VAGINAL DILATION AFTER PELVIC RADIOTHERAPY

by

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ABSTRACT

This quality improvement project addressed the inequity between assessment of female versus male sexual health in patients undergoing pelvic radiotherapy. Women undergoing pelvic radiotherapy suffer from the long-term side effect of vaginal stenosis which has been cited to decrease sexual satisfaction, result in pain with penetration, and decrease overall quality of life. Vaginal dilation has shown to decrease the degree of vaginal stenosis, and increase overall sexual satisfaction in this population. While national guidelines exist for the assessment of sexual health in men undergoing pelvic radiotherapy, no such guidelines exist for women. The setting of interest was a radiation oncology clinic in Montana, and the following procedures took place: phone calls to women who underwent pelvic radiotherapy between January 1, 2020 and September 9, 2020 to assess sexual health utilizing a validated screening form, the FSFI-6. At the initial phone call, adherence to twice per week vaginal dilation was asked, the woman was re-educated on vaginal dilation to prevent stenosis, and offered a vibrating dilator utilized at other radiation sites with increased adherence rates. Eight weeks later a follow-up call was placed, the FSFI-6 was reviewed and adherence to twice per week vaginal dilation was asked. Initial FSFI-6 and adherence scores were then compared to follow-up scores. The project sample consisted of 55 women meeting inclusion criteria, 13 women were lost to death or recurrence (23%); thus, phone calls took place to 42 women. Seven of these 42 (17%) women answered their phones and provided consent, five consented to the mailing of a vibrating dilator (one of these women was lost to recurrence). A mere two of the seven women (29%) were adherent to twice per week vaginal dilation at initial phone call. At eight-week follow-up phone call to those consenting to vibrating dilator, three of four women (75%) were adherent to at least twice per week dilation, and pain with penetration score on the FSFI-6 decreased by an average of three points, illustrating that issuing a vibrating dilator at completion of pelvic radiotherapy has the potential to increase adherence and decrease pain when a validated screening tool is utilized.

CHAPTER ONE

VAGINAL DILATION AFTER PELVIC RADIOTHERAPY

Vaginal Dilation after Pelvic Radiotherapy

Pelvic radiation therapy (RT) is an integral part of curative treatment for many pelvic malignancies. In women, this treatment can result in high doses of RT being delivered to all of, or a portion of the vaginal canal, resulting in the long-term side effect of vaginal stenosis (VS; Kachnic et al., 2017). VS is known to cause shortening and narrowing of the vaginal canal, reduction in the elasticity of the vaginal tissues, vaginal adhesions, dyspareunia and vaginal pain, vaginal bleeding, and vaginal dryness; ultimately resulting in sexual dysfunction, depression, and decreased quality of life (Kachnic et al., 2017). Static vaginal dilation (VD) is the most common treatment prescribed by radiation oncologists to aid in the prevention of VS; however, consistent clinical guidelines are lacking, nursing education practices vary, and patient adherence remains low as women report that static dilators are ineffective.

Background and Significance of the Problem

Pelvic Radiation Therapy and Vaginal Stenosis

Pelvic RT is radiation treatment carried out to the female pelvis, including external beam radiation, high-dose brachytherapy treatment (intra-vaginal radiation), or a combination of both. Cancer diagnoses treated with pelvic RT include cervical (endo and exocervix), endometrial, anal, rectal, ovarian, vaginal, and vulvar cancers. The majority of new cases of pelvic cancers occur in women aged 34 to 56 (Hofsjo et al., 2017). A rising number of female pelvic cancer

survivors are at risk for chronic side effects of treatment, which can impact sexuality and quality of life (Hofsjo et al., 2017; Kachnic et al., 2017). The most widely reported chronic side effect of pelvic RT is VS. VS is vaginal shortening or narrowing as a result of: vaginal dryness, vascular and tissue damage, thinning of the epithelium and atrophy of the vagina, reduction in the elasticity, and the development of fibrosis (Kirchheiner et al., 2016; Miles & Johnson, 2014). Clinically, scarring from VS can limit posttreatment surveillance of the vagina and cervix during pelvic examination, and may be uncomfortable or painful for the patient. Psychologically, pain with physical examination or sexual intercourse may trigger traumatic memories of cancer treatment for these women (Damast et al., 2019). Damast et al. (2019) found women who report VS are more likely to have dyspareunia and sexual dysfunction.

Negative Outcomes. Rates of female sexual dysfunction after pelvic RT range from 30% to 63% and are associated with a high risk of VS (White, 2015). Sexual pain is a frequently reported cause of sexual dysfunction (White, 2015). Sexual fear, loss of confidence, and reduced sexual satisfaction are common psychological consequences, secondary to adverse vaginal and hormonal impacts on desire, arousal, and orgasmic phases of the sexual response cycle (White, 2015). Depression is directly correlated to sexual interest and expression. When overall mood is disconsolate, levels of anxiety are excessive and the woman has a decreased ability to cope with treatment-related emotional stress (White, 2015). Post-treatment consequences coupled with the emotional strain of coping with a cancer diagnoses and its treatment can cause tension in the relationship between the patient and her partner (White, 2015). Combined, these effects can impact the woman's overall quality of life and relationships for the remainder of her lifespan (Hofsjo et al., 2017).

Incidence. The reported incidence of VS from RT varies, with an overall range of 2.5% to 88%, depending on treatment type, RT dose, cancer type, volume of vagina treated, and the use of dilators post treatment (Damast et al., 2019). Miles and Johnson (2014) report about a third of women suffer from VS after pelvic RT. The overall time course of VS is not fully understood, however, multiple studies across disease sites have shown the risk increases over time, with the most significant risk being within the first two to five years post RT (Stahl et al., 2018).

Sexual Assessment

Sexual health is an important component to address in the oncology setting, however, health professionals express difficulty talking to patients about sexual concerns. Brautigam et al. (2020) report a mere 4.9% of radiation oncologists routinely discuss sexual health issues in 61% to 80% of their patients. The main reason for not discussing sexual health is the impression that other problems are more important to patients (Brautigam et al., 2020). Brautigam et al. (2020) found radiation oncologists have a higher awareness for male than for female sexual problems. Acknowledgement of male sexual difficulties during and after cancer treatment is echoed by the American Society of Radiation Oncology (ASTRO)/American Urological Association (AUA) guideline (2019). ASTRO/AUA Guideline for Adjuvant and Salvage Radiotherapy After Prostatectomy (2019) states patients should be informed of the possible short and long-term sexual side effects of radiotherapy as well as the potential benefit of controlling disease recurrence. United States literature is limited on women's sexual health assessment, and no guideline exists regarding informing female gynecological patients of the sexual side effects of RT. In contrast, an AUA guideline for erectile dysfunction (ED) states men with ED should be evaluated with validated questionnaires such as the International Index of Erectile Function-5

(IIEF-5) to assess disease severity, and should be informed regarding the treatment option of an FDA-approved oral phosphodiesterase type 5 inhibitor (AUA, 2018). The American College of Obstetrics and Gynecologists (ACOG) Practice Guideline on Sexual Dysfunction in Women (2011) acknowledges underdiagnosed and undertreated sexual dysfunction is common in women, but state only physicians who feel comfortable discussing sex should discuss sexual health with women. The ACOG guideline (2011) does not discuss use of validated questionnaires to assess severity of sexual dysfunction, further leading to a gap in provider knowledge, variation in practices, and inequity related to assessment of women's sexual health.

Questionnaires Assessing Female Sexual Function. Validated questionnaires assessing women's sexual function exist, yet are underused. These questionnaires help to assess patient-reported outcome measures (PROMs) and sexual dysfunction severity (White, 2015). A PROM can act as a vehicle for detailed discussion of the type and severity of sexual effects, assisting in timely and effective clinical management, specialist assessment, and referral to sexual health specialist when appropriate (White, 2015). For example, the Female Sexual Function Index short form (FSFI-6; Appendix A) has been validated in women after gynecological malignancy diagnosis and treatment (White, 2015).

Vaginal Dilation

To decrease the incidence of VS, radiation oncology clinic standards include providing patients with a VD and instructions for use after the completion of pelvic RT. Regular VD use is thought to reduce vaginal shortening and tightening, and separate adhesions formed by damaged epithelium, thus decreasing VS (Bakker et al., 2015; Miles & Johnson, 2014). Despite evidence

supporting dilator use to minimize VS painful complications, patients report difficulty following the instructions resulting in poor compliance (Bakker et al., 2015).

VD usage is complicated by varying clinical guidelines resulting in a lack of standardized treatment protocols. The United Kingdom (UK) guidelines recommend VD three times weekly for an indefinite time period (Miles & Johnson, 2014). Australian guidelines recommend VD after the completion of RT (within the first four weeks) for at least three years, and indefinitely if possible (Miles & Johnson, 2014). The International Gynecological Cancer Society (IGCS) recommends routine VD after the inflammatory phase of RT for at least two years, or at the clinician's discretion (Miles & Johnson, 2014). In contrast, United States guidelines are lacking in depth and breadth and are contradictory adding to potentially negative outcomes. This is evidenced by the National Cancer Institute (NCI) suggestion that doctors may advise against sexual intercourse or vaginal dilation during and after RT (Miles & Johnson, 2014).

Adherence. Cited adherence rates range from 1% to 35% of pelvic RT patients use their dilator with the recommended frequency, two or more times per week, within the first 12 months post treatment (Bakker et al., 2015). Friedman et al. (2011) cite an adherence rate of 33% based on report of using a VD more than two times per week in the first month after RT. Bakker et al. (2015) found that 33% of women prefer the use of a vibrator over static dilation because they found it to be more enjoyable, less foreign, and easier to integrate during sexual contact.

Scope of the Problem at the Project Site

The project site treats between 60 and 80 women annually with gynecological and pelvic carcinomas within a three-state area. Standard practice is to provide a VD, water-based lubricant,

and an educational handout (Appendix B) to each of these patients at the end of their course of radiation treatment. The dilator provided is a hard plastic, white dilator, costing on average $10.00 per unit incorporated into the cost of pelvic RT. VD is recommended for 10 to 15 minutes while lying in a comfortable position at least twice per week for a minimum of one to two years, with preference for indefinite use post-treatment. The patient then returns at 12 weeks (three months) for a routine follow-up, and adherence to VD is discussed and documented. Overall, providers and nursing report an extremely low rate of adherence to VD in this patient population, as consistent sexual assessment is not incorporated into practice, thus, limiting proactive management of sexual dysfunction.

Provider report is substantiated through a project site chart review on patients who received treatment between January 1, 2020 and September 9, 2020. Chart review identified 55 women had undergone pelvic RT and received dilators. Of those 55 women, 18 (33%) report not using their VD at all when presenting for their three-month follow-up. Ten women (18%) indicate an average usage of once per week. A mere four of the 55 women (7%) were using the dilator the recommended two or more times per week. Dilator use was not documented for 13 (24%) of the 55 patients, and 10 patients (18%) were not yet three months out from the completion of their treatment. Within this group, the most common forms of malignancies treated with RT included endometrial (51%) with an adherence of 45% at least once per week, no documentation on six; and cervical (35%) with an adherence of 23% use at least once per week, and no documentation on six. Anal carcinoma patients made up 7% of this population, vaginal carcinoma comprised 4%, and vulvar carcinoma comprised 2%. Anecdotal information for the poor adherence rate to VD from the patient population includes: uncomfortable hard

plastic dilator, current VDs are “traumatic emotionally and physically”, the process seems “too sterile”, the dilator does not “do anything for them”, reports that “if the dilator vibrated or did something more than just sit there I would use it more often”, there is no time in the day for use, pain with insertion, the dilator is awkward to use, and reports that they were not educated thoroughly on the risk of not using the dilator.

Lack of standardized screening and education process prevents further quantifiable data beyond limited patient report. Nursing and providers at the project site report low adherence to VD has resulted in painful speculum exams, vaginal bleeding with opening of the speculum, nausea, low self-esteem, depression, sexual dysfunction, and decreased quality of life per patient report. Low adherence to VD complicates provider assessment of cancer response and vaginal health, as VS present when preforming a speculum exam limits visualization. Examination pain and vaginal trauma further place the patient at risk for continued sexual dysfunction and increasing severity of VS.

Problem analysis at the project site described in the fishbone diagram (Appendix C), found that nonadherence to VD (use of VD less than two times per week) is multifactorial. Reasons for low adherence range from lack of provider and nursing communication about sexual health/sexual dysfunction, providers not mirroring VD education provided by nursing, nursing providing minimal VD education, hesitancy on the part of the patient to discuss sexual dysfunction, patient dissatisfaction with the static dilator provided, and lack of standardized sexual health assessment leading to omission of dilator adherence in provider follow-up documentation. Lack of standardized screening and practices at the project site may place these women at higher risk of RT negative outcomes such as VS and decreased sexual health.

Project Purpose and Planned Practice Change

The project had three purposes within the eight-week timeframe: implementation of standardized sexual assessment by incorporating the FSFI-6 into the clinical workflow and documentation, decreased pain score (question six) by one point on FSFI-6, and increased VD adherence to at least twice per week by 10% from a baseline of 7%. Project aims for implementation of a clinical workflow guideline incorporating the FSFI-6 and use of vibrating VD were to: increase twice per week adherence to VD after pelvic RT, implementation of department wide use of the FSFI-6 for women undergoing pelvic RT, and decreased report of pain during intercourse on the FSFI-6 questionnaire. Ideal project outcomes were increased twice per week adherence to VD by 10%, implementation of the FSFI-6 in 90% of patients undergoing pelvic RT, and a decreased report of pain during intercourse by an average of one point on the FSFI-6.

Project interventions were twofold including the creation of a clinical nursing and provider workflow process to standardize assessment and discussion of sexual health/dysfunction, including pain assessment, and VD use. The clinical workflow included a standardized assessment tool incorporated into the electronic health record (EHR), the FSFI-6, implemented at consult and post RT follow-up for all women in the identified diagnosis groups. The intervention aimed to quantify sexual health, and further assess if use of VD changes sexual health scores.

Second, a vibrating dilator was provided to consenting women who reported adherence less than two days per week to static VD at their three-month post-RT follow-up. Multiple qualitative studies have found use of vibrating dilators as a facilitator to VD use (Bakker et al.,

2014; Bonner et al., 2011; Damast et al., 2019; Straub, 2016; White, 2015). The vibrating VD (FeMani Vibrating Massage Wand) issued is the only Food and Drug Administration (FDA) approved device for use in post-pelvic-RT female patients, and can be obtained via mail order from A Women's Touch Sexuality Resource Center in Madison, WI (M. Straub, personal communication, September 22, 2020). Cost per unit of vibrating VD was approximately $70, with free shipping on orders over $100, and for the purpose of this project was offset by donations from the clinical site's research department. Use of the FSFI-6 assisted in standardizing clinician documentation related to VD use, and further quantified patient's sexual function and pain level, allowing the site to monitor improvement. Providers and nursing continued to document subjective data in the weekly visit and progress notes as appropriate.

Congruence of DNP Project to Organization's Mission, Goals, and Strategic Plan

The mission of the project site is to provide excellence in cancer care, cancer education, and cancer research (R. Gradwohl, personal communication, August 26, 2020); which directly corelated with this project's aim to improve women's sexual function and quality of life after pelvic RT by utilizing research to identify best practice for VD and patient education. The goal of the organization is to be nationally recognized for premier cancer care and be the first choice for patients, their families, and referring providers (R. Gradwohl, personal communication, August 26, 2020). The organization is constantly undergoing strategic planning processes to become a national leader in providing the best in clinical quality, patient safety, service and value for its patients. The strategic plan within the organization aligned well with this DNP project, as improvement in quality of care during and post RT for these women can decrease

negative side effects, improve long-term quality of life and patient satisfaction. Increased patient satisfaction is often linked to positive public perception, increased referrals, and outside provider awareness of programs offered. This increase in outside referrals can lead to increased revenue for the organization as the post pelvic RT program continues to develop.

Quality improvement and evidence-based medicine are priorities at this organization. According to R. Gradwohl (personal communication, August, 26, 2020) the organization uses care guidelines based on the best available medical research and team collaboration among medical specialists. The DNP project aimed to develop a clinical workflow to increase adherence to vaginal dilation, implementation and sustainability requiring a team effort between nurses, providers, patients, and cancer center leadership.

CHAPTER TWO

REVIEW AND SYNTHESIS OF THE EVIDENCE IN THE LITERATURE

Review and Synthesis of the Evidence in the Literature

A comprehensive literature review (2000-2020) was conducted using a combination of the following search terms: “vaginal stenosis”, “pelvic radiation”, “vaginal dilator”, and “vibrator”. Information was organized by key concepts including VS definition, VD definition, adherence, patient education, and facilitators and barriers to use. Databases searched included: CINAHL, Cochrane library, Medline, and PubMed. Ultimately, forty-one articles were utilized for evidence including: four systemic reviews, four randomized control trials, three case-controlled trials, four prospective studies, five retrospective studies, four observational trials, one cross-sectional study, six case studies/series, six qualitative studies, and four expert opinion articles (Appendix N). Levels of evidence assigned to each study based on Melnyk and Fineout-Overholt’s (2015) Hierarchy of Evidence (Appendix D).

Vaginal Stenosis Post Radiation Therapy

Vaginal stenosis is the most commonly cited toxicity of pelvic RT throughout the literature (Arians et al., 2020; Brand et al., 2006; Hofsjo et al., 2017; Kirchheiner et al., 2016; Yoshida et al., 2015). VS is the result of increased production of collagen and fibrous tissue, leading to narrowing of the vaginal canal (Martins et al., 2017). Existing data regarding the incidence of VS is predominately based on small prospective and retrospective cohort studies, with a wide variation in reported incidence due to disparities in measurement techniques and

reported grading of VS. The most widely cited and validated grading tool for VS is the Common Terminology Criteria for Adverse Events (CTCAE; Appendix E, Table E1), with a Chronbach alpha of 0.76; however, multiple studies including Brand et al. (2006; 2012) developed non-validated grading tools for use in their published studies (Appendix E, Table E2). Brand et al. (2006) cite the prospectively recorded incidence of RT-induced VS as 38%. Brand et al. (2006) further report that VS most commonly occurs within the first-year post-treatment. Another prospective study substantiates the Brand et al. (2006) finding that grade one stenosis occurs within the first year of follow-up, and further reports the time to occurrence of moderate-to-severe stenosis gradually increases up to three years post RT (Yoshida et al., 2015). Actual stenosis rates cited by Yoshida et al. (2015) for grades one, two and three were 97.5%, 60.7%, and 7.4% respectively at three years post-RT. In a small retrospective study, Hofsjo et al. (2017) observed VS in 97% of cervical cancer survivors.

VS incidence rates for women undergoing pelvic RT for gynecological cancers are the most widely reported in literature. The prospective, multi-institutional EMBRACE study enrolled 588 women undergoing RT for locally advanced cervical cancer (Kirchheiner et al., 2014), findings at two years suggested the probability of grade three stenosis was 3.6%. However, mild and moderate vaginal symptoms (grades one and two) were pronounced with a probability of 89% and 29% respectively (Kirchheiner et al., 2014). Whereas the incidence of VS seems to be the highest in women undergoing RT for cervical cancer, women completing treatment for endometrial cancer report much lower rates. A retrospective study of 157 patients completing RT for endometrial cancer found no grade two or higher vaginal stenosis for any patient at two years post-RT (Townamchai et al., 2012).

Although less commonly reported in literature, VS following pelvic RT for gastrointestinal cancers is also recognized. A small, prospective study of 54 patients completing pelvic RT for rectal and anal cancer cites the incidence of VS as 67% for all grades at one-year post RT (Son et al., 2015). More recently, a prospective, randomized, two-armed, open, single-center phase-II trial (DILANA) has begun recruitment with the primary aim of evaluating the incidence and grade of VS in women undergoing RT for anal cancer (Arians et al., 2020). Recruitment for the DILANA trial began in 2019, with a recruitment period of four years to a planned 60 patients (Arians et al., 2020). Follow-up for each patient will be 12 months, with end of study planned at the 12-month follow-up for the last patient, assumed to be the year 2024 (Arians et al., 2020). Given the limited amount of data in literature concerning VS for women undergoing pelvic RT for gastrointestinal cancers, more prospective studies are needed to evaluate the incidence and grade of VS in this population.

Pathogenesis

Morris et al. (2017) cite, the vagina is lined by stratified squamous epithelium which overlay the lamina propria and longitudinal muscle fibers. Vaginal stenosis post RT is divided into acute or delayed (late) reactions. Acute RT reactions are those occurring during or immediately after RT (Morris et al., 2017). Acute reactions include mucosal inflammation, hyperemia and epithelial denudation leading to ulceration and endothelial injury which can cause small-vessel thrombosis, edema, and smooth muscle necrosis (Morris et al., 2017).

Delayed or late RT reactions are those occurring later than 3 months post-RT. VS is considered a late reaction, and is due to damage endured by the vaginal mucosa due to increased collagen production in the fibroconnective tissue layer (Morris et al., 2017). This damage leads

to atrophic changes in the vaginal mucosa and destruction of the muscle and vasculature resulting in hypoxia, tissue atrophy and fibrosis (Morris et al., 2017).

Clinical Assessment

Clinical assessment of VS takes place during post-RT follow-up at the recommended three, six, nine, and twelve-month interval during the first-year, and consists of speculum exam (Elit et al., 2016; Morris et al., 2017). Upon assessment, providers note telangiectasia, mucosal pallor, adhesions and occlusion of the vaginal canal, loss of elasticity, and fragility of the vaginal walls to varying degrees when VS is present (Morris et al., 2017). In an age-matched control trial including 34 patients treated with RT for cervical cancer and 37 healthy control women, Hofsjo et al. (2018) found upon inspection of the vagina that 91% of the cancer survivors had signs of atrophy with pale and/or flat mucosa to varying grade. The survivors had a shorter vagina than controls when measured at examination, and telangiectasia was present in 82% of the survivors (Hofsjo et al., 2018). In an earlier study, Hofsjo et al. (2017) clinically found that 91% of survivors had pelvic fibrosis, with reduced elasticity of the vagina both with speculum exam and palpation. In either study, no women in the control group had visible or palpable changes during examination, further substantiating that VS is a primary toxicity of pelvic RT (Hofsjo et al., 2018). Prevention and accurate assessment of VS is paramount, as VS interferes with pelvic examination necessary for cancer surveillance and identification of abnormal findings that suggest vaginal, pelvic sidewall, or distant recurrence (Brand et al., 2006; Elit, 2016; Stahl, 2018).

Sexual Assessment

Sexual assessment of RT-induced late effects in women post treatment is an important aspect of the overall clinical picture, however; multiple studies cite persistently low communication between women and health care professionals (Flynn et al., 2012; White et al., 2011; White et al., 2013). In an observational study of post-RT follow-up with women after gynecological or gastrointestinal cancer, healthcare providers asked about bowel and bladder toxicity in 70% of office visits, but about sexual consequences in only 24.6% (White et al., 2013). This rate of inquiry about the sexual consequences of pelvic RT among females is low compared with data from a study in prostate cancer survivors, where a discussion rate of 52% at follow-up was cited (Forbat et al., 2011). Similar to the findings of Forbat et al. (2011), a quantitative study (Flynn et al., 2012), assessed the disparity of sexual assessment between male and female cancer survivors and found that health care professionals discussed sexual consequences with 80% of men with prostate cancer, and only 23% of women across pelvic disease sites.

