of the evidence, it was synthesized into a CPG.

I maintained ethical protections during the doctoral project by following the Walden University (2019) *Manual for Clinical Practice Guideline Development*. The project was submitted to the Walden University Institutional Review Board and approved (approval number 01-02-20-0974445) before data were collected. No patient personal health information data were gathered, stored, or utilized for this project.

Analysis and Synthesis

After developing the proposed guideline, the project team reviewed the guideline using the AGREE II instrument. The AGREE II instrument is a validated and reliable tool containing 23 questions, organized into six different domains, that aims to evaluate whether guidelines are free of bias and have been developed methodically and rigorously (AGREE Trust, n.d.). I revised the proposed guideline based on the panel's recommendations and had them complete a second review. Once the CPG was finalized and the doctoral project was completed, the proposed guidelines were shared with clinic administration, and upon their approval, with the multidisciplinary team.

Summary

In Section 3, I described the participants, procedures, and protections that supported this project. The process of analysis and synthesis was also presented. In Section 4, I will review the findings and recommendations from the development of the CPG.

Section 4: Findings and Recommendations

Introduction

Appropriate preparation and setup for prostate cancer radiation therapy can reduce damage to healthy tissue; however, there is a gap in practice that front-line staff has no standardized guidelines from the practice site or industry leaders to prepare patients for prostate therapy setup. The practice-focused question for this project was: What best practices contribute to a CPG for preparing patients with prostate cancer undergoing radiation therapy treatment? The purpose of this doctoral project was to address the gap in practice of the lack of a standardized process for implementing presimulation interventions for patients with prostate cancer undergoing radiation therapy by developing an evidence-based CPG.

The sources of evidence used to create the CPG were primary sources that included translational literature, evidence summaries like systematic reviews, and expert opinion. I obtained evidence through a review of the literature with the publication years of 2014–2020 using databases accessible through the Walden University Library. Additional evidence was added to the results by citation chaining to ensure a thorough search. I then evaluated the results using the JHNEBP model for evidence level and quality of the study. Recommendations for inclusion in the CPG were considered based on quantity, quality, the patient feedback reported in the studies, financial impact, and potential applicability into the clinic.

Findings and Implications

The project team reviewed and analyzed the CPG for validity using the AGREE II instrument. I used the AGREE II instrument instructions to score the CPG based on the project team's evaluation. Each project team member, when asked to participate in the project, was introduced to the concept of the AGREE II method. After developing the CPG, I reviewed the AGREE II instrument with each team member and gave them each a copy of the AGREE II instrument, the CPG, and the literature review. The project team members were to return their completed AGREE II tools within 1.5 weeks; however only 1 of the 3 finished it in that period. Two team members needed an additional 2.5 weeks to complete the AGREE II instrument. Two of the project team members supplied comments in addition to their scores of the questions, and the third team member made no comments. The individual reviewers' scores are presented in Table 1.

The AGREE II instrument contains 23 questions, organized into six different domains, followed by two items that assess the overall score and recommendation for using the CPG evaluated (AGREE Research Trust, n.d.). Each item within the domains are rated as 1 (*strongly disagree*) to 7 (*strongly agree*). However, scoring is represented as a percentage by each domain and is calculated by totaling the obtained score: The minimum possible score over the maximum possible score for the domain minus the minimum possible score (Brouwers et al., 2010). Overall, the expert panel recommended the CPG be published with modifications.

Table 1

Results of the AGREE Instrument Provided by the Expert Project Team

Domain	Expert 1	Expert 2	Expert 3
Domain 1			
Item 1	7	3	6
Item 2	7	4	7
Item 3	7	7	7
Domain 2			
Item 1	7	4	5
Item 2	5	3	5
Item 3	6	7	7
Domain 3			
Item 1	7	7	7
Item 2	6	7	6
Item 3	7	7	7
Item 4	6	7	7
Item 5	5	7	6
Item 6	6	7	6
Item 7	5	6	6
Domain 4			
Item 1	7	6	6
Item 2	6	7	7
Item 3	7	7	7
Domain 5			
Item 1	5	6	7
Item 2	6	7	7
Item 3	4	3	5
Item 4	4	2	6
Domain 6			
Item 1	7	7	7
Item 2	6	7	5
Total	52	52	57
Overall Guideline Assessment			
Item 1	6	6	6
Item 2	Yes	Yes with modification	Yes with modification

Domain 1

Domain 1 of the AGREE II instrument focuses on identifying the robustness of the scope and purpose of the CPG (Brouwers et al., 2010). This section has three questions, and the project team scored Domain 1 as 85.19% overall. One reviewer asked for a clarifying comment about the goals of the CPG. During the review process, the project team members' answers were blinded to me; however, the nurse team member followed up after submitting her responses to state that she understood the goal of the CPG but was seeking more clarification on the downstream effects of the implementation of the CPG.

Domain 2

Domain 2 of the AGREE II instrument focuses on identifying the extent of stakeholder involvement (Brouwers et al., 2010). This section also has three questions; the overall score for Domain 2 in this project was 74.07%. One area of improvement noted was that the views of the target population had been obtained through the literature review findings and that there were limitations within the studies used to develop the CPG.

Domain 3

Domain 3 of the AGREE II instrument concentrates on the rigor of developing the CPG (Brouwers et al., 2010). This section contains eight questions; however, one question was excluded in this project as the CPG lacked a procedure for updating the guideline. When the CPG is finalized, the supporting organization will determine an

appropriate procedure and frequency for updating the CPG. The overall score for Domain 3 was 90.48%. Comments in this section reflected that the reviewers observed the recommendations were clear and based on the literature review.

Domain 4

Domain 4 of the AGREE II instrument sought to identify the clarity of the recommendations and management presentation (Brouwers et al., 2010). Domain 4 comprised three questions and was the highest-scoring domain from the reviewers at 94.44%. The project team commented that the recommendations were clear and specific, and key recommendations were easy to read in the table format.

Domain 5

Domain 5 of the AGREE II instrument assesses the applicability of the CPG to practice, and there are four questions in this domain (Brouwers et al., 2010). The overall score for this domain was 69.45%. The project team made comments in the AGREE II instrument of additional barriers, such as cost information that the CPG did not address. The project team also pointed out that there was a lack of description of how users would measure the CPG as successful.

Domain 6

Domain 6 of the AGREE II instrument focused on assuring there was editorial independence in that the CPG was free from competing interests or those interests were recorded (Brouwers et al., 2010). Domain 6 has two questions, and the overall score was

80.49%. The reviewers commented that it was clearly stated that there were no competing interests from funding bodies.

Overall Guideline Assessment

The overall guideline assessment section in the AGREE II instrument is comprised of two questions (Brouwers et al., 2010). The first question was to rate the overall quality of this guideline on a scale of 1 (*lowest possible quality*) to 7 (*highest possible quality*), and the reviewers unanimously scored this question a 6 out of 7. The second question was "I would recommend this guideline for use." Reviewers could choose: yes; yes, with modifications; or no. One reviewer chose yes, while the other two chose yes, with modifications. No reviewers added notes or comments in the overall guideline assessment section.

One area outside the scope of the development of this CPG was updating the CPG. When a final determination for long-term ownership of the CPG is made, the procedure will be added based on that organization's practices. Another limitation was the lack of cost analysis in the literature review on the various interventions guiding the recommendations; this limitation was reflected in the project team's scoring.

The CPG analysis shows that there are EBPs to develop a CPG to guide radiation oncology healthcare workers to choose more appropriate interventions to improve the planning session for prostate radiation therapy. This can positively impact individual patients by improving their therapy planning session, the population of radiation oncology patients by improving clinical flow, and healthcare institutions by improving

the workflow to the point of cost avoidance. The potential implication for positive social change is that by making this CPG available through publication, easy-to-use, evidence-based interventions would be made available to patients worldwide, from small, generalized radiation clinics to large, highly specialized academic institutions.

Recommendations

Within the CPG, recommendations are broken down into four categories: bladder management, bowel management, imaging/treatment quality, and patient education. By implementing these practice guidelines, radiation oncology practitioners have a standardized tool that they can use to inform interventions for every patient's presimulation. Additionally, the CPG provides secondary recommendations, which may be used for patients who need additional interventions and should not be considered for every patient.

Bladder management interventions had the widest variety of practices in the literature; however, the recommendations that were made in the CPG had some of the strongest studies supporting the findings. Recommendations include having the patient empty their bladder, then drink 500 mL of water finishing 60 minutes before the simulation/treatment (see Maggio et al., 2017, Nathoo et al., 2018; Holden, Stanford, D'Alimonte, Kiss, & Loblaw, 2014). Fujioka et al.'s (2016) findings informed the recommendation that a goal bladder volume on ultrasound is between 100 mL and 250 mL at the time of the simulation. The final recommendation for bladder management is for individuals undergoing prostate radiation to consume at least 1.5–2L of water daily

(see Oates et al., 2014; Smitsmans et al., 2017; Sunshine Coast Hospital, 2017; Yaver et al., 2015). Bladder management is one category of interventions for presimulation for patients with prostate cancer. Another important category is bowel management.

Proper bowel management helps keep the bowel away from the area receiving radiation for patients receiving prostate radiation (Yaver et al., 2015). Specifically, patients should have an empty rectum for treatment; to accomplish this, they should have a bowel movement daily and pass flatulence 1 to 2 hours before treatment (Maggio et al., 2017; Rogel Cancer Center, 2016). Patients should eat an antiflatulence diet by avoiding fermentable carbohydrates, carbonated beverages, dairy, and high-fat foods (Cancer Center of Santa Barbara, 2017; Hosni et al., 2017; Oates et al., 2014; Smitsmans et al., 2017). Patients should also change their eating style to improve gas management; they can do this by reducing aerophagia (i.e., excessive and repetitive air swallowing; Cancer Center of Santa Barbara, 2017; Oates et al., 2014; Smitsmans et al., 2017; Sunshine Coast Hospital, 2017). Additional steps for bowel management include taking an osmolotic laxative nightly, starting 5 days before simulation, and continuing throughout treatment and reducing as needed for excessive stools (Bayles, 2015; Sunshine Coast Hospital, 2017; Weston, 2019). Take a Fleet enema if unsuccessful with other interventions to have a bowel movement daily, or if the rectum is greater than 3.5 cm on simulation CT (McNair et al., 2011Memorial Sloan Kettering Cancer Center, 2018). The final recommendation for bowel management is to increase exercise daily to promote bowel motility (Oates et al., 2014; Smitsmans et al., 2017; Sunshine Coast Hospital, 2017). In

addition to bowel and bladder recommendations for patients, there are imaging/treatment recommendations and patient education recommendations that radiation therapy teams can use to help patients be successful with simulation.

A recommendation to improve imaging quality is to give patients consistent appointment times; this allows them to get into a routine and have them set up the same (see Yaver et al., 2015). Providers can also consider the use of interstitial biodegradable balloons (i.e., hydrogel spacers); when hydrogel spaces are used, they should be injected at least 3–5 days before the patient is simulated (Uhl et al., 2013). As techniques improve, there is still a basic human connection between patients and providers, and patient education has an important role in preparing patients for their simulation.

Radiation oncology staff should provide verbal and written specialized patient education to patients (McGuffin et al., 2018). Whenever possible, add appropriate images to patient education; customizing the images to the treatment center will help patients associate what they were taught and may help them feel more comfortable (Osmar & Webb, 2015). When providing education, radiation oncology staff should speak with plain language, use analogies, and repeat information; if patients need clarity, direct them to a radiation oncologist, and confirm the patient's understanding with the teach-back method (Schnitzler et al., 2017). The full CPG is located in Appendix B for reference.