A common reason cited for the low inquiry to sexual health is a lack of clinical time to address the psychological, social, and sexual aspects of the cancer survivor's disease experience (White, 2015). One suggestion to aid the comprehensive discussion about sexual health is the use of a PROM (White, 2015). A PROM can provide the information needed for a detailed discussion of the type and severity of sexual toxicity in order to guide a timely and effective discussion and subsequent clinical management (White, 2015; Appendix F). Suitable validated PROMs to guide discussion of RT sexual consequences include the FSFI, FSFI-6, Late Effects Normal Tissue/Subjective Objective Management Analytic (LENT/SOMA) questionnaire, European Organization for Research and Treatment of Cancer (EORTC), and Functional

Assessment of Cancer Therapy (FACT). White (2015) cites that while all of these PROMs can help guide discussion, many are lengthy in content and some are not validated for use in women.

Patient Reported Outcomes

Sexual Dysfunction. Rates of female sexual dysfunction post-pelvic RT range from 30% to 63%, with most of these women (62-88%) being at high risk for VS (White, 2015). Evidence suggests dyspareunia is the most frequently reported consequence of VS, at a rate of 20% (Bergmark et al., 1999, White, 2015). More recent literature found that dyspareunia affects 164 out of 243 women post-RT, for a rate of 67% (Kollberg et al., 2015). In the Kollberg et al. (2015) study, the relative risk of deep dyspareunia was 1.87 with impaired patient-reported elasticity, as compared to those who reported moderate to good elasticity. Kollberg et al. (2015) conclude that in order to prevent deep dyspareunia clinicians must find a way to increase vaginal elasticity. Concerning superficial dyspareunia, Kollberg et al. (2015) cite reduced lubrication to be a risk factor 100% of the time. In order to prevent or relieve superficial dyspareunia, Kollberg et al., (2015) state clinicians must find means to increase lubrication in order to reduce atrophy and friction. The findings of Bergmark et al. (1999) and Kollberg et al. (2015) are the only two studies to date which have distinguished superficial from deep dyspareunia. However, the definitions of dyspareunia are not universal, and as such the studies may not be entirely comparable.

Other than dyspareunia, decreased elasticity, and amount of lubrication, PROMs contributing to sexual dysfunction include: decreased vaginal length, difficulty of orgasm, and decreased genital swelling. In an age-matched control trial PROM questionnaire, Hofsjo et al. (2018) cite insufficient vaginal lubrication was present in 39% of pelvic RT patients and 3% of

control women, decreased vaginal swelling present in 35% of survivors and 6% of controls, reduction in vaginal length presented in 52% of survivors and 13% of controls, and decreased frequency of orgasm occurred in 63% of survivors and 32% of controls. Outcomes associated with PROMS include: frequency of vaginal intercourse less than three time a month as 29% in survivors and 50% in controls, satisfaction with present sexuality as 41% in survivors and 86% in controls, and feelings of being sexually attractive as 52% in survivors and 82% in controls (Hofsjo et al., 2018). Further substantiating the findings of Hofsjo et al. (2018), Shankar et al. (2020) found that dyspareunia was reported in 32.9% of women completing pelvic RT, altered sexual life was present in 25.9%, and 22.3% of patients showed altered interest in sex post RT. The Shankar et al. (2020) study is limited by low data collection rates due to the sensitivity of sexual issues in the Indian culture.

Vaginal Dilation

Radiation oncology prescribed dilators are traditionally made from a hard plastic, which women find uncomfortable, and can contribute to nonadherence (Straub, 2016). At the University of Wisconsin Hospital and Clinics in Madison, providers noticed that patients who purchased novelty vibratory dilators had less VS compared to those who used a static dilator or did not use a dilator as prescribed (Straub, 2016). The providers theorized that vibrating dilators may be more effective because of the stimulation of the tissue, which is thought to bring in oxygenated blood to the area while also stimulating the lymphatic system, thus decreasing fibrosis and pain (Straub, 2016). Utilization of vibrating dilators at the University of Wisconsin resulted in increased adherence rates of 35%-40% annually to VD after the completion of pelvic RT (M. Straub, personal communication, September 22, 2020). As a result of increased

adherence to VD providers noted healthier vaginal tissue during examination, patients reported increased sexual satisfaction, as well as decreased reports of pain with vaginal examinations (Straub, 2016). Qualitative reports across the literature support increased adherence with the use of vibrating vaginal dilators (Bonner et al., 2011; Bakker et al., 2014; Rinske et al., 2015; Lee, 2018). Qualitative reports such as, "It'd be better if it had a battery, I think I might get more enjoyment out of it" show how vibrating dilators could increase adherence in this patient population (Bonner et al., 2011). Partnered women reported that use of a vibrator helped decrease sexual fear when incorporated in sexual contact (Bakker et al., 2014). Research from University of Wisconsin and qualitative reports across the literature suggest increased adherence and improved sexual health with use of vibrating versus static VD; however, rigorous studies are lacking.

Educational Interventions/Guidelines for Use

Standardized guidelines for use of VD are lacking in literature, and often are contradictory. No single approach to VD use is uniformly utilized, and advice on when and how often VD should be performed is highly variable (Morris et al., 2017). Cochrane Review key findings cite that women who want to preserve vaginal length post-RT should consider dilation for months to years (Miles & Johnson, 2014). The Cochrane review concludes that there is no reliable high-level evidence to show that regular vaginal dilation prevents RT-induced VS (Miles & Johnson, 2014). A consensus guideline using the Delphi method states sexually active cervical and vaginal cancer patients younger than 70 years should always be provided a VD and information on use (Bakker et al., 2014). Tailored information regarding VD was recommended by the panel for vulvar and endometrial cancer patients younger than 70 years and sexually

inactive patients (Bakker et al., 2014). No consensus was reached for women undergoing RT for gastrointestinal malignancies (Bakker et al., 2014). The panel advised dilation to start four weeks post-RT, be performed two to three times a week for one to three minutes, and to continue for nine to twelve months (Bakker et al., 2014).

Observational studies indicate that regular use of VD post-RT is associated with lower rates of self-reported stenosis. One prospective study advised use of VD dilator kits containing four dilators of increasing size, to be used three times a week (Law et al., 2015). The educational intervention consisted of a uniform patient-education fact card and individualized instruction on use of the VD (Law et al., 2015). VS outcomes at 12 months cite that 82% of women maintained pre-RT VD size, reporting minimal to no stenosis (Law et al., 2015). In another prospective study, Stahl et al. (2018) recommended VD use three times per week, for a total of 10 minutes per session, for at least one year. The education intervention included verbal and written instructions by a specially trained nurse, and reinforcement of education by the radiation oncologist after the last treatment (Stahl et al., 2018). The study findings at 15 months included an incidence of VS in 38.8% of noncompliant patients, 33.5% in those with standard compliance, and 21.4% for those with extended compliance (Stahl et al., 2018). Further, Stahl et al. (2018) concluded that at three years the incidence of grade three VS was 20.2% for those who maintained compliance to VD; thus, substantiating that the degree of VD compliance was associated with a decrease in the probability of VS over time, with the highest compliant patients having the lowest incidence of VS (15.6%). Radiation Oncology clinics must rely on observational data concerning VD use and stenosis as grading systems and advice for VD use

vary across the literature. Standardization of grading scales and guidelines on VD use would be beneficial to provide more rigorous data concerning the link between VS and VD utilization.

Adherence

Due to the qualitative and observational nature of studies regarding VD adherence, in addition to variation in educational practices, cited adherence to VD range widely, and are generally found to be less than 50%. Friedman et al. (2010) cite an adherence rate of 33% in one retrospective study. Law et al. (2015) found that adherence was highest in the first three months post-RT (56%), but fell to 25% by one year. A systemic review reported adherence rates ranged between 25% and 89.2% across 21 studies, with all studies relying on women's self-report to VD use (Lee, 2018).

Several interventional studies have examined methods to improve rates of adherence across female pelvic-RT patients. Much like the proposed quality improvement project, Bakker et al. (2017) performed a pilot study with a nurse-led sexual rehabilitation intervention. Outcome measures included measuring sexual functioning by means of the FSFI and assessing frequency of vaginal dilation with structured interviewing (Bakker et al., 2017). Findings of the pilot study are as follows: at six months 88% of participants reported VD use at least twice per week, at twelve months 75% dilated at least twice per week, and 92% performed VD at least once per week (Bakker et al., 2017). Exit interviews were conducted after the twelve-month follow-up, 94% of women reported the intervention of completing the FSFI and nursing support were helpful for dilator use and resuming sexual activity (Bakker et al., 2017). Women also reported that nursing support provided reassurance and motivated them to begin VD, which they may not have otherwise preformed (Bakker et al., 2017). Limitations of this study include a high attrition

rate (40%), and a low patient sample of 16 women; however, a strength of this study is that the intervention (nurse-led FSFI) was proven to be feasible and may improve support for women during sexual recovery and VD post RT (Bakker et al., 2017).

Facilitators to Vaginal Dilation

An important aspect of motivating women post-RT to adhere with VD is understanding the facilitators to VD use and incorporating these into clinician counseling. Multiple qualitative reports exist in the literature documenting facilitation to VD (Bonner et al., 2011; Bakker et al., 2015; Lee, 2018). According to Bonner et al. (2011), major facilitators emerging from interviews included: concern about stenosis, belief in VD effectiveness, reminders of stenosis, normalization of VD in daily routine, focusing on VD use as an extension of medical treatment, and focusing on the positive aspects of VD use. The issue of sexual relationships also arose as a facilitator, concerning both current and future relationships (Bonner et al., 2011). Medical examinations played an important role in facilitation, as multiple women indicated that reassurance from their medical professional increased the perception that VD was helpful to prevent stenosis (Bonner et al., 2011). Facilitators to use as reported by Bakker et al. (2014) include: starting VD soon after completing RT to make it less of an obstacle, lying in bed and reading a book to help relax, and using a vibrator in place of the oncology issued VD as it was easier to integrate into sexual activity. An underlying theme discovered by both Bonner et al. (2011) and Bakker et al. (2014) was supportive interactions with healthcare providers and significant others (Lee, 2018).

Barriers to Vaginal Dilation

Much like facilitators to use, barriers to VD are completely derived from qualitative reports in the literature. Major barriers emerging from interviews were: uncertainty about VD use, viewing the dilator as a negative experience, lack of private time during the day for use, and an association with sex toys (Bonner et al., 2011). Bakker et al. (2014) cite that more than half of women post-RT express negative emotions about VD use. Major barriers identified by Bakker et al. (2014) include: experiencing pain, tension of pelvic floor muscles, blood loss during use, reminders of cancer treatment, and constant reminder of cancer diagnosis. Cullen et al. (2012) interviewed ten women from a large urban Canadian city, and found that women viewed VD as an embarrassing sex toy, an aversive "hands-on" experience, and women voiced they felt as if they were reliving the invasion of treatment. A major barrier cited across the literature is the persistent variation of VD education post-RT. Consistent clinical guidelines to practice would help to eliminate or decrease this barrier, but until these exist the care team must address VD through assessment and counseling.

Why Practice Change Is Important to the Organization

Adherence rate to twice weekly VD at the project site was identified as 7%, a much lower rate than the 33% reported by Friedman et al. (2010). According to University of Wisconsin data, adherence to VD increased 35%-45% with the inclusion of vibrating dilators (M. Straub, personal communication, September 22, 2020). Evidence from the literature suggests that standard education practices increase VD adherence in women post pelvic RT, yet this is not consistently preformed in the radiation oncology setting. Creation of a nursing and provider clinical workflow can help to reinforce the importance of VD use in this population and

standardize practice. According to Bakker et al., (2017), use of the FSFI opens dialogue between patients and healthcare providers and provides additional opportunities for education in addition to providing support and reassurance to help facilitate VD use. Multiple themes to VD facilitation exist in the literature, one facilitator identified by multiple qualitative studies is the use of a vibrating dilator as women state “it feels less sterile”, and is easier to integrate into sexual activity (Bonner et al., 2011; Bakker et al., 2014). Use of facilitators found in the literature, the FSFI-6 and vibrating dilator, will help guide this project to increase adherence in post pelvic RT women by 10%.

CHAPTER THREE

SETTING AND METHODS

Theoretical Framework

The model utilized for this quality improvement project was the health promotion model (Appendix G), which is useful in practice when the focus of care is on promoting behaviors to enhance health (Masters, 2015). The health promotion model portrays the multidimensionality of people interacting with their interpersonal and physical environments in the pursuit of health, with a nursing perspective of holistic human functioning (Masters, 2015). Emphasis of the health promotion model is the active role of the patient in shaping and maintaining health behaviors and modifying the environment to support health behaviors (Masters, 2015).

Masters (2015) cites, there are three major categories to consider in the health promotion model: individual characteristics and experiences, behavior-specific cognitions and affect, and behavioral outcome. Individual characteristics refers to prior related behavior and personal factors. According to the health promotion model, prior behavior influences current and future health promoting behavior by way of habit formation, as well as through perceptions of self-efficacy, benefits, barriers, and activity related affect of emotions (Masters, 2015). For the purposes of this project, individual characteristics include relationship status, prior sexual activity, and comfort with discussing sexual health.

Behavior-specific cognitions and affect are the behavior-specific variables that are the target of nursing intervention as they are amenable to change (Masters, 2015). Factors to consider within the behavior-specific cognitions are perceived benefits and barriers to action,

perceived self-efficacy, and activity-related affect (Masters, 2015). Benefits to action would include open communication regarding sexual health with providers and partner, return to baseline sexual functioning post RT, decreased pain with penetration, decreased adverse effects of RT such as VS, healthy relationship with partner, healthy perception of self. Perceived barriers to action include negative experience with VD or with health care providers during education, lack of time, need for discretion, and unwillingness to discuss sexual health.

According to Masters (2015), commitment to a plan of action marks the beginning of a behavioral event. Interventions in the health promotion model focus on raising consciousness related to health-promoting behaviors, promoting self-efficacy, enhancing the benefits of change, controlling the environment to support the change, and managing barriers to change (Masters, 2015). As such, the behavioral outcome of this project was adherence to VD use two to three times per week.

Process Improvement Model

Plan-Do-Study-Act

The Plan-Do-Study-Act (PDSA) served as the improvement model for this project. PDSA cycles promote the use of small-scale, iterative approaches to test interventions, allowing for rapid assessment and flexibility to adapt to data feedback (Taylor et al., 2014). The advantage of small-scale tests is they provide an opportunity for the user to act and learn, while minimizing the risk to patients and the organization (Taylor et al., 2014). Taylor et al. (2014) state this allows the organization to build evidence for change, and engage stakeholders as confidence in the intervention increases.

The PDSA cycle is a four-step model for improving a process (Appendix H). Step one is plan, which involves developing the plan for action along with identifying tasks and task owners (Christoff, 2018). The plan involves identification of the when, how, and where the plan will be implemented, and specific objectives as well as predictions of outcome should be stated in this phase (Christoff, 2018). Do involves carrying out the plan and documenting data to identify successes, problems, or unexpected outcomes (Christoff, 2018). Christoff (2018) cite, study is the evaluation of the documented data to determine if a plan is working. Results in the study phase should be compared to those predicted as well as previous performances (Christoff, 2018). Act means the intervention being tested is adopted, adapted, or abandoned based on evaluation of the data in the study phase (Christoff, 2018).

Agency Description

Setting

An outpatient radiation oncology department located in south-central Montana, providing radiation oncology treatments, including the only high-dose brachytherapy site in a four-state area (which includes Montana, Wyoming, and western North and South Dakotas). The department predominately cares for an ambulatory outpatient population; however, it is attached to the main hospital by a skybridge, which allows the opportunity to also care for hospitalized oncology patients. On average, the department treats 450 patients per year, including 60-80 female pelvic patients annually.

Target Population

The population of this project included women treated with pelvic RT who received treatment between January 1, 2020 and September 9, 2020. Included diagnoses utilizing pelvic RT include cervical (endo and exocervix), endometrial, anal, rectal, ovarian, vaginal, and vulvar cancers. A convenience sample obtained through chart review identified patients who met the criteria for this project, any patient not meeting the above criteria was excluded. Women aged in range from 34 to 85 years old, with a median age of 59 years old. Chart review identified 55 women who had undergone pelvic RT and received dilators between the specified time period. Of those 55 women, 18 (33%) reported not using their VD at all when presenting for their three-month follow-up. Ten women (18%) indicated an average of once per week usage. A mere four of the 55 women (7%) were using the dilator the recommended two or more times per week. Dilator use was not documented for 13 (24%) of the 55 patients, and 10 patients (18%) were not yet three months out from the completion of their treatment. Within this group, the most common forms of malignancies treated with RT included endometrial (51%) with an adherence of 45% at least once per week, no documentation on six; and cervical (35%) with an adherence of 23% use at least once per week, with no documentation on six. Anal carcinoma patients made up 7% of this population, vaginal carcinoma comprised 4%, and vulvar carcinoma comprised 2%.

Description of Stakeholders

Stakeholders responsible for implementation of quality improvement project included the Doctorate of Nursing Practice (DNP) student and the chief medical physicist. The primary role of the chief medical physicists was identification of patients meeting project criteria, creation of

excel spreadsheet with patient identifiers and diagnosis for data collection purposes, and input of FSFI-6 into questionnaires section of EHR. The DNP student made phone calls to all patients identified by the chief medical physicist, obtained verbal consent via phone and reviewed and documented FSFI-6 with each patient along with current VD adherence, asked the women if they wanted the option of a vibrating VD and mailed this to those who chose to participate, re-educated all women using the VD education handout, and made follow-up calls at eight weeks to review and document the FSFI-6 and VD adherence then compared to baseline. During the plan phase, the DNP student was responsible for monthly updates to nursing staff and physicians, sharing literature findings and eliciting feedback while developing the implementation process.

Stakeholders identified in planning who would support future state implementation included nursing staff: three Oncology Certified (OCN) RNs and one licensed practical nurse (LPN), three Radiation Oncologists, and female pelvic RT patients, with support from cancer center leadership and project site research department. Nursing staff buy-in was obtained through reviewing current VD adherence at project site and comparing to literature findings. Nursing staff felt this project was important due to the low, 7% adherence, and feedback from previous patients who expressed their dislike of the static VD obtained after treatment. Patient feedback also played a role in implementation of the FSFI-6, as patients routinely expressed to nursing staff the negative effects of radiation on their sexual health, and asked why this was not discussed in further detail prior to initiation of RT. Research department responsible for assisting with IRB review process and funding of vibrating VD distributed during the “Do” phase. Stakeholders who benefited from implementation included female pelvic radiotherapy patients

and their partners, as consistent screening for VS and education regarding VD use has the potential to benefit sexual health.

Training of stakeholders included review of the FSFI-6 questionnaire, VS and VD education. Feedback elicited from nursing staff supported the need for laminated cards in each exam room explaining the process and inclusion diagnoses for review and documentation of FSFI-6. Physician feedback included the need for nursing staff documentation of current VD adherence at follow-up in nursing progress note for consistency of documentation. Physician's stated they would also document VD adherence, but felt the nursing staff should also document as this was a nurse-driven project.

Facilitators and Barriers to Implementation

Facilitators.

Facilitators to implementation included experienced clinical staff, support from Cancer Center leadership, standardized VD patient education handout, and efficient processes (SWOT analysis; Appendix I). Each of the three RNs in the department had obtained OCN certification and had at least four years of oncology experience; with the most experienced RN having 13 years of experience including identification as a department mentor, followed by eight years of experience, and finally four years of oncology experience. The department's Radiation Oncologists had a combined 43 years of experience, with the least experienced provider having worked in the department for five years. Nursing staff and physicians shared a collegial relationship in which each professional was open to questions and mentoring. Both professional groups recognized the variabilities in addressing sexual function between males and females, and were supportive of initiating a change in practice to better meet patient needs.

Cancer Center leadership fully supported quality improvement projects throughout the Cancer Center and includes these in the yearly Cancer Center report. The Chief Medical Officer of the Cancer Center was also the Radiation Oncologist with the most experience, adding further support to the project. One of the goals of the Cancer Center leadership team was to increase nursing staff awareness and participation in evidence-based practice and quality improvement, further substantiating the importance of the project.

The radiation oncology department previously utilized a standardized, printed VD education handout (Appendix B) further facilitating the implementation of the project. Patient feedback regarding the handout was that it was easy to understand and read, step by step, and included use and storage information. Efficient education practice regarding VD use were also embedded into pre-project practice at the site. Physicians initially gave an overview of the importance of VD use to prevent VS throughout treatment and then re-iterated this at final treatment, nursing staff were then responsible for education of VD use, reviewing the standardized VD education sheet, and handing out of VD to patient.

Barriers. Barriers to implementation included patient and healthcare provider hesitancy to discuss sexual health in the female population, patient attitude and negative experiences regarding VD and VD use, and short timeframe of project implementation. Congruent with prior research, site stakeholders reported hesitancy to discuss sexual problems with patients, along with low frequency of patients broaching the topic without prompt. Stakeholders stated hesitancy was due to the "belief that other topics are more important to the woman than sexual dysfunction", that "women do not want to discuss sexual dysfunction", and that "lack of time during the consult limits discussion of sexual dysfunction".

Patient attitude and negative experiences to VD use were widely cited from qualitative reports in the literature, as well as anecdotal findings at the project site. Women routinely reported to nursing staff and physicians that VD "is too sterile", "doesn't do anything for me", "feels like a medical procedure", "reminds me too much of treatment", and "I don't know when I would make the time to do such a thing". These negative attitudes and experiences to VD were substantiated by the low adherence (7%) to VD twice per week at three months post RT.

Time was identified as a major barrier to implementation and data collection for this quality improvement project, since within the radiation oncology setting, VD adherence was measured at three months (12 weeks) from completion of treatment. Due to DNP program constraints, implementation and data collection took place over an eight-week period, with follow-up FSFI-6 and adherence phone calls made to patients within that eight-week timeline. In order to mitigate these time restraints, the project site Institutional Review Board (IRB) recommended obtaining verbal consent only from participants (Appendix J).

Project Design

The quality improvement project had three purposes: implementation of the FSFI-6 into the clinical workflow and documentation, decreased pain score on FSFI-6 (question six) by one point, and increased twice per week VD adherence by 10% from a baseline of 7%. As a means to achieve this, the DNP student provided scripted phone calls to patients treated between January 1, 2020 and September 9, 2020 and after verbal consent was obtained, the FSFI-6 was reviewed at first phone call and again in eight weeks. Phone interview scores were input in DNP student Excel spreadsheet. Patient attitudes regarding use of the FSFI-6 were documented in Excel spreadsheet at follow-up phone call. In order to implement the FSFI-6 into EHR documentation

and clinical workflow, the chief medical physicist was contacted and asked to integrate FSFI-6 into the "questionnaire" section of Aria EHR, integration took place February 11th, 2021. "Go live" documentation of FSFI-6 scores by nursing staff took place February 26th, 2021.

To improve VD adherence, patients contacted by the DNP student were offered the option of a vibrating VD at initial phone call performed between January 4th, 2021 and January 15th, 2021. Adherence to VD, was defined as use two or more times per week for 10 to 15 minutes at a time, which was asked of all patients at initial phone call and again at follow-up phone call performed between February 22nd and February 26th 2021. VD education handout (Appendix B) was reviewed with each patient whose adherence was below two days per week at initial phone call. Data collection included tracking patients who were given a vibrating VD and the impact of the intervention on VD adherence.

SMART Goals

The short-term SMART goal of this project was: Call identified patients to review and document FSFI-6 score in Excel spreadsheet, and mail vibrating VD (if they choose), conducted between January 4th and January 15th, 2021. Mid-term goal of this project was: Train nursing staff and physicians at project site via in-service on use of FSFI-6 achieved on February 26th, 2021, and implementation of a laminated clinical workflow card completed February 26th, 2021. Long-term goal of this project was: Implementation of FSFI-6 into the EHR "questionnaires" completed on February 11th, 2021, increased twice per week VD adherence by 10%, and decreased report of "discomfort or pain during vaginal penetration" on FSFI-6 by one point through follow-up calls, completed February 26th, 2021.

Project Methods

Phase One: Pain Assessment and VD Adherence

Prior to implementation of the FSFI-6 into EHR and clinical workflow, interventions took place in a stepwise fashion (Appendix K). The PDSA cycle served as the improvement model for this project, as the project site utilized PDSA cycles as part of organizational supported process improvement to test change. All staff and team members within the department were familiar with the PDSA cycle and had utilized PDSA cycles previously in process improvement projects. Implementation of the PDSA cycle included:

Plan. (What) Collection of baseline data regarding the number of female pelvic radiotherapy patients treated in the department between January 1st, 2020 and September 9th, 2020 by September 15th, 2020. Also, application submitted to Montana State University (MSU) and project site IRB for project approval on November 20th, 2020. (Who) Chart review performed with the assistance of the chief medical physicist, who had administrative access to run such a review. Medical physicist identified the patients that meet the diagnosis code criteria for the project by September 15th, 2020 and placed the data in Excel spreadsheet emailed to DNP student. Based on this information, chart review was conducted by DNP student between September 15th and September 22nd, 2020 on each individual patient to determine vaginal dilator use at three-month follow-up based on documentation in physician progress note. VD adherence was documented in Excel spreadsheet, and kept on password protected project site computer. IRB application submitted by DNP student with the assistance of project site research department. (Where) Radiation oncology office embedded in ambulatory oncology center. Chart review was performed in Aria, the radiation oncology specific EHR. (Who executed) Chief

medical physicist and DNP student. (When) During project planning (September 15th through the 22nd) to obtain baseline data and monitor improvement.

Do. January 4th, 2021 (after site and subsequent University IRB approval which took place December 23rd, 2020) through January 15th, 2021 calls placed to the female patients identified as meeting criteria, described the quality improvement project, and obtained verbal consent to participate in the project (Appendix L). Participants chose from one of the following: (1) Not complete the questionnaire via phone and state she was not interested, (2) Complete the questionnaire, but state that she was not interested in a vibrating vaginal dilator, or (3) Complete the questionnaire and receive a vibrating vaginal dilator. In order to mitigate the time constraint, the project site IRB approved verbal consent. After verbal consent was obtained (between January 4th and January 15th), the DNP reviewed the FSFI-6 with the patient via scripted telephone (Appendix M) conversation, asking about current VD adherence, and documented in Excel spreadsheet. During the telephone conversation, DNP student asked the patient if she was interested in use of vibrating VD in place of the previously issued static VD. If patient was interested in vibrating VD one was mailed to home address no later than January 15th, 2021 along with standardized VD education handout (Appendix B). If patient was not interested in vibrating VD, a standardized education handout was again reviewed via phone and the patient was allowed to ask questions/concerns regarding VD use. The DNP student then called patients who elected to receiving the vibrating VD one week after the dilator was mailed to review instructions for use and answer any questions.

Study. Between February 22nd and February 26th, 2021 eight-week follow-up call placed to patients, assessed and documented adherence to vibrating VD and comparison of baseline FSFI-6 to follow-up FSFI-6 in Excel spreadsheet, scripted conversation occurred regarding participant's feelings toward use of FSFI-6 to quantify sexual health. Discomfort or pain during vaginal penetration scores were tracked and documented in Excel spreadsheet along with VD adherence and FSFI-6 total score.

Act. The two-pronged approach to this quality improvement project allowed for baseline data to be collected for future PDSA cycles to improve VD adherence at the project site. Based on data collected and patient input regarding static versus vibrating dilator this aspect of the project was positioned to be abandoned, adapted, or adopted in future state.

Separate from the dilator outcome was the implementation of the FSFI-6 into clinical workflow to quantify sexual health in this population. Clinical workflow included incorporation of the FSFI-6 into the EHR, and implementation of the questionnaire at consult and post RT follow-up for all women in the identified diagnosis groups. Standardized documentation of the FSFI-6 in the EHR allowed the project site to further quantify sexual health, assess if use of VD changes sexual health scores, and was intended to prompt future QI or research projects aimed at improving patient outcomes. Implementation of validated sexual health screening for women echoes the recommendation of the AUA for validated and standardized screening in the male population undergoing pelvic RT, providing a proactive approach in equalizing women's sexual health issues and standardizing oncology care.

Phase Two: Implementation

Future state PDSA cycle (Appendix N) was based on findings from phase one of the project, phase two then implemented as:

Plan. (What) Created a nursing and provider workflow for assessment of VS and education of VD, including incorporation of the FSFI-6 into the EHR. FSFI-6 integrated into EHR with assistance the chief medical physicist on February 11th, 2021. Laminated workflow card creation and implementation took place February 26th, 2021. DNP student trained nursing staff and physicians via in-service on workflow, based on laminated card, on February 26th, 2021. Workflow provided on the laminated card and placed in each exam room on February 26th, 2021. (Who) Nursing was determined to be responsible for completing FSFI-6 with patient and documenting in EHR, which began on February 26th, 2021, as well as educating patients regarding sexual dysfunction and VD use. Providers were made responsible for reviewing FSFI-6, reinforcing sexual health education and VD use. (Where) Radiation oncology office embedded in ambulatory oncology clinic. (Who executes) Nursing and providers. (When) At consult, upon completion of RT, and at each routine follow-up thereafter.

Do. Assessment and documentation of FSFI-6 in EHR and education on use of VD by nursing staff beginning February 26th, 2021. Physician review of FSFI-6 questionnaire and discussion regarding sexual health as related to RT. Documentation by nursing and providers regarding VD adherence at each subsequent follow-up appointment.

Study. Project time constraints did not allow for further evaluation of FSFI-6 percentage of completion, pain score, or adherence to VD. Future sustainability of project does rely on these measures.

During planning, costs associated with the project were identified as student time, EHR adaptation, vibrating VD and mailing costs. Approximately 120 hours of DNP volunteered time resulted in implementation of standardized sexual health screening and clinical workflow for education and documentation for women undergoing pelvic RT. A total of five vibrating VD were purchased by the Research Department at a cost of $40 each, with a shipping cost of $14.85. The original retail cost of $70 per unit was offset by a price reduction of $30 per unit by the FeMani Wand manufacturer who felt this project had the potential to increase future sales to the project site radiation department. Adaptation of the FSFI-6 into the EHR took the chief medical physicist one hour with an estimated cost of $92.35 (her hourly salary). Since training occurred during the department's monthly training of physician and nursing staff this cost was accounted for through annual site budgeting. Card printing and lamination was also covered by allotted department supply cost.

Human Subjects Protection

IRB approval for this project was obtained through both Montana State University and project site IRB (Appendices J, L). Due to the quality improvement use of aggregate data with no patient identifiers, the project was determined to meet exempt status by the University. However, after review, project site IRB required an expedited review (Appendices J, L). Project description, voluntary nature of participation and process to address concerns was reviewed in the Project Information sheet (Appendix L) with each patient. In order to protect patient health

information (PHI), all data was accessed and stored on password protected project site computer. Each patient was deidentified by assigning a randomized four-digit code with the code key kept in a locked location within the department. FSFI-6 was documented on hardcopy by DNP student for each patient, and never placed in EHR, with hardcopies stored in locked location, to be kept until December 31st, 2022, at which time they will be promptly shredded and destroyed. Excel spreadsheet stored on password protected project site computer with patients identified by DNP student only by four-digit assigned code. PHI kept on password protected project site computer will be completely deleted by December 31st. Emailing of quality improvement project information sheet did not occur as IRB approved verbal consent, further decreasing the risk of PHI breech. With each of the above security practices in place, there was minimal risk to the patient in participation of the project.

Measures and Instruments

FSFI-6. Morris et al. (2017) cite that for best patient outcomes, sexual function should be assessed pre-RT and reassessed in each post-treatment follow-up. The FSFI-6 (Appendix A) is a validated patient reported outcomes questionnaire abridged from the original Female Sexual Function Index (FSFI-19), composed of six questions covering the domains of desire, arousal, lubrication, orgasm, satisfaction, and pain (Dall'Agno et al., 2019). The FSFI-6 takes no more than three minutes to complete, and can aid in rapid assessment and discussion sexual dysfunction in the clinic setting (Isidori et al., 2009). Each item of the FSFI questionnaire is associated with a five-point ordinal scale, where five represents optimal function, and one the poorest function (Isidori et al., 2009). A total is calculated by summation of the six domain

scores, a score of less than 19 indicates the need for further investigation with either the full FSFI-19 or a dedicated interview (Isidori et al., 2009). The FSFI-6 has been proven to be highly reliable at identifying women at risk for sexual dysfunction, with a Cronbach alpha ranging from 0.789 to 0.84 (Rosen et al., 2000; Isidori et al., 2009; Dall'Agno et al., 2019). The FSFI-6 was chosen for use in this project due to ease of use, literature support in standardized use in this patient population, and open utilization without cost or copyright infringement.

Data Collection Plan

Phase One. Data was collected by DNP student and placed in Excel spreadsheet provided by Chief Medical Physicist, password protected, and only accessed from project site computer. Initial data collected by Chief Medical Physicist and placed in Excel spreadsheet to include all women who meet inclusion criteria for the project. Chart review performed by DNP student to document each patient's adherence to VD at three-month follow-up, as documented by provider in EHR.

Phase Two. After IRB approval, initial phone call placed to each patient and verbal consent obtained. Data collected at initial phone call included current VD adherence and FSFI-6 score (with focus on question number six, "pain or discomfort with vaginal penetration"). Initial phone call data was then entered into spreadsheet for each patient, if the patient chose to receive a vibrating VD, that information was also entered into Excel spreadsheet in order to track which patients receive vibrating VD. In eight weeks, follow-up phone calls were placed to the patients to ask about VD adherence after use of vibrating VD (and/or re-education with VD handout), and

FSFI-6 score. VD adherence, FSFI-6 score (with focus on "pain or discomfort with vaginal penetration") were documented in Excel spreadsheet for each patient.

Data Analysis Plan

Data was analyzed in aggregate based on the FSFI-6 scores, with focus on data from question six, "discomfort or pain with vaginal penetration" component of FSFI-6, at baseline and at follow-up call. Other data analyzed included VD adherence at three-month follow-up (as documented in EHR), at initial phone call, and at follow-up call. These communications and data were documented by DNP student in the Excel spreadsheet. In the interest of validating the intervention of the vibrating VD, data was analyzed regarding adherence to static versus vibrating VD upon follow-up call. All data was analyzed as aggregate data and presented as percentages, with no PHI present. Data to be separated into: Documented VD adherence (from EHR) at three months post-RT, VD adherence at initial phone call, VD adherence at follow-up phone call (after use of vibrating VD, and/or re-education with VD handout); total FSFI-6 score at initial phone call and at follow-up call (after intervention of VD and/or re-education with VD handout); and "pain or discomfort with vaginal penetration" score on FSFI-6 at initial phone call and at follow-up call. Concerning missing data upon follow-up score, data was presented at baseline phone call and DNP student then stated how many patients in the aggregate had incomplete data sets, or did not complete quality improvement project (attrition rate).

Feasibility and Sustainability

Phase Two. Implementation of the FSFI-6 questionnaire into the EHR and clinical workflow at project site aimed to quantify sexual dysfunction in the female pelvic RT population

(Appendix N). Implementation required assistance from the chief medical physicist to incorporate the FSFI-6 into “questionnaire” section of Aria EHR, as the IIEF was already in place to quantify male sexual dysfunction. Feasibility of vibrating VD versus static VD was discussed with providers and Cancer Center leadership following Phase Two project analysis.

CHAPTER FOUR

RESULTS

Results

The quality improvement project had three purposes: implementation of the FSFI-6 into the clinical workflow and documentation, decrease pain score on FSFI-6 (question six) by one point, and increase twice per week VD adherence by 10% from a baseline of 7%. In order to achieve the above purposes, short-term, mid-term, and long-term SMART goals were formed.

Phase One: Pain Assessment and VD Adherence

Chart review conducted on patients who received treatment between January 1, 2020 and September 9, 2020 identified 55 women had undergone pelvic RT and received dilators. Of those 55 women, 18 (33%) reported not using their VD at all when presenting for their three-month follow-up (Table 1). Ten women (18%) indicated an average usage of once per week (Table 1). A mere four of the 55 women (7%) were using the dilator the recommended two or more times per week. Dilator use was not documented for 13 (24%) of the 55 patients, and 10 patients (18%) were not yet three months out from the completion of their treatment (Table 1).

Table 1. Vaginal Dilator Use at 3 Months Post RT

	No Use	Once per week use	Two or More Times per Week Use	Not Documented	Not Yet 3 Months Out
Number/percentage of Women	18/33%	10/18%	4/7%	13/24%	10/18%

Within this group, the most common forms of malignancies treated with RT included endometrial (51%) with an adherence of 45% at least once per week, no documentation on six; and cervical (35%) with an adherence of 23% use at least once per week, and no documentation on six. Anal carcinoma patients made up 7% of this population, vaginal carcinoma comprised 4%, and vulvar carcinoma comprised 2%. See Tables 2 and 3 for breakdown of percentage of population by diagnosis group and adherence to VD at least once per week by diagnosis group.

Table 2. Percentage of Population by Diagnosis Group

Cancer Diagnosis	Endometrial	Cervical	Anal	Vaginal	Vulvar
Percentage of Population	51%	35%	7%	4%	2%

Table 3. Adherence by Diagnosis Group

	Endometrial	Cervical	Anal	Vaginal	Vulvar
Adherence to once/week VD (percentage)	45%	23%	32%	0%	0%
No Documentation (percentage)	27%	46%	50%	100%	100%

All women in the population were of Caucasian descent and from throughout Montana. Median age of patients varied by diagnosis with cervical carcinoma patients being the youngest with an average age of 46 years old, and vaginal carcinoma patients the oldest with average age of 80.5 years old (Table 4).

Table 4. Average Age by Diagnosis Group

Cancer Diagnosis	Cervical	Anal	Endometrial	Vulvar	Vaginal
Average Age	46	65	69	72	80.5

Phase Two: Implementation

Short-Term SMART Goal

The short-term SMART goal of this project was: Call identified patients to review and document FSFI-6 score and VD adherence in Excel spreadsheet, then mail vibrating VD (if they choose), conducted between January 4th and January 15th, 2021. During the implementation phase of calling patients to obtain verbal consent for the quality improvement project, it was discovered that the population had decreased by 13 patients from the time of initial chart review. Of these 13 patients no longer meeting criteria, nine were deceased and four had developed recurrence requiring additional treatment and/or surgery. Overall, 42 patients meeting criteria were called to obtain the short-term SMART goal. Of these 42 women, seven (17%) answered the phone and provided verbal consent to participate in the quality improvement project. These seven women included five women treated for the diagnosis of endometrial carcinoma with an average age of 65.3 years old, and two women treated for cervical carcinoma with an average age of 49.5 years old. Average FSFI-6 score for the endometrial diagnosis group was 15.8, with an average "discomfort or pain during vaginal penetration" score of 3 (which indicated sometimes pain). Three women in the endometrial diagnosis group consented to and were mailed a vibrating VD. Average FSFI-6 score for the cervical carcinoma diagnosis group was 12.5, with an average "discomfort or pain during vaginal penetration" score of 2.5 (indicating most times/sometimes). Two women in the cervical diagnosis group consented to and were mailed a vibrating VD. Tables 5 and 6 indicate FSFI-6 scores and "discomfort or pain during vaginal penetration" scores by diagnosis group. Keep in mind that lower scores are indicative of lower sexual function, with scores less than 19 requiring follow-up interview or the full FSFI.

Table 5. FSFI-6 Scores for Endometrial Diagnosis Group

	Overall FSFI-6 Score	Discomfort or pain with vaginal penetration score
Patient A	27	5 "Almost never or never"
Patient B	7	5 "Almost never or never"
Patient C	22	3 "Sometimes"
Patient D	17	1 "Almost always or always"
Patient E	6	1 "Almost always or always"

Table 6. FSFI-6 Scores for Cervical Diagnosis Group

	Overall FSFI-6 Score	Discomfort or pain with vaginal penetration score
Patient F	21	3 "Sometimes"
Patient G	4	2 "Most times"

VD adherence varied by diagnosis group, with those treated for endometrial carcinoma having higher adherence overall compared to those treated for cervical carcinoma. Of the five women treated for endometrial carcinoma, four indicated they either used their issued static VD at least once per week, or were sexually active at least once per week. Three of these women indicated use of VD and/or sexual intercourse at least twice per week. Of the two women treated for cervical carcinoma, one indicated no use of VD or sexual intercourse, while one indicated sexual intercourse once per week and no use of static VD. See Table 7 for adherence to VD/sexual intercourse by diagnosis.

Table 7. Adherence to VD by Diagnosis Group in Those Who Consented to QI

Endometrial Group	VD Use/Sexual Intercourse per Week
Patient A	VD 3 times per week Intercourse "at least once" per week
Patient B	VD once per week No intercourse
Patient C	No VD Use Sexual Intercourse 2-3 times per week
Patient D	VD use 2 times per week Intercourse 1-2 times per week
Patient E	No VD Use No sexual intercourse
Cervical Group	
Patient F	VD use once per week Intercourse once per week
Patient G	No VD use No sexual intercourse

Mid-Term SMART Goal

Mid-term goal of this project was: Train nursing staff and physicians at project site via in-service on use of FSFI-6 achieved on February 26th, 2021, and implementation of a laminated clinical workflow card completed February 26th, 2021. FSFI-6 was incorporated by the chief medical physicist into the questionnaires section of EHR on February 11, 2021 (Figure 1 and 2). After incorporation of FSFI-6, nursing staff trained on use and meaning of scores, physicians trained on interpreting scores. Nursing staff was pleased with the ease of use as FSFI-6 drop-downs were similar to the male IIEF-5 questionnaire already in use in the department. Physicians were equally pleased with the ease of interpretation. Training of nursing staff and physicians, and implementation of a laminated clinical workflow card took place February 26, 2021. With input from nursing staff several changes were made to original workflow, see Figure 3 for final workflow card.

Figure 1. FSFI-6 Incorporated into Questionnaires in EHR

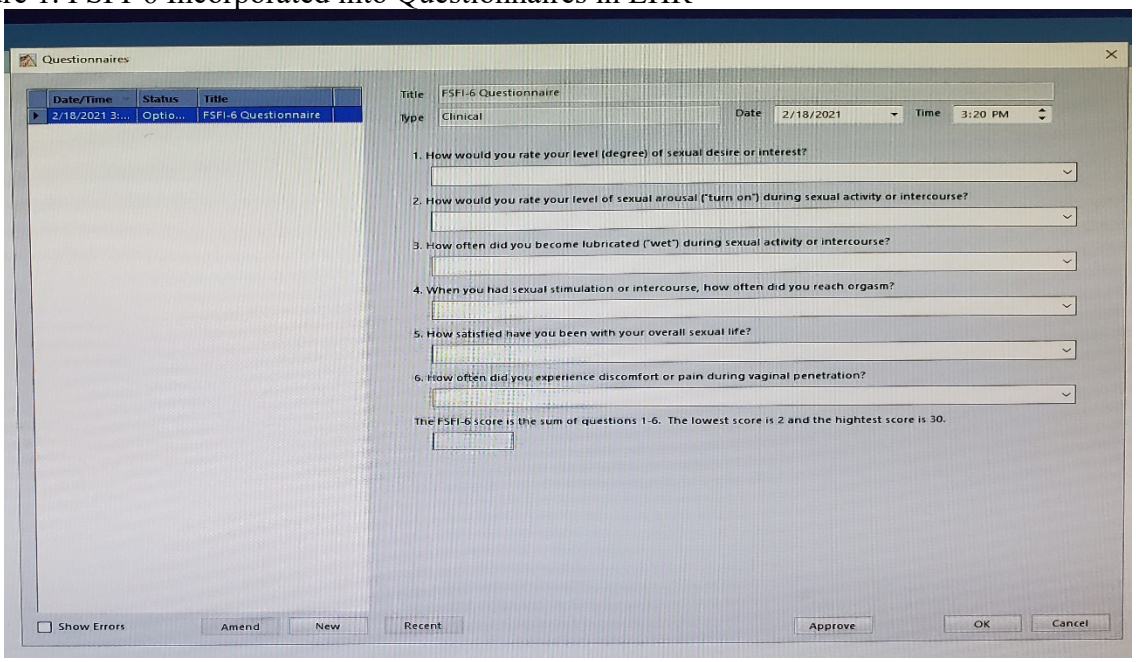


Figure 2. FSFI-6 with Drop-Down Screen

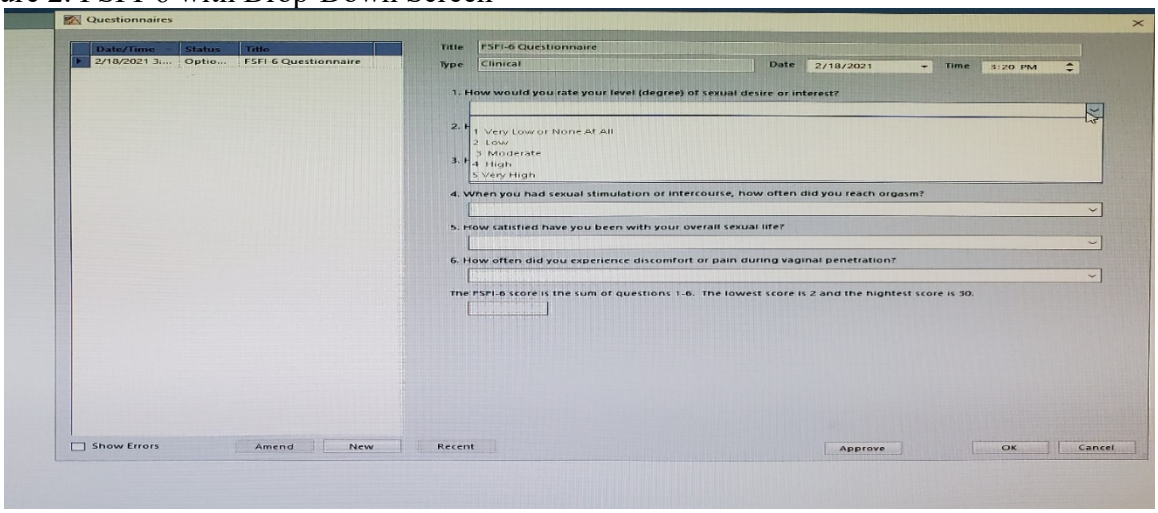
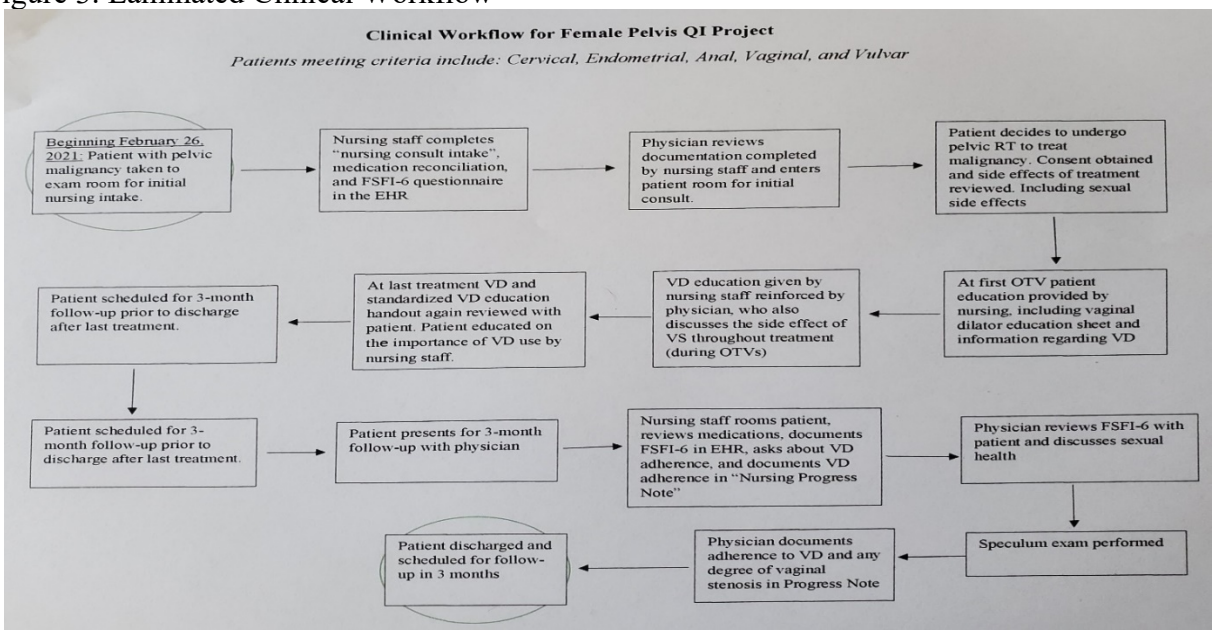


Figure 3. Laminated Clinical Workflow



Long-Term SMART Goal

Long-term goal of this project was: Implementation FSFI-6 into the EHR "questionnaires" completed on February 11th, 2021, increased VD adherence by 10%, and decreased report of "discomfort or pain during vaginal penetration" on FSFI-6 by one point through follow-up calls, completed February 26th, 2021. The project site's chief medical physicist was able to incorporate FSFI-6 into "questionnaires" section of EHR prior to the initial goal of March 8, 2021, as such this SMART goal was completed in conjunction with the mid-term SMART goal, see Figures 1 and 2 above.