Contribution of the Doctoral Project Team

At the start of the project, the doctoral project team was contacted about participating in the project. The project team consists of me, the radiation therapy

director, a primary prostate cancer radiation oncology nurse, and a prostate radiation oncologist. Project team members informed me of potential interventions/keywords to include in the literature review when searching for best practices based on discipline-specific interventions. At the start of the project, the intention was to have the team meet in person; however, limitations imposed by COVID-19 and team member schedules prevented this, and I met individually with team members regarding the project. After I completed the literature review and grading of the articles using the JHNEBP model, individual meetings with the project team members occurred to review findings and identify potential recommendations based on quality and frequency of evidence. After the CPG was developed, the project team assessed the CPG with the AGREE II instrument for validity. The prostate expert physician team member verbalized the importance of the CPG and DNP project findings. He noted that he felt for radiation oncology professional organizations to accept the CPG, the CPG would have to have more depth, and the current version of the CPG would be a good summary for the overall CPG to be published.

After the DNP doctoral project, the project site and project team members have expressed interest in researching the CPG recommendations. The team would like to compare the standard of care (no defined interventions) and the application of the CPG recommendation. They propose measuring success by evaluating the frequency patients undergoing radiation for prostate cancer need to have cone-beam CT images before treatment. Additionally, the team would like to explore areas the CPG could not cover

based on the literature review and findings from primary sources such as financial implications. They also recommended engaging a focus group, which is outside of the scope of this DNP project.

Strengths and Limitations of the Project

This doctoral project had several strengths as well as limitations. Strengths included project site support, from front-line staff to the department chairperson staff at this project site, recognizing the problem addressed in the project, and supporting the effort to address it. Additionally, there was a sufficient of literature to help answer the project focus of what best practices contribute to a CPG for setting up patients with prostate cancer undergoing radiation therapy treatment. Strengths and limitations of the project include the project team; the team was able to give different viewpoints about the gap-in-practice. Nevertheless, a delay in the project occurred during the literature review phase when I was the only team member who knew the grading and scoring for literature using the JHNEBP model.

Recommendations for future CPG development projects include having a moderate-sized interdisciplinary project team. Additionally, consider using mind mapping to help organize recommendations from the literature review. Finally, for topics that seem to have limited research available, citation chaining helps identify additional sources of evidence and potential key search terms.

Section 5: Dissemination Plan

Introduction

The first step in the plan to disseminate this CPG to the institution experiencing this practice problem is to present this to the leadership team. Simultaneously, I plan to present the CPG to the nurses supporting patients receiving prostate radiation and their providers. Many team members may ask for the supporting information for the CPG, so it will be important to have the literature review grid available and the references to the full articles that informed the recommendations. The intended audience is a relatively small group of less than 10 individuals. To sustain the dissemination of this information to incoming nurses to the department, the CPG will be added to the nursing orientation binder.

Radiation oncology nurses caring for patients receiving prostate cancer treatment are the primary audience for this CPG. Radiation oncology residents, therapists, or radiation oncologists may also find the CPG beneficial. The CPG would also be appropriate to disseminate to the Oncology Nursing Society through the national convention and through journal articles to reach their primary audience. Another avenue of dissemination could be through advanced practice nurses and their respective society Advanced Practitioner Society for Hematology and Oncology, journals, and conventions.

Analysis of Self

Reflecting on my roles while completing the doctoral project, I was able to apply the academic skills I obtained in the DNP program and exercise project management

techniques. Using these skills outside my assigned job duties helped prepare me for future endeavors where I may lead an organization-based team/project. The doctoral project was the first time I created a CPG, and I found the entire process very rewarding. I think providing nurses with EBPs can profoundly impact the patient, nurse, and organization/system.

I had anticipated challenges with the completion of this project but nothing to the extent that COVID-19 presented. Initially, I had planned to take time off work to devote to working on the project; however, COVID-19 expanded my working hours as well as those of the project team. We experienced shifted job responsibilities and increased workloads even after the risk had seemed to level out. I had to meet with the project team virtually, not physically seeing some of the team members for months. This lack of a visual reminder of scheduled tasks also meant I had to e-mail the team to remind them to complete and return the completed tools. It was a good practice of holding teammates accountable to a timeline regardless of rank and, at times, required flexibility. Completing this project has given me insight into how to be a better project manager and that CPGs are important and useful for nurses. Additionally, I learned that with the right team and adequate time, developing a CPG is not that challenging.

Summary

Complex treatments can require complex interventions. The setup for patients receiving radiation for prostate cancer is complex, and currently, there are no organizational guidelines to help guide interventions for prostate radiation setup. CPGs

are a way to provide nurses with evidence-based interventions and improve overall care as evidenced by improved patient outcomes, patient care, and staff satisfaction (Medves et al., 2010). With the support of a project team, I identified which EBPs were supported in the literature and then created a CPG for the preparation for patients undergoing radiation for prostate cancer. The project team validated this CPG using the AGREE II instrument. The CPG will be shared with a broader base of oncology nurses, outside of the project site, in the future through conferences.

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Appendix A: Literature Review Matrix

Article #	Author & Date	Evidence type	Sample, Sample Size, Setting, or *Not Applicable*	Findings that help answer the EBP question	Observable Measures	Limitations	Evidence Level, Quality
1	Balyes, Collins, Clarksons (2015)	Systematic Review	*Not Applicable*	**Mechanical Interventions** Interstitial biodegradable balloons- may not completely push rectal volume out of field, invasive- once, patient acceptable Endorectal balloons (ERB)- may not complete push rectal volume out of field, may push anterior rectal wall into high dose areas despite reducing posterior rectal wall dose, possible interfraction motion due to presence of stool,	Rifaximini – not been demonstrated to reduce rectal exertion of flatulence Enemas – reduces geometric misses by >5 mm, highly efficient at limiting prostate motion	No strong recommendations, one reviewer, inconsistent definitions between studies	VB

				invasive-repeated daily for treatment Rectum empting tube (RET)- possible incorrect placement, invasive-repeated prn for treatment **Laxatives** Polyethylene glycol-most effect in stool frequency and formation and faster Senna-lack of placebo control in studies Enemas-Recommending in areas where use of CBCT is limited, used for short duration such as RT, semi-invasive, well-tolerated, complication of risk of mechanical injury, but clears rectum and can restore normal bowel function. Potential limit to simulation. **Gas management** Rifaximini (non-			

				absorbed antibiotic) – not recommend in consideration of long term SE of ABX, discontinue if patients are on during RT for prostate. B-galactosidase- (Simethicone/peppermint oil) used with caution **Diet** High fiber diet- effective at reducing prostate motion during RT, decrease stool, moving gas, and reducing rectal volume. Patients report increased feeling of bloating and flatulence. Probiotics- reduces radiation toxicities and interfraction set up errors			

2	Bell, Cox, Eade, Rinks, & Kneebone (2014)	Nonexperimental study	377 patients, Cone beam CT	Bladder preparation of 600 mL water intake 60 minutes before simulation with bladder volume confirmed to be "adequately full" along with a low residue diet with magnesium to maintain empty rectum (rectum >3.5cm on planning CT resulted in patient being given an enema with rescan) Rectal size had more of an impact on potential geographical misses concluded its more important to have small rectal size at time of simulation and treatments> based on findings now routinely administer enema before all post-prostatectomy simulations.	With this regimen bladder was within 1cm of planned size only 56.2% of the time and rectum within 1cm of planned size 65.8% of time. Of those times when both rectum and bladder were within 1cm of planned size, ~90% of CBCT showed no potential geographic miss. A bladder 2cm larger resulted in 61.5% geographical miss> based on findings now routinely preform bladder ultrasound prior to simulation.	Used surgical clips as surrogate for prostate bed motion. Small volume of patients (40) resulted in sample of 377 images. 1/8 of patients had new plans generated during study	IIIB

3	Braide, Kindblom, Lindencrona, Mansson, & Hugosson (2019)	Quasi-experimental	29 patients, single clinic Sweden	Group 1 (n=13) void and drink 300 mL of liquid (not coffee or tea) 60 minutes before treatment Group 2 (n=16) maintain a comfortably filled bladder at treatment Both groups at simulation if rectum was >4 cm, enema was administered and new CT obtained Instructions were given verbally and written at time of consult, instructions were repeated verbally at start of treatment and weekly during treatment. Ultimately, the variation in bladder volume "hardly affected the CTV" and from a standpoint of ensuring coverage did not affect outcomes.	Estimated bladder volume median- Group 1--120 mL and Group 2--123 mL. The intra-individual variation in bladder volume, assessed as SD for Group 1 was 64 mL (95% Cl: (46, 105) and Group 2 was 61 mL (95% Cl: (45, 94), no benefit to drinking 300 mL of liquid/instructions. 42% of Group 1 prepared as instructed about 50% of the time, approximately 31% patients in Group 2 prepared similar	small sample size, did not consider development of side-effects of RT on ability to maintain bladder volume, did not access impact of rectum volume on CTV	IIA

					to group 1 without receiving instructions.		
4	Cancer Center of Santa Barbara (2017)	Expert opinion	*Not Applicable*	Empty bladder and rectum upon arrival- (15-30 minutes before treatment) then drink 720-960 mL of water. Refrain from eating gas producing foods 4 hours before treatment minimize gas- eat slowly, chew with mouth closed, avoid drinking with straws, avoid chewing gum			VC
5	Dees-Ribber, Detgen, Pos, Witteveen, Remeiger, van Herk (2014)	Quasi-experimental	24 bladder ca patients- single clinic Netherlands	Drink 250 mL 60 minutes before treatment for full bladder	bladder filling rate of about 1.6 mL/min during radiation treatment	small # of patients	IIIB

7	Fujioka, Ishii, Yamanage, Ogino, Kishimoto, Kawamorita, … Nakajima (2016)	Quasi-experimental	64 Vmat prostate IMRT, single center May 2012-Feb 2013	Bladder volume at treatment planning aim to be >100 mL and <250 mL to reduce nursing intervention	Mean relative bladder volume of 70% for treatment without exceeding dose constrains	no daily CBCT	IIB
8	Hamilton, McKenzie, Wasiak, & Fenton (2015)	Quasi-experimental	10 IMRT patients Austria	2 groups – 5 patients taking one capsule of probiotics containing 1*25X10^10 units of Lactobacillus acidophilus NCFM and Bifidobacterium lactis Bi-07 a day (10x normal dose) 5 others taking psyllium-based bulk-forming laxative (Fyboigel tm, reckitt benckiser, Slough, UK; 3-5g/day psyllium husk). >start taking 1 packet nightly starting 1 week prior to simulation to continue throughout treatment	Probiotics significantly increased variation in difference in rectal volume between treatments (p=0.0001) and rectal cross section area (p = 0.008) and relative cross section area (p = 0.007) compared to psyllium prep.	small sample size, retrospective	IIA

				Bladder protocol- empty bladder 30 minutes prior to treatment, drink 500 mL of water			
9	Harder, van Gils, Kotte, van Vulpen, & Lips (2014)	RTC	92 prostate patients IMRT 77Gy in 35 Fx, UMC Utrecht	2 capsules of 250 mg magnesium oxide twice a day (total 100mg daily) starting 2 days before CT, control group of placebo capsules 2 caps/twice daily Using MRI evaluated for >0.5cm^3 of air as significant amount of gas to cause rectal movement, occurred in less than 1degree and was in the intervention group. Does not recommend use of mag ox capsules daily during treatment to reduce rectal gas.	No significant difference between two groups	Limitations listed in original publication	IB