Eight-week follow-up phone calls took place on February 25, 2021 and February 26, 2021. Unfortunately, within the eight-week timeframe "Patient F" suffered a recurrence and was under treatment during the follow-up period, as such no follow-up data was obtained. The remaining six women in the population answered their phones and completed follow-up FSFI-6

questionnaires and reported VD adherence. Qualitative findings were also gathered during this time regarding vibrating VD use and comfort level with FSFI-6 questionnaire.

Follow-up calls placed to the two women who were treated for endometrial carcinoma, opting not to receive vibrating VD revealed no difference between FSFI-6 scores prior to and after VD re-education with standardized VD education sheet (Appendix B). Patient C continued to engage in sexual intercourse two to three times per week in place of the static VD. Patient D continued to use the static VD issued after RT twice per week, and engage in sexual intercourse at least once per week. Of the three women treated for endometrial carcinoma who opted to receive vibrating VD, one woman reported a two-fold increase in FSFI-6 score and a decrease in pain with penetration score by four points, one woman had not opened the package yet, and the third women reported no change in FSFI-6 score or "discomfort or pain with vaginal penetration" score. The woman who reported an increase in satisfaction and decrease in pain score by four points also reported an increase in adherence to three to four times per week. See Table 7 for comparison of scores prior to and after the intervention of vibrating VD, and table 8 for adherence comparison prior to and after vibrating VD. Qualitative statements from "Patient E" indicated that, "turning the vibration on prior to insertion helps to ease the dilator in and decrease discomfort".

Table 8. Comparison of FSFI-6 and Pain Scores After Vibrating VD for Endometrial Group

	Initial FSFI-6 Score	Initial Pain with Penetration Score	Follow-up FSFI-6 Score	Follow-up Pain with Penetration Score	Change in pain score
Patient A	27	5 "Almost never"	27	5 "Almost never"	0 points
Patient B	7	5 "Almost never"	7	5 "Almost never"	0 points
Patient E	6	1 "Almost always"	12	5 "Almost never"	4 points

Table 9. Comparison of Adherence Prior to and After Vibrating VD for Endometrial Group

	Adherence to Static VD Issued by Radiation	Adherence to Vibrating VD	Percent of Change
Patient A	VD 3 times per week Intercourse "at least once" per week	VD 3 times per week Intercourse "at least once" per week	0%
Patient B	VD once per week No intercourse	No VD Use No sexual intercourse	0%
Patient E	No VD Use No sexual intercourse	Using VD 3-4 times per week No sexual intercourse	100%

Follow-up call placed to the one patient treated for cervical carcinoma revealed an increase in total FSFI-6 score of five points, and a decrease in pain score by two points. Follow-up call also revealed the patient went from no VD use to use of vibrating VD twice per week. See Table 9 for comparison of FSFI-6 and pain with penetration scores prior to and after vibrating VD intervention and Table 10 for comparison of adherence prior to and after intervention.

Table 10. Comparison of FSFI-6 and Pain Scores After Vibrating VD for Cervical Group

	Initial FSFI-6 Score	Initial Pain with Penetration Score	Follow-up FSFI-6 Score	Follow-up Pain with Penetration Score	Change in pain score
Patient G	4	2 "Most times"	9	4 "A few times"	2 points

Table 11. Comparison of Adherence Prior to and After Vibrating VD for Cervical Group

	Adherence to Static VD Issued by Radiation	Adherence to Vibrating VD	Percent of Change
Patient G	No VD Use No Sexual Intercourse	VD Use 2 times per week No Sexual Intercourse	100%

Results Summary

The quality improvement project had three purposes: implementation of the FSFI-6 into the clinical workflow and documentation, decrease pain score on FSFI-6 (question six) by one point, and increase twice per week VD adherence by 10% from a baseline of 7%. Implementation of FSFI-6 into clinical workflow and documentation took place on February 26, 2021 with documentation in EHR for the first woman meeting criteria. Nursing staff and the physician reported ease of use of the laminated clinical workflow and electronic documentation of FSFI-6.

Due to the small sample size of four women, change in pain score was difficult to assess. Two women reported no change in pain score as they already reported the lowest score possible, while two women reported a change in pain score. One woman in the endometrial group reported a decrease in pain score of four points, while the woman in the cervical group reported a

decrease of two points. Of these two women, an average of three-point decrease in pain exceeded the goal of a one point average change, thus exceeding the projected goal.

Figure 4. Comparison of Pain Scores After Vibrating VD for Endometrial Group

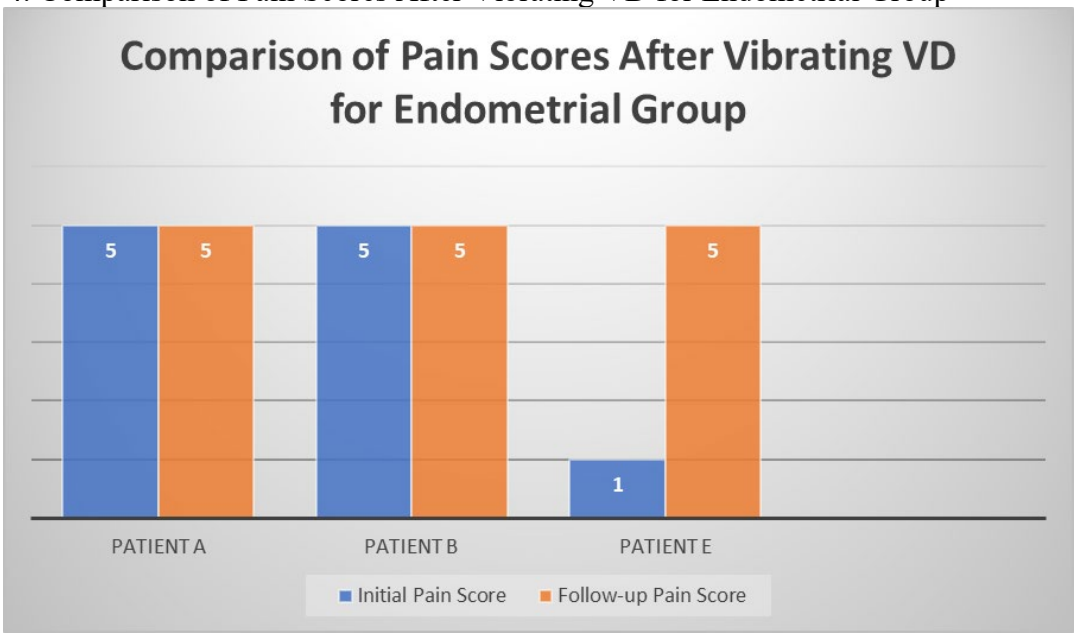
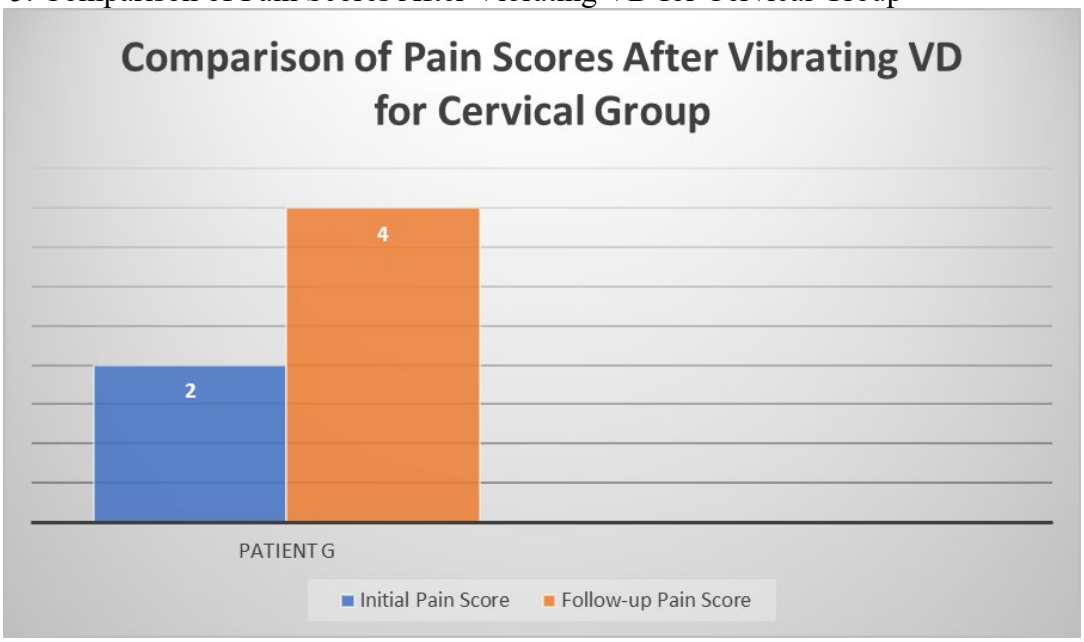


Figure 5. Comparison of Pain Scores After Vibrating VD for Cervical Group



Twice per week adherence to VD from January 1, 2020 to September 9, 2020 was found to be 7% for the 55 women identified to meet inclusion criteria. Within the sample population, twice per week adherence was found to be 25%, when excluding the one cervical patient lost to recurrence. At follow-up, twice per week adherence to VD was found to be 75%. For this small sample population, intervention with a vibrating VD was found to improve overall adherence by 50%, thus exceeding the goal of a 10% increase.

Figure 6. Comparison of Adherence Prior to and After Vibrating VD for Endometrial Group

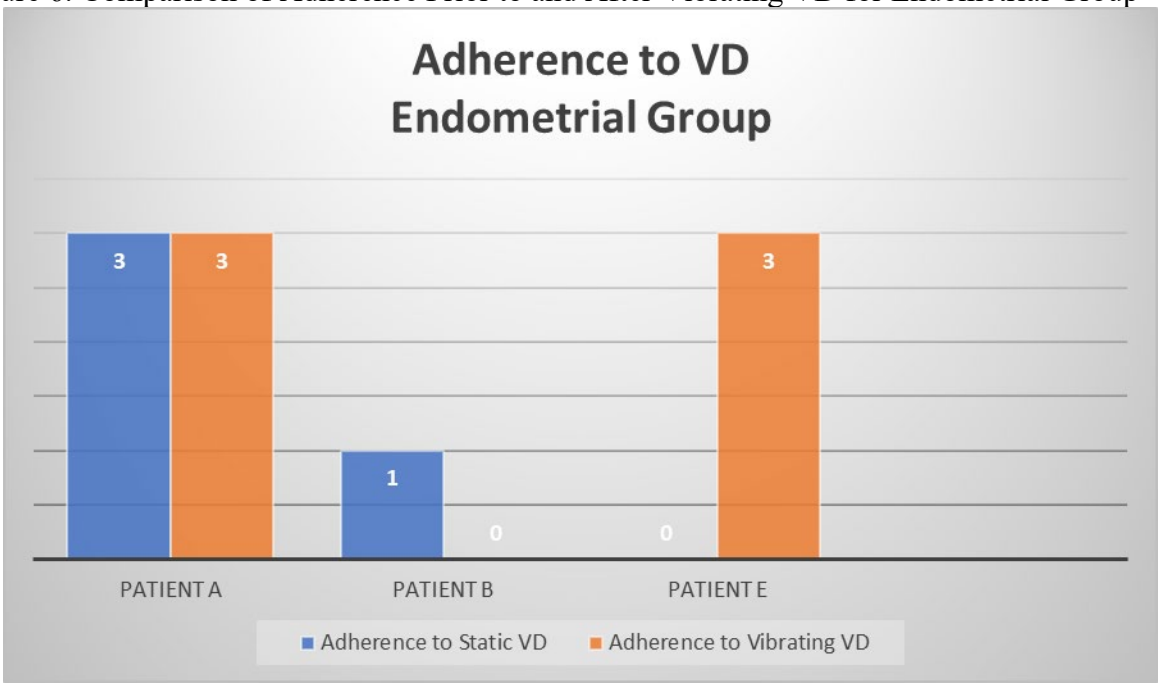
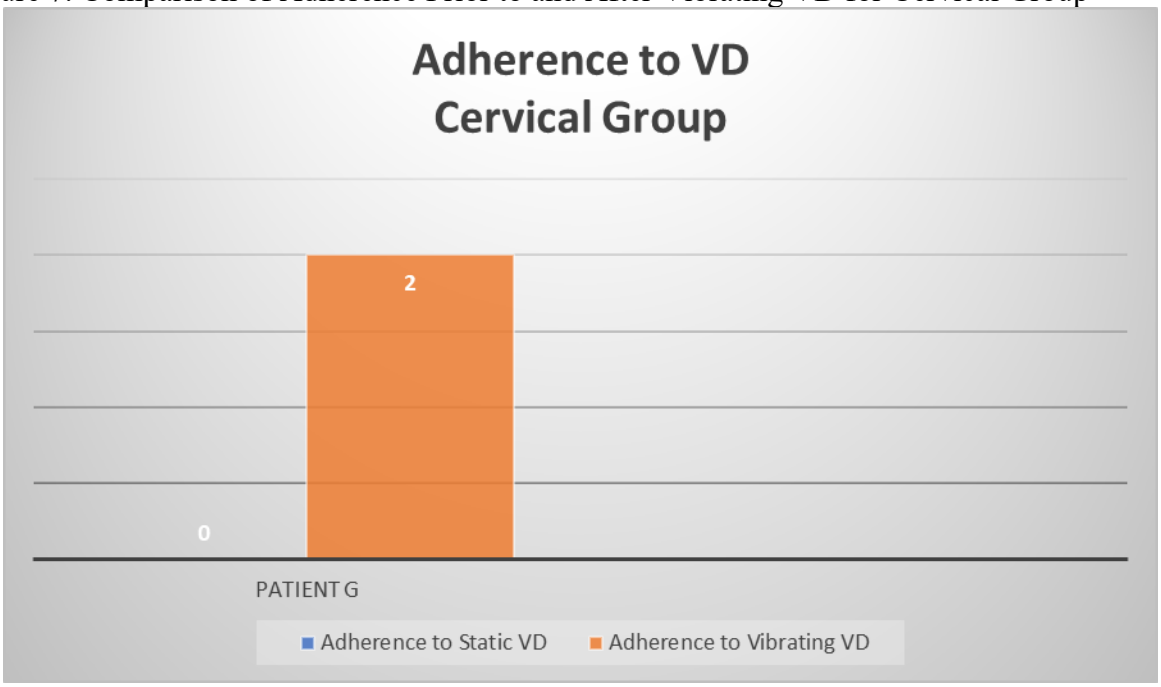


Figure 7. Comparison of Adherence Prior to and After Vibrating VD for Cervical Group



Qualitative reports from women within the QI sample population were that, “turning the vibration on prior to insertion decreased pain on penetration”, “now that this process isn’t so medical I am more willing to use the dilator”. One woman reported that, “the vibrating dilator seemed easier to place due to the contours”, and “I liked that the control for the vibrating dilator is a separate remote and not on the dilator itself”. Another woman stated, “I definitely find myself leaving the dilator in for a longer period of time when the vibrating feature is on”. When speaking to women who consented to the QI project, one woman stated she “could not use a vibrating dilator as I was raised very strict Catholic and would feel like I was sinning. I would have to hide it from my husband and I just can’t live like that”. Concerning the use of the FSFI-6, multiple women stated that use of the FSFI-6 during office visits would help to “open the door to talking about sexual dysfunction and pain”. These women also stated that they “wish the radiation department was utilizing that tool when I underwent treatment”. Overall, the women in

the QI group felt the FSFI-6 would make a positive impact on patient-provider discussions regarding the side effects of RT.

CHAPTER FIVE

DISCUSSION

Discussion of Results in Relation to Relevant Literature and Framework

Despite the small sample, the quality improvement project exceeded its three purposes within the eight-week timeframe: Implementation of standardized sexual assessment which incorporated the FSFI-6 into the clinical workflow and documentation occurred on February 26, 2021, pain scores on the FSFI-6 were decreased by an average of three points, and adherence to VD at least twice per week increased by 50%. These findings are congruent with findings in literature which suggest that nurse-led educational interventions have the potential to extend VD compliance and lower the incidence of VS (Stahl et al., 2018). Results from the project also echo University of Wisconsin data, which reported increased compliance to VD with the use of an FDA approved vibrating VD (Straub, 2016).

Vaginal Dilation Adherence

VS in literature findings is most widely reported for women who have undergone RT for endometrial and cervical cancers. According to literature, mild and moderate VS (grades one and two) were pronounced in women treated for cervical carcinoma, with a probability of 89% and 29% respectively (Kirchheiner et al., 2014). Whereas the incidence of VS seems to be the highest in women undergoing RT for cervical cancer, women completing treatment for endometrial cancer report much lower rates. A retrospective study of 157 patients completing RT for endometrial cancer found no grade two or higher vaginal stenosis for any patient at two years post-RT (Townamchai et al., 2012). While radiation dose certainly plays a role in VS in the

endometrial and cervical populations, adherence to VD may also be considered a factor. Initial chart review at the project site revealed that the most common forms of malignancies treated with RT included endometrial (51%) with an adherence at three-months post-RT of 45% to at least once per week to VD; and cervical (35%) with an adherence of 23% use to at least once per week VD. This data shows a 22% difference, or almost double adherence to VD, for those treated for endometrial carcinoma.

Due to the qualitative and observational nature of studies regarding VD adherence, cited adherence to VD range widely throughout literature, and are generally found to be less than 50%. A compounding factor to the interpretation of VD adherence throughout literature is the varying definitions of VD adherence. Friedman et al. (2010) cite an adherence rate of 33% to twice per week VD in one retrospective study. A systemic review reported adherence rates ranged between 25% and 89.2% across 21 articles, with all studies relying on women's self-report to VD use (Lee, 2018); however, the Lee (2018) article does not provide a definition of "adherence" in the literature findings. For the purposes of this project, chart review performed on progress notes from three-month follow-up visits found an adherence rate to twice per week VD of 7% for a sample of 55 women. Initial phone calls to seven women during implementation found an adherence rate of 29% to twice per week VD, and 57% to at least once per week VD. Results from the project site findings are difficult to interpret without a definition of adherence in literature findings to compare, the 7% adherence to twice per week VD is significantly lower than any of the cited literature, while the finding of 57% adherence rate to once per week VD during implementation is higher than reported literature.

Vibrating Vaginal Dilator

Given the small sample size consenting to the QI project, conclusions as to whether or not a vibrating VD would increase adherence and decrease FSFI-6 pain score in the female pelvic RT population are difficult to assess. Within the QI sample, half of the women noted an increase in twice per week adherence and a decrease in pain score of at least two points. These findings are congruent with University of Wisconsin literature which state utilization of vibrating dilators resulted in increased adherence rates of 35%-40% annually, and patients reported increased sexual satisfaction, and decreased pain (M. Straub, personal communication, September 22, 2020; Straub, 2016). Qualitative findings from this QI project are also congruent with those found in literature, as reports across the literature support increased adherence with the use of vibrating vaginal dilators (Bonner et al., 2011; Bakker et al., 2014; Rinske et al., 2015; Lee, 2018). Qualitative reports such as, “It’d be better if it had a battery, I think I might get more enjoyment out of it” and “it feels less sterile” show how vibrating dilators could increase adherence in this patient population (Bonner et al., 2011). Two women from the project site stated, “turning the vibration on prior to insertion decreases pain”, and “when the dilator is on vibrate I find that I keep it in place for longer, and am willing to use it more times per week”, substantiating literature findings.

Standardized Screening

Lack of standardized screening at the project site prevented assessment of quantifiable data beyond limited patient report. Incorporation of the FSFI-6 into the EHR aimed to quantify sexual health, and further assess if use of VD improves sexual health scores and decreases the report of pain. A secondary aim of incorporation of the FSFI-6 was to increase provider

awareness regarding discussion of sexual health in this population, and aid in provider-patient conversations regarding sexual health both during and after pelvic RT. White (2015) cites, use of a PROM such as the FSFI-6 can provide the information needed for a detailed discussion of the type and severity of sexual toxicity in order to guide a timely and effective discussion and subsequent clinical management. Use of the FSFI-6 during both the initial and follow-up phone calls during implementation assisted in direct conversation with the women regarding sexual health. Multiple women stated, "I wish this questionnaire was used when I was undergoing treatment", another stated, "this tool decreases the shame I felt every time I wanted to talk about vaginal pain, and would have enabled me to talk more openly about it with my provider". Use of the FSFI-6 also proved beneficial in assisting with quantifying data for the sample population during implementation. Improvements in FSFI-6 total score and "pain with penetration" score were easily tabulated by tracking changes in the Likert score for each woman. Moving forward at the project site, data for each woman's FSFI-6 score can be placed in Excel spreadsheet and quantified over time to assess change.

Health Promotion Model

The model utilized for this quality improvement project was the health promotion model (Appendix G), emphasis of the health promotion model is the active role of the patient in shaping and maintaining health behaviors (Masters, 2015). As such, the behavioral outcome of this project was adherence to VD use two or more times per week. Two of the four women followed to completion of project implementation documented a behavior change related to VD. These women went from no VD use to VD use at least two times per week with the use of vibrating VD. When eliciting qualitative feedback, these two women stated that the static VD was the

barrier they needed to overcome in order to support at least twice per week adherence as it was "sterile and uncomfortable". Both women felt strongly they would be able to maintain at least twice a week VD with use of the vibrating VD. Both women also stated the "need for the option of vibrating VD at the completion of RT". They stated they were educated on the fact they "could go to a novelty store to purchase one, however, did not feel comfortable doing so. Having the option of vibrating VD from the radiation department would be so beneficial".