10	Holden, Stanford, D'Alimonte, Kiss, & Loblaw (2014)	Quasi-experimental	Single center, 30 patients receiving radical course of RT (78 Gy in 38 Fx)	At time of simulation patients were asked to maintain a comfortably full bladder and then for treatments. Patients were preloaded with either 250 mL or 500 mL of water, had their bladders measured and when bladder scanned volume was 180 mL preceded with treatment. Serum Creatinine had no significant correlation with the time to achieve bladder volume of 180 mL. After treatment, patients voided and post-void residuals were measured.	Some patients were not able to achieve a bladder volume of 180 mL, d/t urgency or insufficient filling by 120 minutes. Group 1 (250 mL) average bladder fill to 180 mL was 64 minutes. Group 2 (500 mL) average bladder fill to 180 mL was 46 minutes ($p = 0.03$). The time for 95% of patients to reach the volume of 180 mL was 75 (group 1) and 57 minutes (group 2).	small prospective, IPSS not collected, prostate only radiation (no nodes)	IIB

11	Hosni, Rosewall, Craig, Kong, Baylaey, Berlin, … Chung (2017)	Quasi-experimental	80 VMAT 79gy/39fx group 1 diet+ Milk of Magnesia group 2 diet only	Group 1 Antiflatuance Diet + Milk of Magnesia starting 3 days before planning CT, continuing through treatment. Milk of Magnesia initial once a day (bedtime 30cm3, adjusted 15-60 cm3 to achieve a soft BM in AM and stop with lower GI toxicity-graded with RTOG acuity toxicity. Group 2 Antiflatuance Diet only starting 3 days before planning CT, continuing through treatment	40% of Group 1 patients stopped taking Milk of Magnesia by last week d/t toxicity. G2 diarrhea in G1 3 patients (7.5%) vs. 2 patients (5%) and G1 diarrhea 21 patients (52.5%) vs 7 patients (17.5%), with onset reported as early as week 2 of treatment for both groups. Most importantly, no significant difference in interfraction rectal movement, and therefore no clinical impact on accuracy of treatment	retrospective, not an RCA, compliance with diet not quantified	IIA

					delivery.		
12	Maggio (2017)	Quasi-experimental	1080 prostate 3dcrt, single site	NRBP-no rectum and bladder preparation protocol RBP-protocol preparation to empty rectum and comfortably full bladder by drinking 500 mL of water 1 hour before planning CT scan and before each treatment fx	RBP significantly decreased probability of death from prostate cancer, also biochemical and clinical failures. Hazard Ratio less than 1 in COX regressions confirm the protective effect of a RBP on prostate cancer outcome P<0.001 mean bladder volume between RBP mean bladder	retrospective, not able to correct for 'will rogers phenomenon'- which occurs when comparing cohorts of cancer patients by staging	IIA

					=305.8 +/- 187.8cm3 and NRBP 125.9 +\- 74.5 cm3		
13	McGuffin, Devji, Kehoe, Carty, Russel, Di Prospero, … D'Alimonte (2019)	RTC	78 prostate patients, bowel and bladder prep, or + 80mg simethicone BID	Education on bowel and bladder prep process empty bladder and bowels before drinking 500 mL of water 30 minutes before appointment Intervention arm take one 80-mg pill or chewable ovol(simethicone) tablet twice per day for 2 days before CT simulation, 2 days before first treatment and then continuously throughout the course of treatment. On first day of treatment radiation therapist provided new	The addition of antiflatulent medication to the bowel prep did not make a clinical or statistical significance. However, overall the study participants had less CT rescans then the general population (17% compared to 31%) which may be in part to the specialized education that was prepared to educate patients on bowel and	small sample size, underpowered, dropout after randomization	IB

				patient teaching and confirmed compliance with bowel bladder and intervention, received daily CBCT	bladder prep; previously the patients were given very little verbal information and no written information on how to achieve an empty rectum and full bladder.		
14	McNair, Wedlake, Lips, Andreyev, Van Vulpen, Dearnaley (2014)	Systematic Review	*Not Applicable*	Oral and IV medication- some effectiveness with diet, laxatives and scheduling, no effectiveness (adverse effect) with Milk of Magnesia Diet- in studies with just dietary advice there was no significant or clinically relevant findings with high fiber or anti flatulent diets Probiotics- positive result in rectal volume but did lead to rectal			IIB

				distention Rectal Evacuation-significant differences in rectal volume and corresponding prostate motion, 1 technique was inserting an index finger into the rectal canal and flushing with water and another used a rectal emptying tube Enemas- 5 studies with enemas found some reduction of rectal volume of prostate motion			
15	MSK (n.d.)	Expert opinion	*Not Applicable*	Marker Placement-Fiducial or beacon transponders Starting 7 days before simulation take 1 rounded teaspoon of psyllium powder in 8 oz. of water, do daily Day of simulation do a fleet enema 3 hours before simulation Use plastic mold to help with positioning			VB

16	Nathoo, Loblaw, Davidson, Masunuru, Khojaste, & Ravi (2018)	Quasi-experimental	Nathoo, Loblaw, Davidson, Masunuru, Khojaste, & Ravi (2018)	Void before simulation given 500 mL of fluids to drink over 5-10 minutes. Ultrasound measurements obtained in 15-minute intervals for up to 4 measurements before sim. On treatment patients voided, drank 500 mL and measured a single time, typically 30 minutes after voiding. Optimal bladder filling was 60 minutes after voiding and drinking 500 mL of water. Adding ultrasound increased demand on patient and department resources	Greatest variation occurred in the AP direction; bladder volume was on average larger 0.5 cm larger on treatment. No patients had to get off the couch because of inadequate bladder filling. The kinetic prediction model was successful at improving the reproducibility of the bladder volume on treatment.	Lack of comparator data set without the US intervention. No shift data info, Treatment unit delay coupled impact bladder filling on machine result.	IIA
17	NHS (n.d.)	Expert opinion	*Not Applicable*		Drink water (unspecified amount) do not advise fruit juice, soda, tea or coffee		VC