PDSA Cycles

For the purposes of this project, two PDSA cycles were ran. The first PDSA cycle (Phase One) focused on collection of baseline data regarding the number of female pelvic radiotherapy patients treated in the department between January 1st, 2020 and September 9th, 2020, as well as phone calls to these patients to obtain verbal consent, initial and follow-up FSFI-6 scores, and adherence data to static and vibrating VD. Overall, four women were followed over an 8-week period, data from initial FSFI-6 score, follow-up score, and adherence to vibrating VD was tracked. Data from Phase One of the project positioned the project site to adopt use of FSFI-6 into the EHR leading to Phase Two. Taylor et al. (2014) cites, the advantage of small-scale tests is they provide an opportunity for the user to act and learn, while minimizing the risk to patients and the organization. This allows the organization to build evidence for change, and engage stakeholders as confidence in the intervention increases (Taylor et al., 2014).

Lessons learned from Phase One of the PDSA cycle were that: data from the FSFI-6 were easily quantifiable, improvements in FSFI-6 score including pain score aided in project site buy-in leading up to implementation, and that giving the women the option of vibrating VD may increase adherence and decrease FSFI-6 pain scores.

Phase Two focused on implementation of the FSFI-6 into the EHR and clinical workflow to support day to day use of the tool at the project site. Feedback elicited from nursing staff aided in creation of a final clinical workflow, which was laminated and placed in each exam room for ease of use (Figure 3). On February 26, 2021, the first FSFI-6 score was documented in the EHR at initial consult. Per the clinical workflow (Figure 3), FSFI-6 score will again be documented on this patient after RT at her three-month follow-up appointment. Due to project time constraints, further evaluation of FSFI-6 percentage of completion, pain score, and adherence to VD was not assessed. However, ease of use of the FSFI-6 in the EHR and positive feedback from clinical staff support the project for future state implementation. Future state implementation will focus on documentation, which will be audited and reviewed every six months by DNP student to ensure greater than 90% adherence to FSFI-6 documentation, as future sustainability of project does rely on these measures.

Challenges Encountered and How Addressed

Several challenges were encountered during the course of this project. Two challenges in particular caused delay to the project timeline and shorted the duration of time between initial and follow-up phone calls to consenting women. Ideally, duration of time between these calls would have been 12 weeks, which is when follow-up for these women occurs after completion of RT at the project site. Shortened duration between calls could have led to decreased quality of data, interpretation of data in a 12-week timeframe may lead to a more meaningful analysis.

IRB Review

Initial emails to project site and University IRB occurring on September 18, 2020 indicated this project would meet exempt status; however, after submission of IRB forms on November 18, 2020 to the University, it was determined that the project required project site IRB review. The project site's Research department was contacted, university IRB forms were submitted to project site IRB, and it was determined that the projected needed to undergo an expediated review by project site centralized IRB. As part of the centralized IRB process, a standardized format was needed for IRB submission as well as a processing fee, which the project site's Research department graciously covered. With assistance from the Research department, finalized IRB forms were submitted to the centralized IRB on December 9, 2020, feedback elicited from the IRB led to several changes in project implementation plan, and on December 23, 2020 the project received final approval. With final approval from the project site's IRB, the University also granted approval on December 23, 2020. Overall, the IRB process resulted in a delay in project implementation of over 30 days. However, there was a silver lining to the IRB process, due to the nature of the project and time constraints, the project site IRB granted a waiver to informed consent to allow verbal consent to occur. The ability to obtain verbal consent from women shortened the amount of time that would have been spent waiting for returned consent forms.

Phone Calls to Patients

Due to the delay in site IRB approval, the project was further delayed by a lack of patient response to phone calls over the holidays. As a result, initial phone contact did not occur until January 5, 2021. Altogether over 10 hours of DNP student time was put into calling the 42

women who met criteria for the project, of those 42 women only seven answered the phone over a 10-day period. As such, the lack of response rate to phone calls was found to be a major hinderance to the project. Phone numbers were double-checked in each of the two project site EHRs and found to be correct. One theory on the low response rate to calls is that patients may screen their phone calls, as all calls from the project site have the same phone number. As such, patients know the number which is associated with the project site as an organization. The organization has found that patients are more apt to call back if a voicemail is left versus answering a phone call.

Project outcomes depended on the seven women to answer the follow-up phone call in eight weeks, and all seven women did answer the call and gave qualitative feedback regarding the vibrating VD and FSFI-6. Three of the women stated that they thought response rates would be much higher if this process was implemented at consult as a face-to-face visit and not over the phone.

Limitations

Limitations included the retrospective nature of the project, low response rate, small sample size, attrition rate due to death or recurrence, and shorted timeframe from Phase One to Phase Two. The retrospective nature of the project contributed to the limitations of low response rate and small sample size. Future studies should be prospective in nature, occurring face-to-face at the initial radiation visit and every follow-up after RT. Presenting the FSFI-6 and vibrating VD at initial consult will allow for increased response rate, relationship building between the provider and patient, and hopefully increased dialogue concerning VD, VS, and sexual health.

Attrition rate due to death or recurrence was a limitation not previously thought of during the planning process. Of the 55 women initially identified as meeting criteria for the project, only 42 remained living and free of recurrence at the time of initial phone calls, an attrition rate of 24%. During implementation, another patient was lost to recurrence in the time frame between initial and follow-up phone calls, for an attrition rate of 14%.

The shortened timeframe between Phase One and Phase Two did not allow data to be quantified at the 12-week interval as it would be in the clinic setting, thus limiting the applicability of the data. Ideally, Phase Three of this project would be a retrospective pilot study utilizing the FSFI-6 at consult and the option of vibrating VDs to women meeting criteria. These women would then return after RT for a 12-week follow-up, the FSFI-6 would be documented again, as well as adherence to VD. Documentation of the FSFI-6 at each follow-up would allow for data regarding total score and "pain with penetration" score to be quantified.

Strengths and Contributions to Practice

Strengths of the project included incorporation of a standardized and validated assessment tool, collegial relationship between nursing staff and physicians, support from Cancer Center leadership and Research department, and established relationship between DNP student and patients. Use of the validated FSFI-6 at the project site to assess sexual health will not only help to quantify sexual health and pain with penetration scores, but will also aid in directing physician conversations with women, drawing attention to this important aspect of women's cancer care. Use of the FSFI-6 has the potential to decrease the inequity in sexual health assessment between men and women at the project site. Future research aims to call attention to

this inequity, and aid in the development of a nationwide sexual health assessment guideline for women.

The collegial relationship between nursing staff and physicians, and the support from Cancer Center leadership and site Research department aided in the success of this project. Without buy-in from these key stakeholders, implementation of the project would not have occurred. The importance of this project, and the buy-in from key stakeholders were so great that Cancer Center leadership is now discussing sexual health training for their social workers, as sexual health plays a large role in mental health and overall quality of life for these women.

Another strength of the project was the relationship between the DNP student and the patients. The DNP student works in the role of RN at the project site, as such she had spent countless hours with each woman who took part in the project throughout their course of RT. Although this relationship did not aid in response rate to phone calls, it did make a large difference with the seven women who answered the phone. All seven women remembered the DNP student, and stated that they were happy to "help this project in any way I can". This strength in the project further substantiates the finding of Stahl et al. (2018) that nurse-led interventions have the ability to increase compliance.

Recommendations for Future Work

Future study should be prospective in nature from initial consult through continued follow-up to consistently quantify changes in FSFI-6 scores from pre to post-RT. Prospective study should also include a pilot study of vibrating VD use post RT in order to assess feasibility and sustainability of use, changes in FSFI-6 pain scores and adherence scores compared to static VD at project site. These findings should then be published, and presented at ASTRO and

Oncology Nursing Society (ONS) conferences in order to draw attention to this important aspect of women's cancer care.

Project Work as Related to DNP Essentials

DNP Essentials important in the formation of this project included Essentials I, II, III, IV, VI, and VIII. Essential I, scientific underpinnings for practice applies scientific knowledge to real-life problems and looks to identify actions and their consequences (Zaccagnini & White, 2017). Thorough understanding of nursing theory provides a solid foundation for the DNP to integrate nursing science with organization, biophysical, and analytical sciences to enhance healthcare delivery and improve patient outcomes (Zaccagnini & White, 2017). Through use of the health promotion model and PDSA cycles, the FSFI-6 was integrated into clinical workflow and qualitative and quantitative data was collected in an attempt to increase VD adherence and decrease pain scores on the FSFI-6.

Essential II organizational and systems leadership for quality improvement is the entire premise of this project, as it focuses on the ability of the DNP to evaluate, translate, and disseminate research into practice (Zaccagnini & White, 2017). Key skills important to essential II are the development of clinical practice guidelines, designing evidence-based interventions, and evaluating practice outcomes (Zaccagnini & White, 2017). Interventions developed for this project included the incorporation of the FSFI-6 into clinical workflow and documentation, and the use of vibrating VD, as literature findings suggested increased compliance and decreased pain scores with use of vibrating VD. Future state outcomes from this project would include the creation of a clinical practice guideline to assess and educate women on sexual health in relationship to pelvic radiotherapy.

Essential III clinical scholarship and analytical methods for evidence-based practice focuses on the DNPs ability to assure accountability of quality care and patient safety, and examine the ethical dilemmas present in patient care (Zaccagnini & White, 2017). This project was formed out of the need to draw attention to the inequity present in health care when it comes to assessing the sexual health during pelvic RT of men vs. women. Nationally, AUA/ASTRO guidelines recommend assessment of sexual dysfunction in men with a validated screening tool, the IIEF-5, prior to initiation of RT and at each subsequent visit. Currently, no such guideline exists for women undergoing pelvic RT, and validated screening tools are not utilized the majority of RT centers in the United States. Future state goals of this project include presentation to ASTRO and ACOG, resulting in the creation of a clinical practice guideline for assessment of sexual health in pelvic RT women; thus, decreasing the gender gap in sexual health assessment.

Essential IV information/systems technology and patient care technology for the improvement and transformation of health care focuses on the use of information and patient care technologies to support practice leadership and clinical decision making (Zaccagnini & White, 2017). For the purposes of the project, essential IV was important as integration of the FSFI-6 into the EHR has the ability to transform the discussion practices between providers and patients regarding sexual health during pelvic RT, as well as quantify sexual health scores to assess changes over time.

Essential VI inter-professional collaboration for improving patient and population health outcomes prepares the DNP student to lead and work in inter-professional teams to analyze practice and systems issues through collaboration and effective communication (Zaccagnini & White, 2017). Essential to this is the ability of the DNP student to take a leadership role in the

development of practice models, standards of care, and scholarly projects (Zaccagnini & White, 2017). Throughout the DNP scholarly project process, the DNP student maintained an active leadership role, implementing a clinical workflow, listening to staff feedback, and revising workflow to better meet the needs of patients and clinical staff. Collaboration and effective communication with staff at project site and the patients who took part in the project was paramount to the success of this project. DNP leadership will continue to be important as the project moves forward to implementation and sustainability within the department.

Essential VIII advanced practice nursing focuses on improving patient outcomes through delivery of evidence-based care, conducting needs assessments, mentoring other nurses, and guiding patients through complex situations and transitions (Zaccagnini & White, 2017). The DNP scholarly project process helps to guide the DNP student through each of the above-mentioned processes. During the implementation phase, the DNP student mentored and educated nursing staff on the applicability and use of the FSFI-6 for women undergoing pelvic RT, utilizing evidence-based practice. The ultimate goal of this project is to improve sexual health and quality of life for women after RT, and to be there to guide these women on that journey.

Feasibility and Plan for Sustainability

Future feasibility and sustainability of the project relies heavily on continued involvement and adherence to use of FSFI-6 and clinical workflow by nursing staff and physicians. Nursing staff responsible for reviewing and documentation of FSFI-6 in the EHR during nursing intake at consult and each scheduled follow-up, questioning about VD adherence and documenting in nursing note in EHR, reviewing VD education handout with patient and providing a copy, supplying the patient with VD, and data collection regarding percentage of

FSFI-6 documented in EHR and VD adherence at each scheduled follow-up. Physicians responsible for reviewing the documented FSFI-6 questionnaire, education regarding sexual health, and reinforcement of VD education.

Standardized documentation of the FSFI-6 will aid in data collection in order to assess the benefit of the intervention. For long-term goal monitoring, documentation will be audited and reviewed every six months to ensure greater than 90% adherence to FSFI-6 documentation. FSFI-6 scores will be reviewed for each female pelvic RT patient and compared from baseline in order to assess for decrease in score of "discomfort or pain during vaginal penetration". Standardized documentation also has the potential to increase radiation oncologist awareness for female sexual problems, as nationwide this is not standard practice and is underreported per literature.

If data shows improvement in adherence to VD with vibrating dilator, issuing of vibrating VD can be sustained through charging each unit out per patient as individual durable medical equipment (DME; personal communication, M. Straub, September 22, 2020). M. Straub (personal communication, September 22, 2020) states that University of Wisconsin is able to charge each FeMani Vibrating Wand as DME per patient with an upcharge of 35%, and this is covered by insurance 100%, as FeMani is FDA approved. Nursing staff should show patient the VD in order to reduce some of the stigmatism and anxiety related to VD post RT. Once the clinical workflow is implemented, assessment of FSFI-6 documentation will take place every three months by a volunteer member of the nursing staff, with a goal of 90% adherence to new EHR documentation. Patient adherence to VD will also be assessed via chart review of nursing and physician progress notes every three months in order to further quantify. In order to improve

patient and nursing staff relationship and to provide further education, each patient will be called by a member of the nursing staff two weeks post RT to re-review the VD education handout and answer any questions. During future state implementation (March 1st, 2021 to March 8th, 2022), clinical staff will report weekly feedback to DNP student regarding FSFI-6 implementation and documentation. In turn, DNP student will review this information and email project updates every two weeks to clinical staff, including suggestions from staff to promote sustainability of PDSA cycle.

In Conclusion

Women undergoing pelvic RT for the treatment of malignancy face many challenges during and after treatment. Lack of a clinical guideline regarding sexual assessment and education in these women leads to low rates of discussion between the provider and patient resulting in gaps in education, increased rates of VS due to poor VD adherence, and ultimately decreased sexual satisfaction and quality of life. As such, this quality improvement project aimed to decrease these disparities by incorporation of the FSFI-6 into clinical workflow and documentation, and use of a vibrating VD in an effort to increase twice per week VD adherence and decrease pain score on the FSFI-6. The three purposes of the project were all exceeded within the eight-week timeframe: Implementation of standardized sexual assessment which incorporated the FSFI-6 into the clinical workflow and documentation occurred on February 26, 2021, pain scores on the FSFI-6 were decreased by an average of three points, and adherence to VD at least twice per week increased by 50%. Future sustainability of the project will require collaboration between nursing staff and physicians to adhere to the clinical workflow and documentation of the FSFI-6 and VD adherence in the EHR. Moving forward, a retrospective

pilot study assessing adherence to static versus vibrating VD is needed in order to further quantify the findings of this project.

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APPENDICES

APPENDIX A

FSFI-6 QUESTIONNAIRE

FSFI-6 Questionnaire

Subject Identifier_____ Date_____

Over the past 4 weeks:

1. How would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

2. How would you rate your level of sexual arousal ("turn on") during sexual activity or intercourse?

No sexual activity	Very high	High	Moderate	Low	Very low or none at all
0	5	4	3	2	1

3. How often did you become lubricated ("wet") during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times	Sometimes	A few times	Almost never or never
0	5	4	3	2	1

4. When you had sexual stimulation or intercourse, how often did you reach orgasm?

No sexual activity	Almost always or always	Most times	Sometimes	A few times	Almost never or never
0	5	4	3	2	1

5. How satisfied have you been with your overall sexual life?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

6. How often did you experience discomfort or pain during vaginal penetration?

Did not attempt intercourse	Almost never or never	A few times	Sometimes	Most times	Almost always or always
0	5	4	3	2	1

Total Score (2-30) _____

Isidori, A. M., Pozza, C., Esposito, K., Giugliano, D., Morano, S., Vignozzi, L., Corona, G., Lenzi, A., & Jannini, E. A. (2010). Development and validation of a 6-item version of the female sexual function index (FSFI) as a diagnostic tool for female sexual dysfunction. *Journal of Sexual Medicine, 7*, 1139-1146.

APPENDIX B

PATIENT INFORMATION SHEET: VAGINAL DILATOR INSTRUCTIONS

Patient Information Sheet
Vaginal Dilator Instructions

A vaginal dilator is a cylinder or tube, most often made of plastic or rubber, used to "dilate" or stretch out the vaginal canal. Dilators also help women learn to relax the vaginal muscles.

Vaginal dilators are often used after radiation to the pelvis, cervix, or vagina to help prevent stenosis, or narrowing, of the vaginal canal. Using the dilator several times a week (**a minimum of three times**) will help to keep the vagina from developing scar tissue. The only real alternative to using a vaginal dilator is to have intercourse a few times a week.

Since scarring in the pelvis after radiation can develop over many years, you will need to continue using the dilators for the rest of your life.

Dilators work best when used soon after radiation treatment is complete. You will receive various sizes of dilators and can move up in diameter as your vagina stretches and you can tolerate the increased size.

To Use The Dilator:

1. Lubricate the dilator with a water-based gel (i.e. KY Jelly).
2. Lie down on your bed at a time when you know you will have at least 15 minutes of privacy. Gently and slowly slip the dilator into your vagina. Hold the dilator still while you relax your vaginal muscles.
3. When your vagina feels more relaxed, push the dilator farther in. You may need to repeat the process a few times before the dilator is inserted to the top of the vaginal canal.
4. When the dilator is in as far as possible, leave it in your vagina for about 10 minutes. If the dilator slips out, gently push it more deeply into your vagina.
5. After removing the dilator wash it with mild soap and water taking care to rinse all the soap off so no irritating film remains on the dilator.

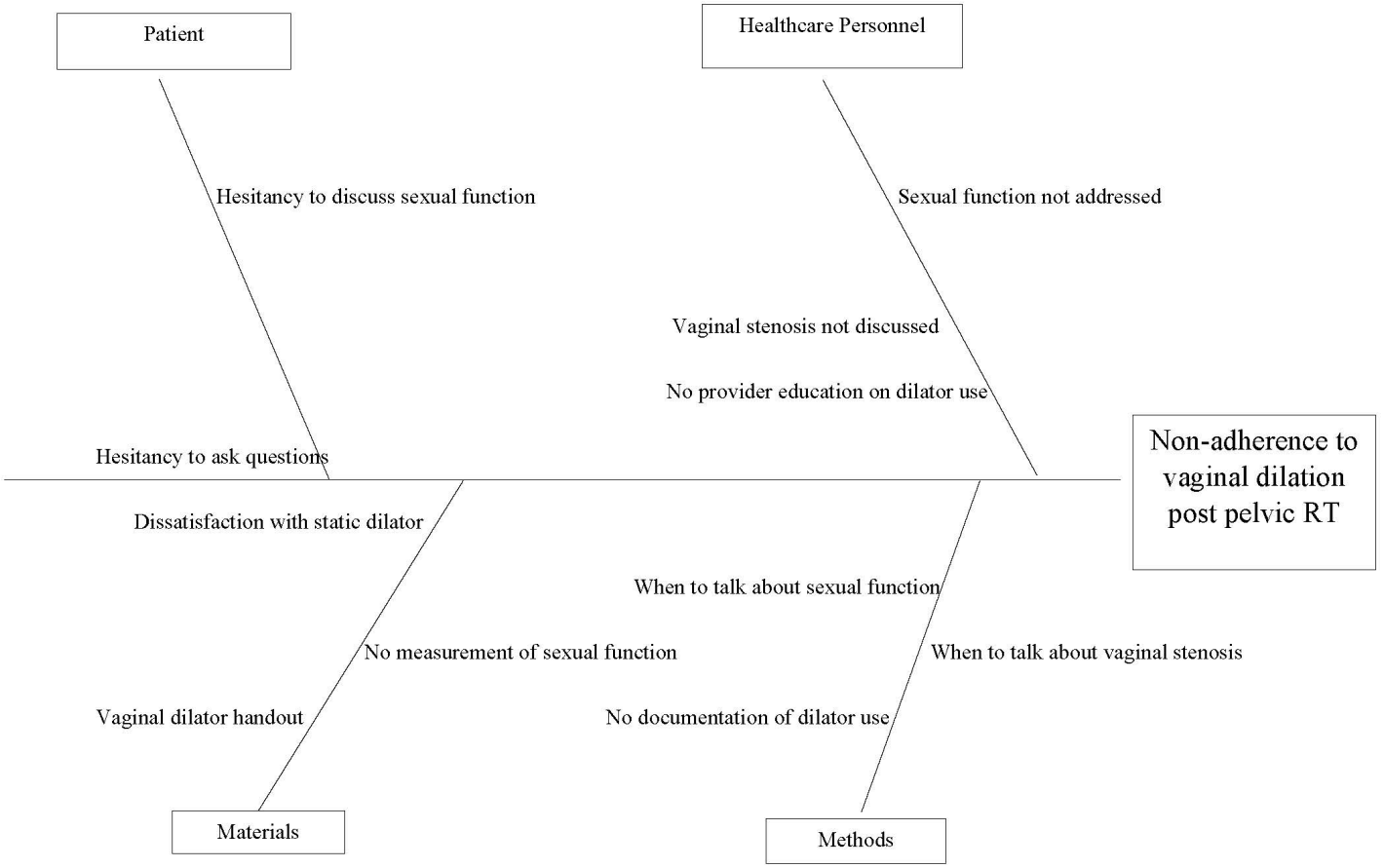
It is not uncommon to have some minor spotting after using your dilator, especially as you move to a larger size. If your spotting continues or becomes worse please contact your physician immediately. Or if you have any other questions or concerns about using the dilator please do not hesitate to call your nurse or physician at 406-435-7150 Monday through Friday 8:00 a.m. to 5:00 p.m.