18	Oates, Schneider, Joon (2014)	RCT	30p, 50+ yr., EBRT, intact prostate TNM tafge T1- T3b. implanted fiducials	**Standard Therapy bladder and bowel prep**- consume 750 mL of water 30 minutes before treatment and take 5g/d Fybogel if needed to promote regular bowel movements. **Diet Intervention**- consumption of psyllium 20 g/d + at least 2 L of water; and antiflatulant diet (avoid excessive dairy, hot/spicy foods, skins/stems of fruits and veggies, eat cooked veggies warm. Reduce fat intake (can delay the transmission of gas). Instructions on reducing aerophagia (excessive and repetitive air swallowing i.e. chewing gum) and increase exercise to increase bowel	Results show diet intervention had significant differences in the intervention arm for rectal filling with a the center with while empty and with gas and feces. It suggests that the diet intervention may reduce rectal variability compared to standard therapy and a larger study should be completed with at least 50 enrolled in each arm.	Sample size	1B

				movements. Empty bowel and bladder 50 minutes before treatment drink 750 mL water from 45 minute to 0 minutes before treatment and to hold bladder full until treatment complete. If patients were felt to have gas, they were encouraged to expel the gas. Also, avoid caffeine for the two hours before treatment. Complete diet diary for the two weeks prior to CT simulation until the end of treatment.			
19	Osmar & Webb (2015)	Mixed Methods	Odette Cancer Centre, Canada- Patients and RT staff	Created a images only picture book to help with patient education	Staff had comments of success.	Patients with limited English proficiency were not able to complete the survey.	IIIC

20	Pang, Knight, Hussain, Fan, Baird, Tan, … Tuan (2018)	Quasi-experimental	Duel sites, 60 IMRT/VMAT patients	Bladder protocol empty bladder, then drink 400-600 mL water 30-60 min before simulation appointment. Intervention TMH- same bladder protocol + bladder ultrasound. No rectal empty or dietary advice given expect all patients encouraged to empty bowels before each treatment only 1/3 of patients were able to obtain the goal of >200cm3 for simulation. There was no correlation between bladder or rectal volumes and treatment IPSS scores. S	Bladders that were filled to 82-113% of the filling at simulation experienced significant Superior/inferior (p=0.008) and Anterior/posterior (p=0.0001) movement.	Limited to short follow up. Did not account for pretreatment procedures.	IIA

21	Picardi (2015)	Quasi-experimental	20 prostate patient, 10 with hydrogel, Switzerland	Bladder protocol empty bladder, drink 600-700 mL 60 minutes before simulation and each treatment. Rectal enema before simulation and each treatment. Received hypofractionations, 3 fiducial markers 10 patients received SpaceOar hydrogel spacer	Study confirmed that the spacer helped limit dose to rectal wall but failed to prove reduction of prostate movement, which would have then allowed for dose escalation.	single study	IIA
22	Roger Caner Center	Expert opinion	*Not Applicable*	Hydrate a few days before hand (drink at least 6 cups of water a day) Between 75- 60 minutes before simulation/treatment, empty bladder then drink 600 mL water Have BM within 4 hours of simulation and radiation treatment			VB

				Pass flatus 1 hour before simulation/treatment Inform nursing staff if you do not have daily BM			
23	Schnitzler (2017)	Nonexperimental study	58 pts, 10 RT; Australia, urban teaching hospital; age 18+, English speaking, ineligible if had prior RT	Teachings contained medical (specialized words) and contextual (common words used differently in relation to treatment) jargon that was confusing for patients. Response include jargon substitute, unsolicited jargon explanation, use of analogies and plain language, visual tools, and repetition of information. Use empathy when responding and refer to Radiation Oncologist when unable to answer question. Confirm understanding with	Patients did not remember how many treatments they were scheduled for	Inconsistencies in who information was presented to. Single encounter, audio reorderings only a small part of the education process, being aware of audio recording can lead to bias	IIIB

				teach back.			
24	Smitsmans (2009)	Quasi-experimental	49 prostate cancer patients; 23 STD, 26 Diet intervention	**Standard treatment**- full bladder by drinking 250 mL of liquid 60 minutes before simulation and treatment and empty bowel. **Dietary intervention**- standard treatment and starting 1 week before simulation until end of treatment eat regularly (no skipping meals), drink 1.5-2 L liquid per day, and increase physical activity. Avoid food: whole wheat bread, cereals, nuts, fermentable carbohydrates (peas,	In dietary intervention group the presence of feces, gas pockets, and moving gas in rectum was significantly less ($p \leq 0.001$). Within the DI group there was greater success ($p < 0.001$) in scans acquired after 10 am; additionally in the standard treatment group the success rate	Changes in CT imaging protocols between the two groups, single study	IIA

				beans, cabbage, onions, garlic, peppers, asparagus), fruits (oranges, bananas, prunes, dried fruits), hot and spicy foods, carbonated beverages, more than >4 cups of coffee per day; avoid swallowing air by eat slowly and chew food well, chew with your mouth closed, avoid chewing gum, sip beverages. Take 2 tablets of Mag Oxide 500mg per night starting 2 nights before simulation, and then 2 nights continually through treatment at same time daily; treatments scheduled after 10am.	was lower in treatment scans acquired before 10 am (p =0.07).		