APPENDIX C

FISHBONE DIAGRAM

Fishbone Diagram

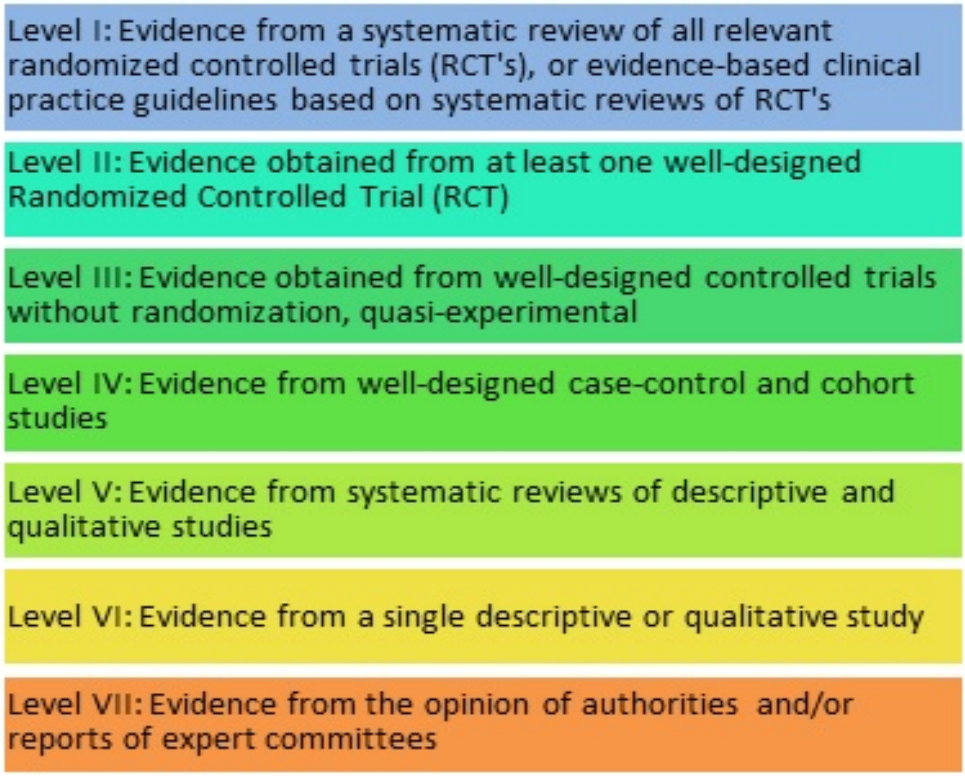
Appendix C Fishbone Diagram



APPENDIX D

MELNYK AND FINEOUT-OVERHOLT'S HIERARCHY OF EVIDENCE (2015)

Melnyk and Fineout-Overholt's Hierarchy of Evidence (2015)



APPENDIX E

GRADING SCALES OF VAGINAL TOXICITY

Table E1. Common Terminology Criteria for Adverse Events v3.0 grading for vaginal stenosis (Chronbach alpha 0.76)

Adverse Event	Short Name	Grade 1	Grade 2	Grade 3
Vaginal stenosis/length	Vaginal stenosis	Vaginal narrowing and/or shortening not interfering with function	Vaginal narrowing and/or shortening interfering with function	Complete obliteration not surgically correctable

(Data from Common Terminology Criteria for Adverse Events [CTCAE]. Version 3.0)

Table E2: Grading of vaginal toxicity (Brand et al., 2006)

Adverse Event	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Vaginal stenosis	None. Flimsy adhesions easily broken down	Partial stenosis or shortening but less than complete occlusion	Complete occlusion. Telangiectasia with frequent bleeding	Radionecrotic ulcer	Fistula to bladder, bowel, or peritoneal cavity

APPENDIX F

MANAGEMENT OF SEXUAL/VAGINAL HEALTH AFTER PELVIC RADIOTHERAPY

Management of sexual/vaginal health after pelvic radiotherapy

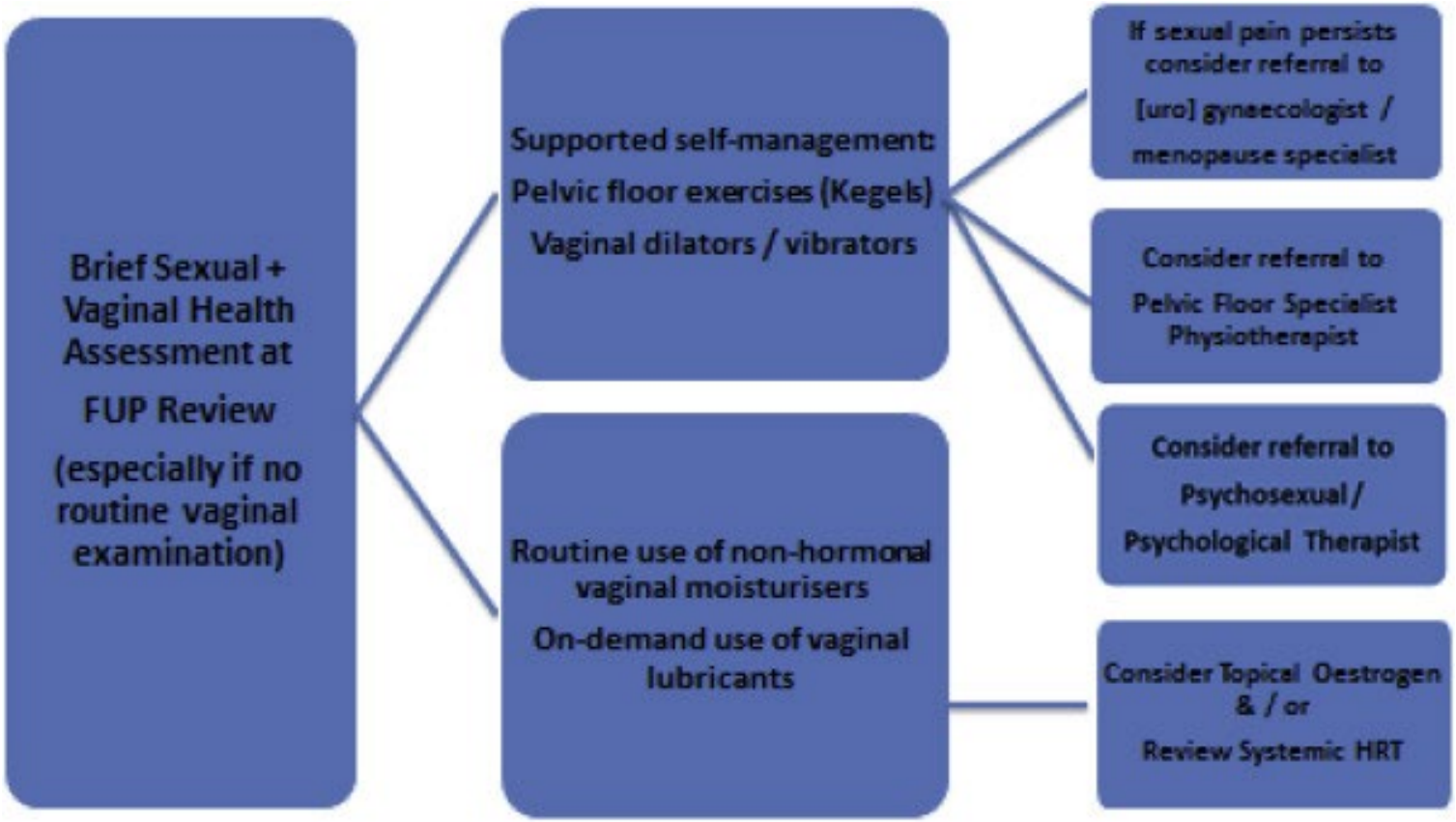
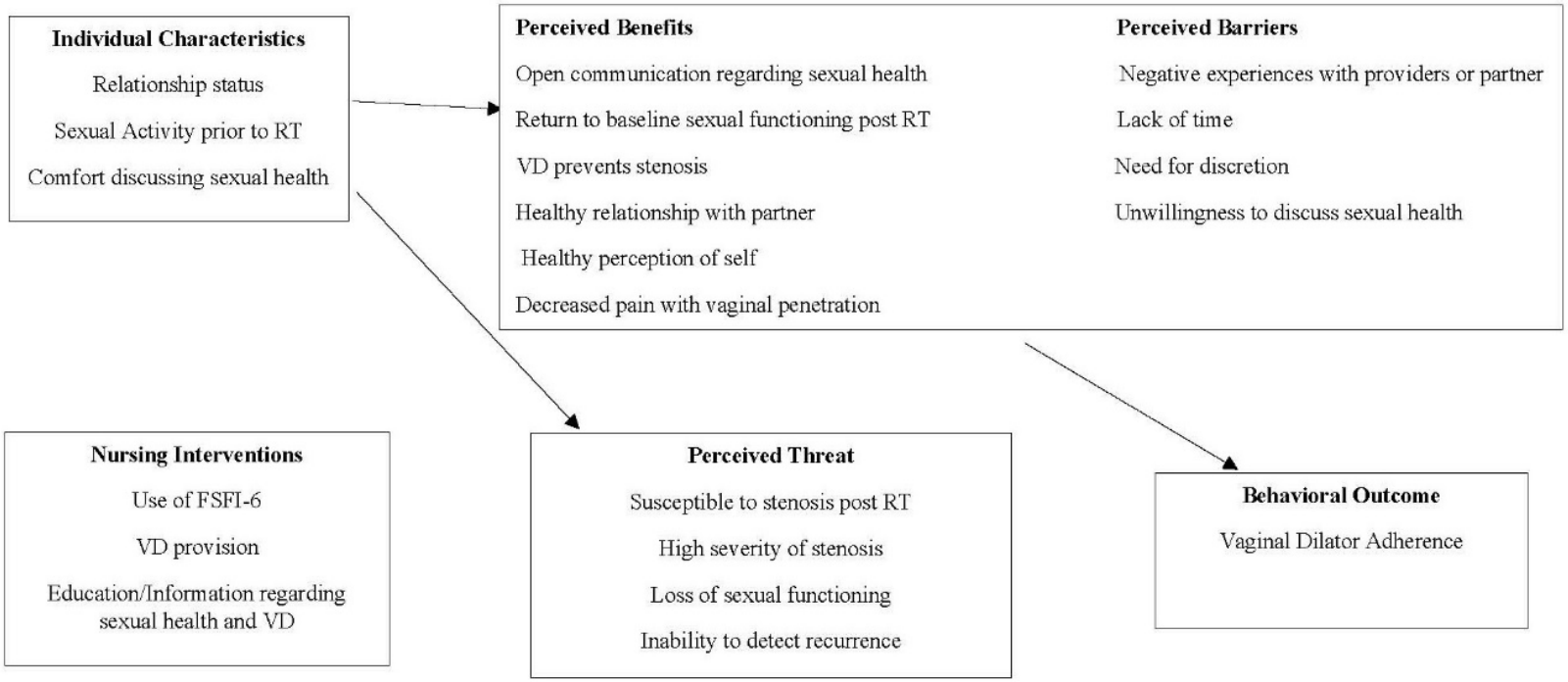


Image retrieved from White (2015), adopted from Carter et al. (2011)

APPENDIX G

HEALTH PROMOTION MODEL

Health Promotion Model



Adapted from Bonner, C., Nattress, K., Anderson, C., Carter, J., Milross, C., Philp, S., & Juraskova. (2012). Chore or priority? Barriers and facilitators affecting dilator use after pelvic radiotherapy for gynecological cancer. *Supportive Care Cancer, 20*, 2305-2313.

APPENDIX H

PDSA WORKSHEET

PDSA WORKSHEET

Project Name:	Date of test:	Test Completion Date:
SMART AIM:		
What is the objective of the test?		
What long-term goal does the change impact?		

PLAN:

Briefly describe the test:

How will you know that the change is an improvement?

What driver does the change impact?

What do you predict will happen?

PLAN

List the tasks necessary to complete this test (what)	Person responsible (who)	When	Where
1.			
2.			
3.			
4.			
5.			
6.			

Plan for collection of data:

DO: Test the changes.

Was the cycle carried out as planned? ☐ Yes ☐ No

Record data and observations.

What did you observe that was not part of our plan?

STUDY:

Did the results match your predictions? ☐ Yes ☐ No

Compare the result of your test to your previous performance:

What did you learn?

ACT: Decide to Adopt, Adapt, or Abandon.

☐ Adapt: Improve the change and continue testing plan.
Plans/changes for next test:

☐ Adopt: Select changes to implement on a larger scale and develop an implementation plan and plan for sustainability

☐ Abandon: Discard this change idea and try a different one

APPENDIX I

SWOT ANALYSIS

SWOT Analysis

Strengths	**Weaknesses**
-Experienced clinical staff -Support from Cancer Center leadership -Standardized VD patient education handout -Efficient processes -Patients already have email listed in EHR for purposes of continuing care	-Patient and healthcare providers lack of communication regarding sexual health -Patient attitude regarding VD -Lack of time to implement process
Opportunities	**Threats**
-Collaborate with University of Wisconsin regarding VD patient education -Initiation of clinical trial at project site	-Taboo nature of women's sexual health

APPENDIX J

PROTOCOL APPROVAL WITH MODIFICATIONS

PROTOCOL APPROVAL WITH MODIFICATIONS

DATE: 22 Dec 2020

TO: Alecia Besel, RN, BSN, OCN

PROTOCOL: [redacted] - 20.009, Vaginal Dilation After Pelvic Radiotherapy: Quality Improvement Project (Pro00048278)

APPROVAL DATE: 14 Dec 2020

EXPIRATION DATE: 14 Dec 2021

IRB APPROVED DOCUMENTATION:

Protocol Version:	• Protocol (Not Dated)
Consent Form:	• Informed Consent Form (Advarra IRB Approved Version 14 Dec 2020)
Product Information:	• Product Information for FeMani® Vibrating Massage Wand (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 14 Dec 2020:

- **Modifications to the Informed Consent Form**

If you wish to appeal the IRB's determinations and/or imposed modifications, you may follow the procedures outlined below:

1. Submit supporting documentation that addresses the IRB's concerns.

2. Provide a written justification for relief of any IRB imposed condition.

Please note the following COVID-19 considerations:

1. Please ensure that you have adequate study staff and resources before you begin conducting the study.

2. Please consider delaying enrollment if your study procedures may be impacted by the pandemic; or please submit a modification to change the procedures.

3. Please note that screening questions relating to COVID-19 are not considered research questions unless you will be collecting data on COVID-19.

The IRB granted a Waiver of Documentation of Consent for verbal consent.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

Approved investigators and sites are required to submit to Advarra for review, and await a response prior to implementing, any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

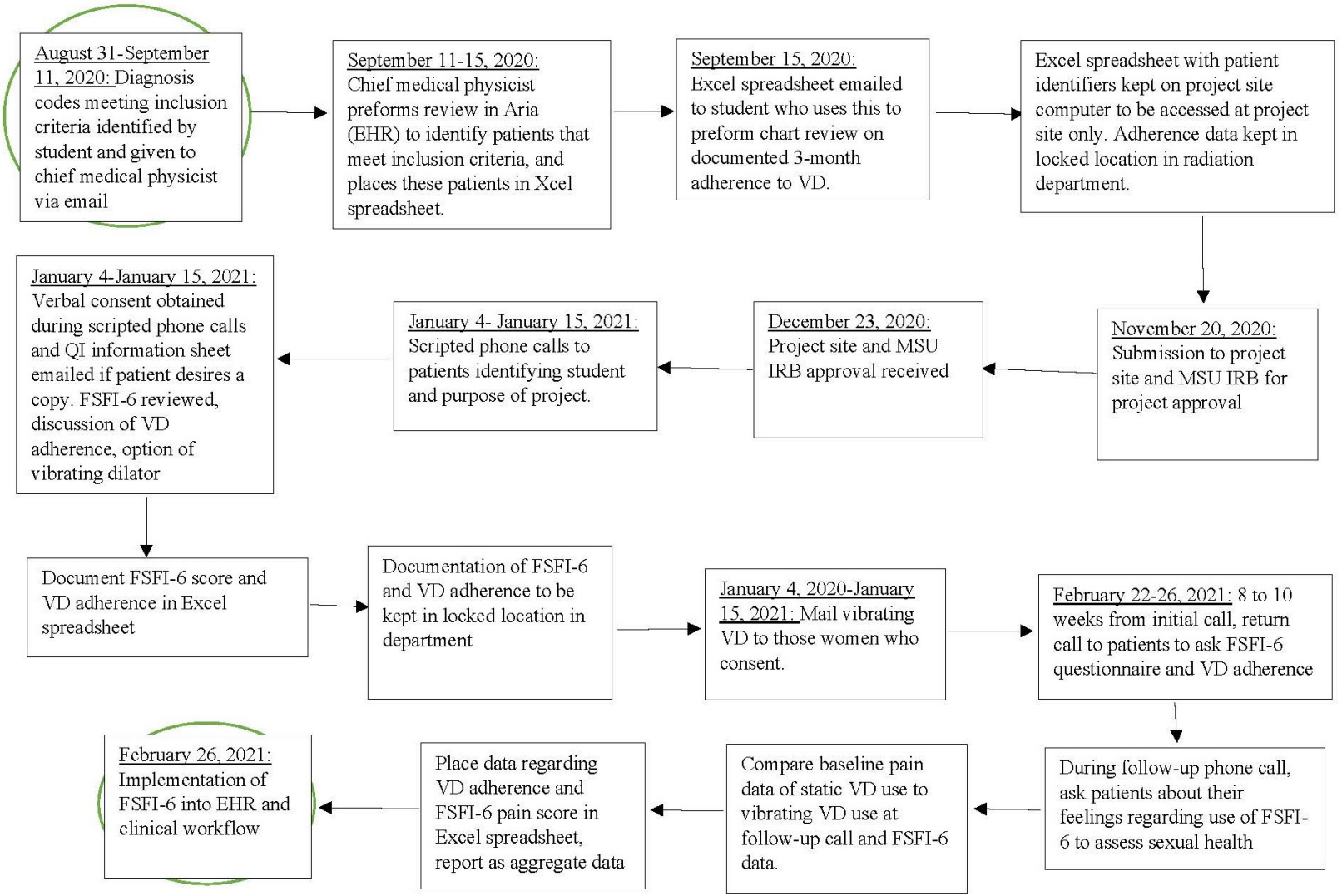
Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available. Thank you for selecting Advarra IRB to provide oversight for your research project.

APPENDIX K

PROCESS MAPPING OF QUALITY IMPROVEMENT PROJECT

Process Mapping of Quality Improvement Project



APPENDIX L

INFORMATION AND CONSENT FORM

INFORMATION AND CONSENT FORM

Sponsor / Project Title:	**[redacted] and Montana State University / "Vaginal Dilation After Pelvic Radiotherapy: Quality Improvement Project"**
Protocol Number:	**20.009**
Principal Investigator: (Project Investigator)	**Alecia Besel, RN, BSN, OCN, DNP student**
Telephone:	**(406) 657-2500 (24 hour)** **(877) 992-4724 (24 hour)**
Address:	[redacted]

You are being asked to participate in a quality improvement project.

- Participation in this quality improvement is voluntary – your choice.
- You can stop participating in the quality improvement project at any time.
- No one can promise that a quality improvement project will help you.
- Do not join this quality improvement project unless all your questions are answered.

After reading and discussing the information in this consent form you should know:

- Why this quality improvement project is being done;
- What will happen during the quality improvement project;
- Any possible benefits;
- The possible risks;
- Other options you could choose instead of being in this quality improvement project;
- How your personal health information will be treated during the quality improvement project and after the project is over;
- Whether being in this quality improvement project could involve any cost to you; and
- What to do if you have problems or questions about this quality improvement project.

When we have answered all your questions, you can decide if you want to be in the project or not. This process is called 'informed consent'.

Why is this quality improvement project being done?

We would like to learn more about how participants who undergo pelvic radiotherapy view sexual health before and after therapy, and how we can help facilitate adherence to vaginal dilation. The purpose of this quality improvement project is to integrate a validated sexual health questionnaire (the FSFI-6), and optional U.S. Food and Drug Administration (FDA) approved vibrating VD in order to improve vaginal penetration pain scores post treatment. We also want to explore how this project may aid sexual health communication between you and your healthcare provider, and what you view as facilitators or barriers to vaginal dilator use.

How many people are taking part in this project?

This project will enroll 50 adult female participants who have undergone pelvic radiotherapy.

How long does the project participation last?

Participants will be in the quality improvement project from the time of consent to eight weeks post-intervention. The project will last 10 weeks, which is about 2.25 months.

What will happen if you participate in the project?

As a participant in the project, you will receive 2 phone calls from the project investigator. During the first phone call the sexual health questionnaire (FSFI-6) will be reviewed and your answers documented, you will be asked about current vaginal dilator adherence, re-educated regarding vaginal dilation post pelvic radiotherapy, and given the option of receiving a FDA approved vibrating dilator. Eight weeks later, the project investigator will call to follow-up with you regarding vaginal dilator adherence in the last eight weeks, review and document the FSFI-6, and ask you about perceived facilitators/barriers to vaginal dilation and whether you believe the FSFI-6 can improve sexual health communication between you and a healthcare provider.

You will continue regular follow-up as set forth by your radiation oncologist.

What are the potential risks, stress, or discomfort in this project?

It is unlikely that participation in this project will cause any problems for you. Very few people are upset by the surveys. If you are bothered by specific questions, you may skip those questions. You will be participating in 2 phone calls with the project investigator who also works in the radiation oncology department. We will ask that participants maintain confidentiality, however, we cannot guarantee this. There may be risks which are currently unknown.

What are the potential benefits for participating in this project?

It is unknown as to whether you will receive any benefits from participating in the project. It is possible that you may report symptoms and concerns that normally may not have been

reported, resulting in better management of your care. The results of this project may lead to more effective education and communication to assist women after pelvic radiotherapy.

What are my other choices if I decide not to participate in this project?

You are free not to participate in this project. If you choose not to participate, your care will not be affected in any way.

Who will see my information?

The investigators will maintain strict confidentiality about you and will not disclose individual identifying information. All the information gathered will have a unique code. The list that links the unique code to your name will be kept separate from your survey results and health information. Any [redacted] project staff with access to the list have undergone training and been certified regarding confidentiality. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as [redacted]; Advarra Institutional Review Board (IRB); and the U.S. Food and Drug Administration (FDA).

New Findings

Any new important information that is discovered during the project and which may influence your willingness to continue participation in the project will be provided to you.

What incentives are there to participate?

You will not be paid for your inclusion in this project. To thank you for your time, if you opt to use the FDA approved vibrating dilator it will be provided at no cost to you.

What are the costs for taking part in this project?

No direct costs are associated with participating in this project. You will not be charged for any of the quality improvement procedures in this project.

What are my rights in this project?

Participation in this project is voluntary. Your choice of whether to participate will not influence your future relations with [redacted]. If you decide to participate, you are free to withdraw your consent and to stop your participation at any time without penalty or loss of benefits to which you are otherwise entitled. The project sponsor or the project investigator can stop your participation in the project without your consent.

If you are an employee of this project site, you are under no obligation to participate in this project. You may withdraw from the project at any time and for any reason, and neither your

decision to participate in the project, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this project site.

You may refuse to participate or you may withdraw from the project at any time without penalty or anyone blaming you.

Whom to contact about this project

During the project, if you experience any medical problems, suffer a project-related injury, or have questions, concerns or complaints about the project, please contact the project investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research project, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00048278.

VERBAL CONSENT:

This project has been explained to me, and I have been told what the project involves. Do you agree to participate in this quality improvement project?

APPENDIX M

SCRIPTED PHONE CONVERSATION

Scripted Phone Conversation

- "Good morning/afternoon, my name is Alecia, I am a RN with [redacted] radiation oncology, and a graduate school student finishing my Doctorate at Montana State University".
- "As part of my Doctoral degree I am conducting a quality improvement project aimed at assessing post-radiation side effects in women who have undergone radiation to the pelvis, which includes questions about sexual health, pain and use of recommended vaginal dilator use. Chart review identified that you meet the criteria for this project. I am wondering if you would be interested in reviewing a brief information sheet about my project? I can email you the sheet, I will call you in one week to ensure you have adequate time to review the information, if you would like to take part in this project you may give verbal consent during this phone call".
- After return verbal consent obtained:
- "Thank you for your interest in this project. To begin, I would like to ask if you are currently using your vaginal dilator? How many times per week on average have you used your dilator in the last month? How long do you typically leave the dilator in place with each use?"
- "I would now like to review a questionnaire with you aimed at assessing sexual health." (Ask the FSFI-6 questionnaire and document responses).
- Ask if patient is interested in trialing a vibrating dilator as literature supports increased adherence, decreased vaginal stenosis, and decreased pain during intercourse. If yes mail them the dilator (follow-up phone call in 1 week to ensure the participant received the

dilator and review the vaginal dilator education sheet). If no, and woman is not adherent to VD use, review VD education sheet with her. “Thank you for your participation, I will call you again in eight weeks to review the questionnaire and VD adherence once again”.

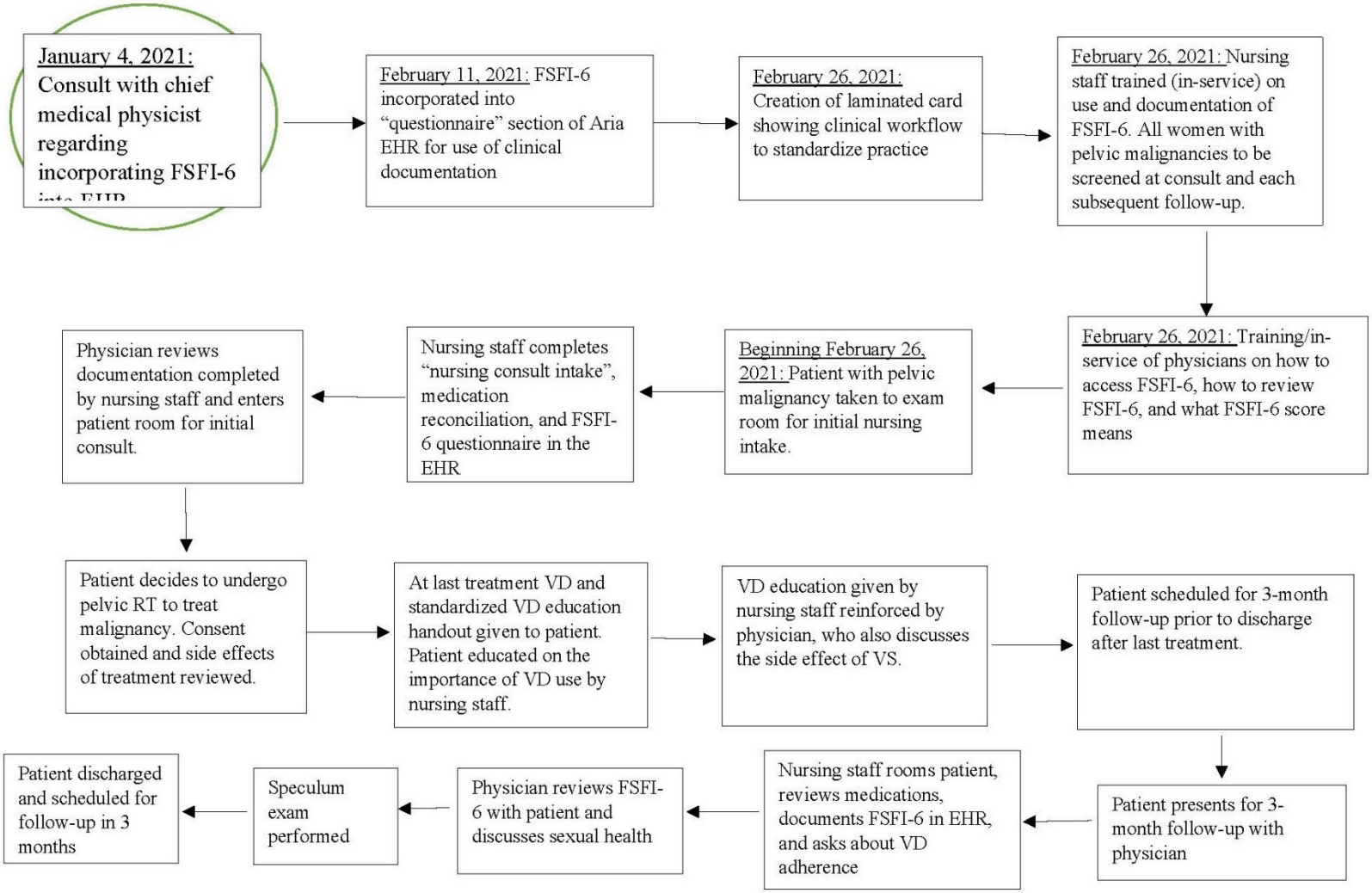
Eight Weeks Later:

- “Good morning/afternoon, this is Alecia, with the vaginal dilator quality improvement project. I am calling to ask some follow-up questions regarding the project and the vibrating vaginal dilator”.
- “First, I would like to start with reviewing the FSFI-6 with you again, do you have a few minutes to complete this with me?”. (Ask FSFI-6 questions).
- “Thank you. Now I would like to inquire about the vibrating vaginal dilator. How often did you find yourself using this on average per week?”.
- “Did you find the vibrating dilator easier to use than the previously issued static dilator?”.
- “If you had the choice of vibrating vs. static dilator at the completion of radiation therapy which do you feel you would choose and why?”.
- “If the FSFI-6 was reviewed with you at consult and each additional follow-up, do you feel that would have assisted in discussion of sexual health with your health care professionals?”.
- “Do you have any suggestions moving forward with this project that would improve the process for other women undergoing treatment?”.
- “Thank you for your time in assisting me with this project. Please feel free to contact me with any further questions or concerns”.

APPENDIX N

IMPLEMENTATION PLAN

Implementation Plan



APPENDIX O

EVIDENCE REVIEW TABLE

Evidence Review Table

Citation: (i.e., author(s), date of publication, & title)	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses])
1.	N/A	-prospective, randomized two-armed, open, single-center phase-II-trial -evaluating the incidence and extent of vaginal fibrosis in female anal ca pt treated with chemo-RT -all pts receive standard chemo-RT to pelvis and inguinal nodes	-60 female pts undergoing chemo-RT for anal cancer -ECOG 0-2 -Age>18 -Heidelberg Institute of Radiation Oncology Heidelberg Germany	**DV:** incidence and grade of vaginal fibrosis 12 months post-RT **IV:** diameter of VD	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** baseline measurement of vaginal diameter and appropriate diameter VD	-logistic regression model -one-sided significance level -odds ratio -descriptive statistics	-study will end in 2024, no published findings at this time, only protocol	Level II- RCT **Strengths:** RCT, aim is to develop a guideline for VD use in female anal cancer patients **Weaknesses:** No published data at this time
2.	N/A	-Qualitative using the Delphi method to reach consensus -3 round delphi process using questionnaire -questionnaire consisted of 7 different categories measured on Likert scale -Delphi study questionnaire was completed online to allow	-30 clinicians (10 radiation oncologists, 10 gynecological oncologists, 10 oncology nurses) -mean age 48 y.o -8 males, 22 females -12 gyn cancer centers in the Netherlands	**DV:** None **IV:** None	**DV:** None **IV:** None	-descriptive statistics to measure consensus	Panel agreed that: -info about sexual rehab using VD should be provided by RadOncs prior to treatment -info should always be provided to sexually active cervical & vaginal cancer pts younger than 70 -info should be tailored for vulvar & endometrial pts older than 70 & sexually inactive pts	Level VI- Qualitative study/expert opinion **Strengths:** 3 round Dephi study to reach consensus. Panel was equally represented between RadOncs, GynOncs, & nurses. **Weaknesses:** Only 8 men vs. 22 women. No patient opinion taken into consideration. Don't know if this consensus is applicable to clinical practice.

		anonymous inclusion					-VD is recommended to prevent vaginal adhesions, tightening, & shortening -VD should start 4 wks after treatment and performed 2-3 times a week for 1-3 minutes -VD should continue for 9-12 months -Plastic dilators were most often recommended -gradually use the biggest diameter cylinder	
3.	HAPA	-Qualitative interview of women treated w EBRT/BT for Gyn cancers -2 female researchers conducted semi-structured face-to-face interviews -interviews were digitally recorded & transcribed verbatim	-30 women, 32-67 y.o, treated w EBRT/BT for Gyn cancers 2-36 months prior to interview -2 university medical centers in the Netherlands	**DV:** None **IV:** None	**DV:** None **IV:** None	-transcriptions were analyzed with QSR International's NVivo 10 software using the Framework Approach -emerging themes identified using a priori coding scheme -Descriptive statistics calculated using IBM SPSS version 21	-Almost all women attempted VD use -Intended dilator use was determined by the expectation it would prevent VS -determinants of initiation and maintenance of VD included: making VD part of a routine, use of lubricants, and vibrating VD -factors influencing negative emotions included: hard plastic design, reminder of the trauma of treatment	Level VI- Qualitative study **Strengths:** Accounted patient determinants of VD use including motivation and volition processes determining initiation and maintenance. Motivating/influencing factors gleaned from these patients could help determine best practices or how to change practice to increase adherence **Weaknesses:** Semi-structured interviews

4.	N/A	-pilot study -prospective, longitudinal, observational -semi-structured interviews	-20 women that received RT for gyn cancers -ages 26-71 -14 were in a partnered relationship -Netherlands	**DV:** VD use and sexual functioning **IV:** nurse-led sexual rehabilitation intervention	**DV:** self-reported at 3, 9, and 12 months; FSFI used for sexual functioning **IV:** informational booklet and nurse resource; patient and nursing exit interviews	-descriptive statistics -non-parametric tests -two-sided, Friedman's AVONA -post-hoc Wilcoxon signed rank test -Effect sizes	-At 6 months out from RT 88% of participants were using VD regularly -At 12 months 75% of participants were using VD regularly -40% discontinued VD at 3 to 9 months -Sexual functioning improved between 1 to 6 months post RT with further improvement at 12 months -75% of women stated the informational booklet and nurse resource were helpful at resuming intercourse	Level III- prospective study **Strengths:** use of reliable tool (FSFI), qualitatively patients felt supported throughout the intervention, high rate of VD use even at 12 months post RT **Weaknesses:** non-randomized, selection bias, high rate of attrition
5.	Health Belief Model	-qualitative study -investigate the pt experience of dilator use	-15 women recruited by clinicians from major oncology center -completed RT for cervical or endometrial cancer between 2 months and 2 years ago -pts had been given VD -Sidney Australia	**DV:** None **IV:** None	**DV:** None **IV:** None	-Qualitative data were analyzed using thematic analysis until theoretical saturation was reached -descriptive statistics for data from questionnaire	-barriers to dilator included: uncertainty about when/how to use them, viewing VD as a negative experience, lack of time or forgetting, and the need for discretion -facilitators to VD use included: concern about stenosis, acceptance as part of normal routine, or viewing as an extension of	Level VII- Expert opinion **Strengths:** first study to investigate the patient experience of VD use. **Weaknesses:** Low response rate shows VD use is difficult for women to discuss, all participants were English speaking and well educated which is not all-inclusive and may not translate to other facilities.

							medical treatment and focusing on positive aspects.	
6.	N/A	-retrospective chart review -prospective database containing data regarding VS	-188 patients with carcinoma to the cervix treated w pelvic RT -Mean age of 58.6 y.o -Median f/u of 64 months -Westmead Hospital, Sydney Australia	**DV:** VS **IV:** incidence, timing, severity	**DV:** Grading of vaginal toxicity (developed at the site, and not validated) **IV:** percentage, months out from RT, grading of vaginal toxicity	Descriptive statistics	-RT-induced VS was reported as 38% -VS most commonly occurs within the 1st year post-RT -stenosis of any grade was noted at a mean of 9.6 months and median of 7.5 months from completion of RT -only prognostic factor associated with increased risk of VS was age >50	Level III- retrospective study **Strengths:** chart review of 188 patients **Weaknesses:** no validated tool to assess VS, not able to document the extent of vaginal involvement in all pts
7.	N/A	-prospective 12-month study -structured educational intervention regarding dilator use -questionnaires at baseline, 36, 9, and 12 months post-RT	-60 women undergoing pelvic RT for gyn cancer -median age of 60 -primary site uterus (56.6%) and cervix (40%) -Westmead Hosptial, Sydney Australia	**DV:** VD compliance and VS **IV:** educational intervention	**DV:** compliance questionnaire, grading of vaginal toxicity (developed at the site) **IV:** self-developed non-validated questionnaire with 3 questions	-two tailed tests -percentages and continuous data using median and interquartile range -Chi squared test -Fisher exact test	-At 12 months 52% of pts were using dilators -35% were using dilators at least 2-3 times a week -frequency of dilator use was greater in those over 50 (P=0.005) -Dilator use was less frequent in those who were sexually active (P=0.035) -At 12 months 11% had flimsy adhesions, 6.5% had partial stenosis, no pts had complete stenosis	Level III- prospective study **Strengths:** cervical and endometrial post-RT data **Weaknesses:** non-validated toxicity grading scale and non-validated questionnaire, no baseline data on sexual activity, not controlled

8.	N/A	-survey of radiation oncologists -3 part self-assessment questionnaire: sexual health, health care structures provided, participant's professional profile	-41 questionnaires filled out by radiation oncologists in Austria after the 2017 Austrian Society of Radiation Oncology conference	**DV:** care for sexual health in Radiation Oncology **IV:** reasons why not addressed	**DV:** self-assessment questionnaire **IV:** other problems more important, lack of time, lack of training	-Wilcoxon rank sum test -Kruskal Wallis test -Kendall's tau -Chi squared	-only 4.9% of radiation oncologists routinely address sexual health in 61-80% of their patients -31% suspected sexual problems but did not address -most common reason for not addressing was "other problems are more important" (73.2%) -Another reason was "lack of time" (36.6%) -none had training in sexual medicine	Level VI- qualitative study **Strengths:** Response rate of 44.5% **Weaknesses:** selection-bias from use of self-administered questionnaire, used estimated percentages
9.	Health Promotion Model	-comprehensive review -qualitative reports -provides a treatment algorithm, based on scientific literature, supported by clinical experience, for treatment of VS	-interview of physicians at 2 major cancer centers on the East coast -Literature review from CINAHL, Medline, PubMed	**DV:** Vaginal health **IV:** Education and non-hormonal interventions	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** Qualitative interviews	Descriptive statistics	-vaginal lubricants, moisturizers and dilators can decrease the morbidity of vaginal atrophy -Educating cancer survivors about methods to promote vaginal health can reduce or eliminate vaginal discomfort -treatment recommendations include routine use of non-hormonal vaginal moisturizers, on-demand use of vaginal lubricants, and routine use of vaginal dilators or vibrators	Level VI- Mixed methods qualitative study **Strengths:** Opinions of female cancer survivors who are living the experience, use of literature to support qualitative reports **Weaknesses:** Expert opinion, too many methods used to arrive at conclusion and treatment recommendations

10.	N/A	-Comprehensive Review	-Review of 8 studies on PDSA cycles	None	None	None	-change must occur for any improvement effort to be successful -Clearly define the purpose or aim -determine what data must be collected to assess change has occurred -develop a change that is predicted to result in improvement, which leads to PDSA	Level IV- case study/case series **Strengths:** review of 8 studies and guidelines for PDSA use **Weaknesses:** small sample
11.	N/A	-cross-sectional observational study -voluntary completion of a general questionnaire regarding health habits, socioeconomic data -voluntary completion of FSFI-6 and menopause rating scale	-715 women in the community ages 40-55 y.o not using hormonal contraception & sexually active in last 4 weeks -performed in areas of free access and transit (i.e. parks, shopping malls) -3 states of the southern region of Brazil	**DV:** FSFI-6 and MRS **IV:** assessment of middle-aged women's sexual function and variables	**DV:** confirmatory factor analysis to validate the FSFI-6 and MRS **IV:** questionnaire	-mean or standard error of mean -median and 25th to 75th percentiles -Shapiro-Wilks test to determine normality of data distribution -Kruskal-Wallis test to analyze differences in FSFI-6 domains and total scores -chi squared of degrees of freedom -Chronbach alpha	-FSFI-6 has Cronbach alpha of 0.840 -MRS has Cronbach alpha of 0.854 -total FSFI-6 scores were positively correlated w family income, higher parity, and educational level	Level IV- Cross-sectional study **Strengths:** Findings agree with other studies validating FSFI-6. Privacy was preserved which may lead to more honest answers on self-reporting questionnaires **Weaknesses:** Only women who were sexually active in the last 4 weeks were included. Information collected through self-reporting questionnaires lack diagnostic precision. Difficult to measure the extent to which symptoms cause distress or suffering for each of the participants.

12.	N/A	-Comprehensive literature review (1972-2017) -literature search through PubMed -observational and retrospective studies	-80 citations found -14 described surgical intervention studies for VS -8 were interventional dilator studies -10 reviews -4 practice surveys -18 observational outcomes studies (cervical, uterine, anal, rectal, & vulvar)	**DV:** VS **IV:** VD use	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** length of VD use, type of VD, number of times per week VD used	Relative Risk	-VS is a well-described consequence of RT -RT-induced vaginal changes can interfere w sexual function -use of VD can mitigate the risk of VS -no standard protocol for VD exists	Level IV- case studies/case series **Strengths:** review of 80 articles regarding VD and VS **Weaknesses:** no level I studies in the review. con
13.	N/A	-systemic review -evidence based guideline developed by Cancer Care Ontario's PEBC -used methods of the practice guidelines development cycle -evidence selected and reviewed by the Cervical Cancer Follow-up Guideline Working Group -articles assessed for quality using 11-item AMSTAR tool	-search of literature in Medline, Cochrane Library, ClinicalTrials.gov, Canadian Medical Association Infobase and Embase -November 2007 to August 2014 -6 full-text studies and 1 systematic review	**DV:** cervical cancer follow-up **IV:** treatment modality	**DV:** screening tests **IV:** surgery, RT, chemotherapy	-None	-Follow-up recommendations include: every 3-4 months for the first 2 years, every 6-12 months during years 3-5 -At a minimum follow-up should include patient history and complete physical exam (including speculum and bimanual exam) -PET-CT or other imaging is not recommended unless concern of distant metastasis -evidence does not suggest testing with HPV or serial Pap test	Level I- Systematic review **Strengths:** Systemic review with both internal and external review, reviewers were experts in the field, articles assessed for quality using 11-point AMSTAR tool **Weaknesses:** Reimbursement for certain tests are not paid for in Canada so those were not included in guidelines

14.	N/A	-qualitative -patients' experiences with oncology providers regarding communication about sexual issues during and after treatment for cancer -PROMIS Network, development of PROMIS sexual function measure -focus groups and surveys (online or interviewer administered over phone)	-109 cancer patients and survivors (of varying diagnoses) -men and women -819 oncology professionals - mailed invitations to patients at Duke University in North Carolina and NexCura Internet Panel (self-selected) -primarily middle aged between 51 and 64 y.o (44%) -non-hispanic/latino (94%), white (84%) -equal representation of men and women	**DV:** None **IV:** None	**DV:** None **IV:** None	None	-74% of pts thought discussions with oncology professionals about sexual function were important -whether pts received information varied by cancer type (23% lung, 29% breast, 39% colorectal, 79% prostate) -45% reported receiving information regarding sexual changes with cancer treatment	Level VI- qualitative **Strengths:** qualitative data from a wide range of cancer patients and survivors, low rate of missing survey data (6%) **Weaknesses:** researchers did not ask what kind of information patients received regarding sexual health
15.	N/A	-Ethnographic observations -aimed to report the impact of prostate cancer treatment on pt's sexual relationships -non-participant observation	-60 consultations -clinical oncology and prostate cancer urology clinics -2 NHS Trust Cancer Centers in South East England	**DV:** None **IV:** None	**DV:** None **IV:** None	None	-sexual functioning was discussed infrequently in both clinic settings -involvement of the partner in discussions during consultation was minimal -discussions of wider psychosexual concerns were marginalized in consultations	Level VI- observational **Strengths:** 60 consultations **Weaknesses:** observational only with no data collection
16.	Health Belief Model	-retrospective study -eligible pts received a letter	-78 women aged 18 or older with stage IA to stage IIIB endometrial	**DV:** adherence to VD, sexual functioning and vaginal changes	**DV:** answers to questionnaire "what best describes the average frequency of	- t tests for comparison between adherence groups	-33% of pts were adheres to 2+ days a week of VD use	Level III- retrospective study **Strengths:** consistent with other studies, found that

		describing the study and offering the opportunity to participate -Questionnaires were completed by mail or phone interviews	carcinoma who had received HDR intravaginal BT -completed treatment between September 2008 & January 2009 -University Hospitals of Cleveland Case Medical Center (Cleveland, OH)	**IV:** physician recommendation, health beliefs, dyadic satisfaction	VD use", SVQ (chronbach alpha 0.76-0.83) **IV:** physician recommendation measured by "yes" or "no" did the MD recommend use of a VD, health beliefs measured using 8 item checklist for reasons for using a VD, dyadic satisfaction measured by a single item on the DAS (likert scale) (chronbach alpha 0.848)	-Wilcoxon rank-sum to compare groups w respect to variables on a Likert scale -Pearson's chi-square test or exact chi-square test for between group comparisons -2 sided binomial test	-nonadherers reported that their vaginas were smaller after BT -pts reported significant (66.7%) sexual dysfunction after HDR BT	sexual dysfunction is associated with HDR BT, **Weaknesses:** no printed instructions for VD use, no determination of causal relationship between adherence, health beliefs, and perceived changes in vaginal dimension, due to cross-sectional design pre and post-treatment changes in dyadic and sexual functioning could not be assessed, factors other than cancer can affect sexuality
17.	N/A	-pilot randomized trial -tested vaginal dilator educational methods & subsequent adherence with use -pts randomized to standard institutional instruction for use of dilator or a theoretically guided, nurse-led, one-on-one EEP for vaginal dilator use w telephone f/u	-42 women treated w postoperative vaginal BT for stage I to IIIc endometrial cancer -24 women to standard instruction -18 to EEP -participants recruited from 2 institutions from 3 RadOnc practices (2 at Northwestern & 1 at Univ. of Pennsylvania)	**DV:** VD adherence **IV:** standard institutional instruction or EEP	**DV:** use of vaginal dilator 2+ days a week or use less than 2+ days a week **IV:** type of education given by nurse based on randomization	-descriptive statistics to characterize sociodemographic and clinical characteristics -Bivariate logistic regression models to assess individual impact of intervention group, SD information -Fisher exact and 2-sample t tests for categorical and continuous variables	-There was no difference in adherence between standardized instruction and EEP arms -20% and 8.3% were adherent to use of dilator 3 times per week -64% and 16% were adherent to use at least once per week at 6 weeks & 6 months -Adherence was greater among those motivated by vaginal health and w lower BMI -nonadherence was greater among those who are college educated in the EEP	Level II- RCT **Strengths:** pilot randomized trial, provides realistic estimates of attrition to help guide future research ample size calculations, dilator adherence rates in the study correlated w previous studies **Weaknesses:** results show that adherence to dilator use is more multifactorial than previously believed, "adherence" had different definitions at each of the 2 institutions the trial took place