25	Sunshine Coast Hospital (2017)	Expert opinion	*Not Applicable*	Fluid bladder and empty rectum. Hydrate with at least 1.5 L fluid (preferred water) daily. Take ClearLax or Movicol daily, starting 5 days before planning simulation. Reduce gas formation by: eat slowly, chew food well with mouth closed, avoid skipping meals, sip fluids, avoid straws, increase physical activity gently On day of planning, and drink 600 mL of water 30-40 minutes before scan.			VC

26	Tsang & Hoskin (2017)	Quasi-experimental	60Gy/20fx (20 patients) IGRT; IPSS <7, localized prostate cancer, treated between Oct 2014 and March 2015. Gleason Score ≤7, no nodes treated.	Full bladder protocol, void bowel and bladder then 45 minutes to the start of CT simulation drink 300 mL of water within 15 minutes. No bladder protocol given for intervention group.	There was a significant difference in dose objectives due to bladder size V42Gy ($p < 0.05$) and V50Gy ($p < 0.05$) however there was no significant difference GI ($p=1.0$) and GU ($p=0.6$) toxicities; no patients had grade 3 or 4 toxicities.	small sample size	IIB
27	Uhl, van Triest, Eble, Weber, Herfarth, De Weese	Nonexperimental study	Multisite, prospective, single arm; 52 men, prostate	Injection of hydrogel spacer had 3-5 days later had simulation scan, received 78 Gy.	12% of patients experienced grade 2 GI toxicity. No stage 3 or 4 toxicities reported in acute toxicity. In late toxicity, only 7% of patients reported grade 1 GI toxicity no 2,	Single arm, small sample size-assessing for stability primarily	IIIB

					3, or 4. Gel was stable during radiation and absorbed within 9-12 months in 42/43 patients		
28	Vanneste, Hoffmann, van Lin, van de Voorde, Pinkawa, & Lambin (2016)	Quasi-experimental	26 patients (IMRT + IRS arm) (IMRT - IRS arm) localized prostate cancer, Netherlands, treated in 2011	10cm3 intrarectal spacer (IRS) gel injected into recto-prostatic space	No significant PTV volume difference between both groups. Dose of V75GY was significantly reduced to the to the median anorectum ($p < 0.0001$). Additionally, there was significant reduction in doses to the medical MARD, median MRD, and median MAD. Significant acute lower GI	CI for nomograms not incorporated into analysis. Nomograms only internally validated	IIA

					toxicity in between the +IRS and -IRS group favoring +IRS p=,0.001, as well as 3year grade 2-3 lower rectal bleeding <0.0001 and 3 year grade 3 lower rectal bleeding <0.002 as well as chronic grade 2-3 late fecal incontinence 0.006.		
29	Wang, Bui, Deville, Plastaras, Bar0Ad, … Both (2014)	Quasi-experimental	30 patients, prostate radiation with CBCT, endorectal balloon (ERB), treated 12/2008-1/2010 at the Hospital of Pennsylvani	All patients received same bowel and bladder prep including dietary guidelines, anti=gas tablets, and before planning CT were instructed to self-administer two Fleets enemas, 1 hour apart. Daily, patients were instructed to empty their rectum, and to	Patient comparing anterior stool/gas volumes (<10 cm3) (small) to those who had large volume (10-60 cm3), larger gas volume were twice as likely to experience twice	bladder filling was not measured and can effect prostate motion, small sample size, single setting, needs more frequent imaging	IIA

			a	consume 500 mL of water 20-30 minutes before treatment. The patient was positioned supine, with an indexed knee wedge, foot lock, and lumen 100 mL water-filled endorectal balloon. Patients received at least weekly post-treatment CBCT scans. The study found that 100 mL water filled balloon may not be large enough to immobilize the prostate in rectums with large gas/stool volumes- 76% of images showed stool/gas volume less than 30 mL with 90% of total images revealing stool/gas volume less than 10 mL.	as much prostate movement in the 6th minute of treatment.		

30	Weston, Luscombe, & Duncanson (2019)	RTC	CBCT scans 17 patients prostate radiation, 6-12/2016, single center Australia, receiving EBRT 78 Gy in 39 Fx	**Intervention group**- bulking laxative (Metamucil equivalent of 10 g soluble fiber per day) with probiotic **Standard treatment**- osmotic laxative (Movicol half strength, Macrogol 3350 6.563 g) both low gas diet (low in fermentable carbs, gastric irritants, and carbonated beverages) provided by dietitian prior to radiation therapy planning appointment and weekly throughout treatment, gold fiducial markers	Osmotic laxative was significantly more effective ($p<0.001$) at reducing rectal gas volume	subjective analysis of gas levels, limited external validity, probiotic only in IG group	IB
31	Yaver, Foo, Larsen, Fineberg, Zeng, McGowan, & Jones (2015)	Quasi-experimental	Ontario cancer center. 59 prostate cancer radiotherapy patients	Cohort 1- (Laxative) - fleets enema the morning of simulation planning, Milk of Magnesia daily during treatments Cohort 2 (consistent timing) - appointment times aligned with	There was no difference between the two cohorts in gas volume, rectal volume, bladder volume in PTV, rectal volume in PTV, and target	Interobserver variability on CBCT, exclusion of dose analysis, toxicity outcomes, and patient reported outcomes/difficulties with	IIA

				natural bowel habits, time collected during prescreening intact appointment. Additionally, those patients with no preexisting urinary conditions were instructed to drink 2L water daily before simulation and during treatment All patients instructed to drink 250 mL water 60 minutes before planning and daily appoints.	coverage. Patients should be offered a choice. The bladder regimen for cohort 2 was superior for consistency with slightly larger maintained bladder volume over the duration of treatment.	maintaining regimens	

Appendix B: Interventions to Prepare a Patient With Prostate Cancer for External Beam Radiation Therapy

Introduction

The intent of this clinical practice guideline is to provide guidance for radiation oncology healthcare to choose more appropriate and achievable interventions (Institute of Medicine, 2011). Specifically, this guideline will aim to help improve the planning session for prostate radiation therapy as it relates to modifiable factors such as bladder management, bowel management, and image quality. Patients that are the target population of this CPG are males, with localized prostate cancer, planned to receive intensity modulated radiation therapy (IMRT). Providers may consider these guidelines for other radiation treatments such as hypofractionated treatment and proton radiation however, the sources of evidence were primarily IMRT studies and that consideration should be made when applying the CPG outside of this population. Patients who prior to starting radiation therapy have challenges with bowel management or known dietary/fluid restrictions may need to be recommended a modified version of the clinical practice guideline and healthcare providers should consider consulting a nutritionist for assistance.

Formulating the recommendations

A literature review was conducted using CINAHL Plus with Full Text, MEDLINE with Full Text, PubMed, Ovid Nursing, Embase, ProQuest Nursing and Allied Health Source, and Google Scholar. The following terms were used in the literature search: *prostate*, *prostate cancer*, *radiation therapy*, *radiotherapy*, *simulation*, *bladder filling*,

bladder regimen, bladder protocol, bowel emptying, bowel regimen, bowel protocol, fiducials, prostate motion, clinical practice guideline, AGREE II, implanted rectal spacer, and *hydrogel*. Additionally, the Boolean strings *and/or* were used to obtain a more comprehensive search. Abstracts were reviewed to identify articles that best appeared to match the practice question, 62 articles were identified. Publication years were limited to 2014-2019 initially, an additional search to update any articles that added providers (MDs, advanced care practitioners, registered nurses, radiation therapists) to prepare patients with prostate cancer for radiation therapy planning session and treatment. The expected benefit of having clinical practice guidelines improve equity of care, reduce variations in care, assist in social change, and aim to define best practices in healthcare. CPGs allow the provider to identify barriers and thus choose more appropriate and achievable interventions.

The initial literature review had publication years limited to 2014-2019 initially, so an additional search in the summer of 2020 was conducted to ensure all up to date articles were included; historical research were identified through the citation chaining methods. Sources of evidence were not be limited to those published in the US so spelling variation was included to account for international studies. A final 31 sources of evidence were used to inform the CPG.

After evidence is acquired through the literature review, it is evaluated for level and quality using the Johns Hopkins Nursing Evidence Based Practice (JHNEBP) model. The JHNEBP is used to evaluate the level and quality of each evidence source, then summarize the evidence, and synthesize the collective evidence for quality and strength

(Dearholt & Dang, 2012). In the JHNEBP model evidence is leveled based on the source or evidence ranging from I-V including both research and non-research forms of evidence, then the evidence is rated based on quality; evidence may receive a score of A for high quality, B for good quality, and C for low quality or major flaws within the evidence. Based on the JHNEBP evidence from all types of sources can be considered, this allows for includes of internal and external forces when considering the application of identified best practices which is helpful in the development of a practical CPG. The evidence selected that informed this CPG was based on the reported outcomes, quality, level, frequency, ability to implement, and patient tolerability.

Clinical Practice Guideline Recommendations

Primary recommendations

Category	Recommendation	Highest Level of Evidence
Bladder Management	Empty bladder then drink 500 mL of water finishing 6o minutes before simulation/treatment	IIA
	Goal bladder volume via ultra sound of >100 mL and <250 mL at the time of simulation	IIB
	Consume at least 1.5L- 2L water daily	IB
Bowel Management	Patient should have an empty rectum for treatment, to do this they should strive to have a bowel movement daily before treatment and should pass flatulence 1-2 hours before treatment.	IIA
	Gas Management (Diet)- Provide education and recommend an antiflatulance diet: avoid fermentable carbohydrates including lentils, beans, peas, broccoli, cauliflower, Brussel sprouts, cabbage, sauerkraut, cucumber, turnip, onions, garlic, apples, bananas, carbonated beverages, dairy, high-fat foods.	IIA
	Gas Management (Eating Style) - Reduce aerophagia (excessive and repetitive air swallowing). Do this by eating with mouth closed,	IB

	eat slowly, and chew food well. Do not use chewing gum, avoid using straws if able, and sip beverages.	
	Recommend osmolotic laxative, nightly starting 5 days before simulation and continue through treatment, reduce as need for excessive stools.	IB
	Recommend Fleet® enema if unsuccessful with other interventions and/or rectum is greater than >3.5 cm on simulation CT.	IIIB
	Recommend increase exercise to promote bowel motility.	IB
Imaging/Treatment Quality	Give patients consistent appointment times that align with their daily bowel habits.	IIA
	Interstitial biodegradable balloons (hydrogel spacers) should be injected at least 3-5 days before simulation.	IIA
Patient Education	Provide verbal and written specialized patient education.	IB
	Add images to patient education.	IIIB
	Use analogies, plain language, repeat information. Refer to radiation oncologist when unable to answer a patient's direct question. Confirm patient's understanding with the use of teach back method.	IIIB

Secondary recommendations-

- **Magnesium**-several studies found no benefit of the addition of magnesium (Milk of magnesium or magnesium tablets) for bowel management on a routine basis. One study found that most patients stopped taking routine Milk of Magnesium due to GI toxicity before the end of treatment.
- **Rectal emptying tube** is not recommended related to possible incorrect placement and invasive nature, as well as repeated need for each treatment.
- **Rectal balloon**- patients that receive rectal balloons instead of interstitial biodegradable balloons may need >100cc volume instilled if they experience larger rectal gas volumes to reduce prostate motion.

- **Probiotics**- daily probiotics had conflicting evidence and no recommendations can be made without further studies on the impact of daily probiotics on prostate radiation side effects or bowel management for prostate radiation.
- **Gas management**-
    - Rifaximini, a non-absorbed antibiotic, is not advised for use during radiation treatment of prostate cancer and should be discontinued if patients are one prior to treatment.
    - Simethicone/peppermint oil, should be used with caution and were not shown to have statistical or clinical significance when added as preventative management for gas management.

Strengths within the body of evidence include obtaining patient feedback on interventions were taken into consideration when developing the recommendations, the large number of sources of evidence often addressed several aspects areas within the recommendations allowing for multilayered support of the recommendations put forward. The limitations within the body of evidence include inconsistent definitions between studies, studies having small sample sizes, lacking control, and limited randomized control trials. Additional limitations include advancements of, and variations in, radiation therapy administration between the bodies of evidence, which had potential impact on the patient experience during the studies that informed the evidence.