							group & higher weight	
18.	N/A	-aged matched cohort study -clinical assessment, vaginal biopsies, epithelial measurement, radiation dose, and questionnaire	-34 women treated for cervical cancer, & 37 age-matched control women scheduled for benign gyn surgery -aged less than 51 yo -time from treatment was between 2 & 5 years -Danderyd Hospital, Stockholm	**DV:** morphology of vaginal epithelium **IV:** serum levels of sex steroid hormones & sexual function, radiation dose at biopsy site, questionnaire	**DV:** pelvic exam by GynOnc (vaginal atrophy, existence and quantification of telangiectasia) measured by CTAE (chronbach alpha 0.76). Vaginal length measured w vaginal cylinder. Vaginal biopsies **IV:** blood samples of serum estadiol, progesterone, testosterone, FSH, LH, & SHBG. Radiation dose measured with dosimetry measurements from treatment plan. Questionnaire included 49 questions regarding sexual dysfunction, QoL, & psychological health	-Student's t test or Mann-Whitney U to analyze data from the survivors & controls -Pearson correlation coefficient R to test the correlation between hormonal levels & epithelial measurement -Relative risk for responses to questionnaire -Spearman's rank correlation test to correlate vaginal atrophy & responses from questionnaire to epithelial measurements	-in cervical cancer pts treated w RT the vaginal epithelium volume was reduced compared to controls -longer distance between dermal papillae ($p< 0.001$) and a shorter distance from the basal layer to epithelial surface ($p< .05$) were measured -Mucosal atrophy was observed in 91% of the survivors -no difference in serum estradiol -survivors reported more physical sexual symptoms -the highest RR was found for insufficient vaginal lubrication (RR 12.6), vaginal inelasticity (RR 6.5), reduced genital swelling when sexually aroused (RR 5.9), & reduction of vaginal length during intercourse (RR 3.9)	Level IV- controlled cohort study **Strengths:** use of a variety of methods, such as combining clinical examination, epithelial measurements, hormonal analysis, & psychosocial questionnaire to provide more detailed information on the consequences of RT **Weaknesses:** small sample size, no chronbach alpha reported for psychosocial questionnaire
19.	N/A	-controlled cohort study with	-34 cervical cancer survivors treated	**DV:** vaginal changes	**DV:** atrophy, fibrosis, vaginal length, elastin, collagen	-Fisher's exact test to compare categorical	-cervical cancer survivors who received the highest RT dose had the	Level IV- Controlled cohort studies

		age-matched controls -clinical examination and vaginal biopsies -blinding to grouping	with RT & 37 age-matched controls -mean age ≤ 51 y.o -Setting: Stockholm	**IV:** RT dose	**IV:** Gy	variables between pts and controls -Mann-Whitney U and Kruskal-Wallis for analyzing median radiation dose -Mann-Whitney U for differences in median elastin & collagen content	most vaginal changes -Mucosal atrophy was observed in 91% & pelvic fibrosis in 97% of survivors -a shorter vaginal length was measured in control -area fraction of elastin was higher in survivors (10% vs. 3.4%) -increased collagen density (fibrosis) was greater in survivors	**Strengths:** standardized sampling, inclusion of premenopausal women, blinded samples analyzed by same pathologist and examiner **Weaknesses:** small sample size, heterogenous material concerning treatment
20.	N/A	-Qualitative questionnaires -administration of the FSFI-19 and FSFI-6 with a gap interval between administration of 18 to 24 days -test re-test	-160 women aged 18 or older in a stable sexual relationship w male partner for at least 6 months -prospective recruitment from 3 outpatient clinics for sexual and reproductive medicine between June 2007 & September 2008 -received no compensation	**DV:** FSFI-6 **IV:** completion time and retest reliability	**DV:** 5-point ordinal scale **IV:** minutes and Chronbach alpha	-ROC curves for each questionnaire item -AUC -Pearson's r	-The FSFI-6 takes no more than 3 minutes to complete -using the cut-off score of 19, these sensitivity and specificity of the FSFI-6 was 0.93 and 0.94 respectively -the FSFI-6 has a Chronbach alpha of 0.789	Level III- Outcomes research **Strengths:** Ease of use and brevity of the FSFI-6. High Chronbach alpha on retest **Weaknesses:** FSFI-6 renders FSD as a one-dimensional concept. Women scoring below the cutoff still need further evaluation (w FSFI-19).
21.	Health Promotion Model	Qualitative survey of radiation oncologists' perceptions and	233 responses from radiation oncologists to the 4-part online survey via Survey Monkey	**DV:** None **IV:** None	**DV:** None **IV:** None	Cross-tabulation analysis using Chi squared to examine differences in survey response by sex, experience level, practice	-No differences in responses when data were examined by sex, experience level, or practice setting.	Level VII- Expert opinion **Strengths:** Expert opinion

		practices regarding VS				setting, and types of malignancies treated All analysis was 2-sided	-Those who treated GYN only versus non-GYN only pelvic malignancies were more likely to distribute written instructions for VD use (92% vs. 59%), and to refer pt to a sexual counselor if they experience sexual dysfunction following treatment (59% vs. 28%)	**Weaknesses:** Content validity of questionnaire. Low response rate to questionnaire. Wide range of perceptions may reflect conflicting data and differing manner in data interpretation. Did not survey patient's perceptions and understanding of vaginal toxicity and VD use
22.	N/A	-prospective, observational RCT	-620 female cervical cancer patients who underwent RT/chemo and BT -24 radiation oncology centers worldwide	**DV:** VS **IV:** recto-vaginal reference point dose, EBRT dose	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** Gy	-data reported w mean & standard deviation or median & IQR -Cox proportional hazards model -Hazards Ratio -Confidence intervals	-2 year estimate for VS greater than grade 2 was 21% -EBRT dose > 45 Gy is associated with a higher rate of VS (HR=2.259, $p<0.001$)	Level II- Prospective RCT **Strengths:** large patient population from several oncology centers worldwide. **Weaknesses:** no defined recto-vaginal reference point
23.	N/A	-prospective study -observational	-588 women who had completed IGABT for cervical cancer -median f/u time of 15 months -24 participating centers worldwide -sample population taken from EMBRACE study which included more than 1,000 pts	**DV:** early to late vaginal morbidity **IV:** IGABT	**DV:** CTCAE (chronbach alpha 0.76) measured every 3 months for the 1st year and every 6 months in the 2nd year **IV:** target concept & dose prescription to the high-rsk CTV, intermediate-risk CTV, and OAR (bladder, rectum, sigmoid, & bowel)	-crude incidence in symptoms & overall vaginal morbidity calculated w maximum symptom grading -prevalence rates for proportion of pts w vaginal symptoms in relation to overall pts at a time point -actuarial incidences calculated w	-at 2 years the actuarial probability of severe vaginal morbidity (grade ≥ 3) was 3.6% -actuarial probability of grade ≥ 1 was 89% -actuarial probability of grade ≥ 2 was 29% -VS was the most often observed symptom after treatment with	Level VI- observational trial **Strengths:** showed data for VS after prolonged f/u (15 months) **Weaknesses:** observational trial, grading of CTCAE is subject to interpretation, physician and pt reported symptoms are not always in accordance, crude incidences tend to underestimate morbidity because they do not take into account the increasing

						Kaplan-Meier method -confidence intervals	incidence of 59% for grade ≥1, 16% for grade ≥2, & 1% for grade ≥3 -the prevalence rates of grade 1 & 2 VS increased continuously during the 1st 2 years of follow-up -vaginal dryness had crude incidence of 47% for grade ≥1	probability of pts remaining at risk
24.	N/A	-population-based study -questionnaire mailed to 616 gyn cancer survivors, 243 chosen for study	-243 gynecological cancer survivors who reported they had had intercourse in the last 6 months -age <80 -Sweden	**DV:** dyspareunia (deep/superficial) **IV:** vaginal elasticity, lubrication, swollen lower abdomen	**DV:** self-developed questionnaire (no Chronbach alpha sited) **IV:** self-developed questionnaire (no Chronbach alpha sited)	-descriptive statistics -relative risk -confidence interval -multiple imputations by chained equations -Bayesian Model Average -Posterior Probability Value	-in the group of sexually active women 55% reported deep dyspareunia, 36% reported both deep and superficial dyspareunia -RR of deep dyspareunia was 1.87 with impaired pt reported elasticity -variables associated with deep dyspareunia included decreased lubrication PPV 100%, and swollen lower abdomen PPV 87%	Level VII- Expert/patient opinion (qualitative) **Strengths:** large study population with high participation rate, questionnaire answered in private and mailed reducing the risk for measurement errors, participants taken from national data base decreasing bias **Weaknesses:** self-developed questionnaire with no Chronbach alpha cited, difficulty deciphering deep from superficial dyspareunia
25.	N/A	-prospective study of VD use, adherence, and efficacy post-RT -self-reported use & VD size in monthly diaries	-109 females undergoing pelvic RT for GI or GU cancers -ages 28-81 -Memorial Sloan Kettering Cancer	**DV:** VS **IV:** VD use	**DV:** ability to maintain or return to pre-RT baseline size w dilator in place for 10 minutes **IV:** VD journal and self-report	-Fisher's exact test -Wilcoxon rank sum test -Kruskal-Wallis test	-effectiveness at preventing VD in all groups at 6 & 12 months after VD start was 73% & 82% respectively -At 1 month post-RT 49% had a decrease in VD size from pre-	Level III- prospective study **Strengths:** first prospective study on VD adherence in women treated with RT for GI cancer

		for 12 months post-RT	Center, New York, NY				RT, of those, 52% reported return to baseline by 6 months, and 71% by 12 months after VD start -Adherence at 4 weeks to VD use was 45% declining to 20% at 35 weeks, and 5% at 52 weeks -Adherence was lowest among rectal cancer pts	**Weaknesses:** Only studied physical barriers to VD use and not psychological, lack of standardized VS measures, no uniform start time for use of VD
26.	Health Belief Model	-systematic review -PubMed, CINAHL, & Scopus databases -search terms: "vaginal dilator", "experience", "perception", "adherence", "compliance", "factors", "sexuality"	-21 reviewed studies (2 RCTs, 2 case studies, 3 quantative, 4 prospective, 7 retrospective, 2 qualitative, 1 case study)	**DV:** VD adherence **IV:** barriers to adherence & facilitators	**DV:** VD use 2+ days a wk **IV:** 5 barrier categories, 6 facilitator categories	None	-adherence to VD was between 25% & 89.2% -barriers to adherence include: unhelpful circumstances, negative perceptions toward VD -facilitators to adherence include: supportive interactions with healthcare providers, risk perception and positive outcome expectancies	Level I-Systemic Review **Strengths:** Systemic review, symbolic interactionism **Weaknesses:** Variance in definitions & methods for assessing VD adherence. Includes Qualitative studies. Overall low level of evidence in study composure (2 RCTs_
27.	N/A	-Pilot study -feasibility, safety, & acceptability of psychosexual rehab booklet -retrospective	-20 women treated with pelvic RT for gyn or anorectal cancer in the last 5 years -all white, English speaking, with college educations	**IV:** Radiation/sexual education **DV:** psychosocial status, distress/post-traumatic stress	**IV:** knowledge scale (non-validated, self-made questionnaire), feedback scale (non-validated, self-made questionnaire) **DV:** HADS (Chronbach alpha	-Descriptive statistics -mean and median	-booklet was perceived as helpful, informative, and not distressing (85% of women); provided additional information to discuss with clinicians.	Level III- retrospective study **Strengths:** pilot study, use of 2 valid and reliable tools **Weaknesses:** low response rate, semi-qualitative, use of 2 non-validated questionnaires, not generalizable to other

			-Sydney, Australia		0.83), IES-R (Chronbach alpha 0.94)		-Increased understanding of strategies to reduced sexual impact post pelvic RT (87% of women)	treatment settings as all women were white, English speaking, and well educated
28.	N/A	-descriptive, longitudinal study -clinical trial on the effects of various treatments for VS after RT -prior to treatment a questionnaire -prior to treatment a full gyn exam by same researcher -after treatment full gyn exam by same researcher	-139 women with cervical cancer treated with RT -up to stage IIIB -ages 18-75 -Women's Hospital of the University of Campinas, Brazil -January 2013 to November 2015	**DV:** VS **IV:** characteristics of neoplasm, clinical and sociodemographic data, RT dose, surgery/none	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** medical records and patient questionnaire	-Chi squared -Kruskal-Wallis -Mann-Whitney -Poisson regression	-30.2% had no stenosis -69.1% had grade 1 stenosis 0.7% had grade 2 stenosis -advanced clinical stage and receiving brachytherapy associated with higher incidence of VS (coefficient -1.17, $p<0.01$)	Level IV- case studies **Strengths:** same researcher carried out pre and post RT gyn exams, use of validated toxicity tool **Weaknesses:** use of both qualitative and quantitative data, lower reported VS than multiple other studies
29.	N/A	-systemic review	-2 RCTs -2 comparative studies -5 correlational studies -1 case series -search conducted in Cochrane Central Registrar of Controlled Trials, MEDLINE, EMBASE, and CINAHL for the years 1950-2013	**DV:** VS **IV:** VD	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** length of use, duration of use, use of static vs. vibrating VD, size of VD	None	-consistent guidelines for VD in the U.S. is lacking -women who report use of VD seem to have less VS -some women with VS can regain patency with use of VD	Level 1- Systemic Review **Strengths:** Cochrane review **Weaknesses:** One small RCT only. Most studies have small sample sizes.

30.	N/A	-Critical review	-review of 49 research articles regarding vaginal stenosis	**DV:** VS **IV:** risk factors, prevention, treatment options	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** RT dose, cancer grade, RT volume, age, diagnosis, smoking status	-descriptive statistics	-Increasing dose and volume of RT is associated with all grades of VS (doses >45 Gy had highest morbidity) -cervical cancer pts had the highest incidence of VS -Pts >age 50 had increased risk of VS -smokers were predisposed to VS	Level IV- case studies/case series **Strengths:** Review of VS studies **Weaknesses:** not a systemic review, search criteria not identified
31.	N/A	-outcome research -initial validation study -questionnaire administration to examine FSFI for construct validity -test-retest reliability	-131 normal controls and 128 age-matched subjects with FSAD -ages 21 to 70 -5 research centers	**DV:** None **IV:** None Aim was to develop a brief, valid, and reliable self-report measure to female sexual function	**DV:** None **IV:** None	-Pearson product-moment correlation -Chronbach alpha	-test-retest reliability coefficients were high for each individual domain (r=0.79 to 0.86) -FSFI has Chronbach alpha of 0.82 -good construct validity of FSFI (p,0.001)	Level IV- case control study **Strengths:** FSFI showed a high Chronbach alpha of 0.82, high test-retest reliability (r=0.79 to 0.86), and good construct validity with highly significant mean difference scores between FSAD and control groups for each domain (p<0.001), easy to administer **Weaknesses:** Use in areas outside of FSAD had not been studied
32.	N/A	-prospective -questionnaire derived directly from LENTSOMA scales during personal interviews w pts -scales ranged from 1 to 4	-85 women who were treated for cervical cancer w surgery, RT, chemotherapy alone or in combination -Stages I to IV -women aged 40-59 y.o	**DV:** Quality of Life and Sexual health **IV:** Disease stage, treatment modality, age	**DV:** LENTSOMA scale (Chronbach alpha 0.786) **IV:** stage I through IV, surgery, RT, chemotherapy, or a combination; ages 40-59 y.o	-non-parametric tests -descriptive statistics -mean -percentage	-pain during intercourse and altered sexual function reported by 32.9% and 25.9% -vaginal stenosis was seen in 75.29% of pts after treatment -16.4% of pts reported decreased	Level III- prospective study **Strengths:** use of reliable tool **Weaknesses:** low data collection rates, no baseline data to compare to, sexual functioning is

		depending on severity of symptoms -maximum subjective score of 16	-India				frequency of intercourse post treatment	subjective and influenced by relationships
33.	N/A	-prospective study investigating compliance with VD use and risk factors for development of VS	-54 women with rectal or anal cancer who underwent pelvic RT -ages 29 to 78 y.o. -February 2008 to June 2011 -Memorial Sloan Kettering Cancer Center, New York	**DV:** VS **IV:** RT dose and volume	**DV:** difference in VD size before and after RT **IV:** Gy	-generalized equivalent uniform dose model -Spearman rank correlation -Area under the curve	-1 month post RT there were 35 pts in the VS group and 19 in no VS group -there was a significant difference between pt w anal and rectal cancers (P=.003) -1 year post RT 10 pts had VS and 31 did not -pts began having VS at a mean dose of 25 Gy	Level III- prospective study **Strengths:** measurement of VS guided by quantitative VD size and not subjective, prospective design may minimize underreporting seen in retrospective design, good VD compliance **Weaknesses:** high VD compliance may cause underreporting of the severity and presence of VS, high attrition
34.	N/A	-Case control study -Identification of patients undergoing vaginal cylinder BT alone -each pt was provided w a VD & instructed on use at least 3 times per week for at least 1 year -pts then received a follow-up visit	-243 stage 1A-II endometrial carcinoma pts who received adjuvant BT at an academic tertiary referral center in CT	**DV:** VS **IV:** VD	**DV:** CTCAE (Chronbach alpha 0.76) **IV:** use 3 times per week for a total of 10 minutes per session, for at least 1 year (compliance or noncompliance to the above)	-log-rank test -multivariable Cox proportional hazards modeling -chi-squared -multivariate logistic regression modeling	-at 15 months the rate of VS for noncompliant pts was 38.8%. -33.5% for those w standard compliance -21.4% for those with extended compliance -median time to VS grade ≥ 1 was 17.5 months -extended compliance was a significant predictor of reduced VS (HR	Level IV- Case control study **Strengths:** large cohort of patients treated with homogenous therapy. Primary outcome measured in a consistent manner. Prospective recording of even grade 1 vaginal toxicity. **Weaknesses:** Lack of randomization prevents determination of cause and effect relationship. CTCAE is physician determined

							0.38, 95% CI, p= 0.012)	toxicity based on physical examination. Lack of patient journal entry to validate compliance. Findings are only applicable to those w endometrial cancer who underwent BT alone
35.	N/A	-Expert opinion	-generalized to women who have completed pelvic RT at the University of Wisconsin in Madison -all patients receive vibrating dilator	**DV:** None **IV:** None	**DV:** None **IV:** None	None	-observed that women using vibrating VD had less VS and increased sexual satisfaction	Level VII- Expert opinion **Strengths:** Expert opinion based on observation of many patients **Weaknesses:** Expert opinion with no data to support the use of vibrating VD.
36.	N/A	-Systematic review	-NHS and Cochrane databases searched by 3 independent reviewers -Search dates ranged from 1950 to 9/25/12 -Included studies reported application of PDSA cycle in healthcare -47 articles	**DV:** PDSA cycle **IV:** application of PDSA cycle in healthcare	**DV:** use of PDSA **IV:** how applied in healthcare	-descriptive statistics	-Less than 20% of PDSA cycles fully documented the application of a sequence of iterative cycles -lack of adherence to small-scale change is apparent, only 15% reported use of quantitative data and intervals to inform progression of cycles	Level I- Systematic Review **Strengths:** Systemic review **Weaknesses:** Risk of bias across studies
37.	N/A	-retrospective review of 157 women with stage IA to stage II endometrial cancer treated with	-records of 157 women w endometrial cancer treated with HDR -Brigham and Women's/ Dana	**DV:** local control, survival, and toxicity in women treated with RT **IV:** novel low dose regimen	**DV:** high-intermediate risk criteria **IV:** low-dose rate brachytherapy	-Kaplan-Meier analysis	-Of 157 patients, had grade 1 VS -No grade 2 or higher VS, GI, GU toxicity was noted	Level III- retrospective **Strengths:** findings were in line with RCTs **Weaknesses:** retrospective, toxicities may have been

		brachytherapy alone	Faber Cancer Center -November 2005 to May 2011					underreported by physicians
38.	N/A	-structured observation of RT outpatient clinics -purpose of observation was not disclosed in order to not guide discussion of pt-led discussion of sexual health	-3 Gyn clinics and 2 colorectal RT clinics -South England -cervical, endometrial, and rectal cancer treated w RT	**DV:** None **IV:** None	**DV:** None **IV:** None	-percentages	-physical toxicity assessment focused on bowel 81% and bladder 70% symptoms -vaginal toxicity was less discussed 42% -sexual issues discussed in 25% of consults	Level VI- observational **Strengths:** Purpose of study not disclosed to physician so not to guide discussion of sexual health **Weaknesses:** number of observations is not stated
39.	Social constructionism	-focused ethnographic study -qualitative -observation in follow-up with gyn patients post RT	-69 follow-ups observed over 5 months -2 National Health Service cancer centers in the UK -49 in-depth interviews (24 women, 5 partners, 20 health professionals)	**DV:** None **IV:** None	**DV:** None **IV:** None	-None	-2 themes emerged: culture of the clinic, constructions of female sexuality after cancer treatment -women's psychosexual needs remained largely invisible and marginal to medical and nursing legitimacy -the failure of health professionals to include questions about sexual morbidity reduced the likelihood that women would initiate the discussion	Level VI- qualitative **Strengths:** in-depth focused ethnographic account of women's and their partners experiences after cancer **Weaknesses:** small sample of women and their partners, lack of diversity within participants

40.	N/A	-Comprehensive review	-Search in PubMed with a selective had search of key review papers, psychosexual and sexual medicine texts -years 2000-2015, clinical research and review papers	**DV:** sexual consequences of pelvic RT **IV:** clinical management	**DV:** assessment tools such as FSFI-6 **IV:** variety of treatment methods/modalities including VD	None	-implementation of a sexual health questionnaire in oncology could help increase clinical discussion of sexual consequences of RT -Increased identification can help w clinical management at earlier stage	Level IV- case studies/case series **Strengths:** Comprehensive review of sexual difficulties post RT **Weaknesses:** No data. No real suggestion other than implementation of sexual health questionnaire.
41.	N/A	-retrospective study -longitudinal analysis	-57 patients who were post pelvic RT -convenience sample -Radiation Oncology department in Osaka, Japan	**DV:** VS **IV:** Time	**DV:** Dische score (chronbach alpha unknown) **IV:** months out from RT	-Kaplan-Meier -Cox regression proportional hazard model	-VS gradually increased with time. -mild stenosis appeared in the 1st year post-RT in more than 50% of pts -pallor reaction grade 2-3 at 6 months was predicative of late grade 2-3 vaginal stenosis at 3 years post RT	Level III- retrospective study **Strengths:** retrospective design **Weaknesses:** single institution retrospective analysis, small patient cohort, limited f/u period, chronbach of Dische score is unknown

Legend

Abbreviation	Meaning
AUC	Area under the curve
BMI	Body mass index
BT	Brachytherapy
CT	Connecticut
CTCAE	Common Terminology Criteria for Adverse Events
CTV	Clinical target volume
DAS	Dyadic Adjustment Scale
DV	Dependent variable
EBRT	External beam radiotherapy
EEP	Educational Effectiveness Plan
FSAD	Female Sexual Arousal Disorder
FSD	Female sexual dysfunction
FSFI-6	Female Sexual Function Index-6
FSFI-19	Female Sexual Function Index-19
FSH	Follicle stimulating hormone
f/u	Follow-up
GI	gastrointestinal
GU	genitourinary
Gy	Gray (measurement of radiation dose)
GYN	Gynecologic
GynOnc	Gynecological oncologists
HADS	Hospital Anxiety and Depression Scale
HAPA	Health Action Process Approach
HDR	High dose radiotherapy
HPV	Human Papilloma Virus
IES-R	Impact of Event Scale-Revised
IGABT	Image-guided adaptive brachytherapy
info	Information
IQR	Interquartile range
IV	Independent variable
LH	Luteinizing hormone
MD	Medical doctor
MRS	Menopause Rating Scale
N/A	Not applicable
OAR	Organs at risk
OH	Ohio
PEBC	Program in Evidence-Based Care
PPV	Posterior Probability Value
PROMIS	Patient-Reported Outcomes Measurement Information System

pt	Patient
RadOnc	Radiation Oncology/Radiation Oncologist
Rehab	Rehabilitation
RCT	Randomized controlled trial
ROC	Receiver Operating Characteristic
RR	Relative risk
RT	Radiation therapy
SD	Sociodemographic
SHBG	Sex hormone-binding globulin
SVQ	Sexual Function-Vaginal Changes Questionnaire
Univ.	University
VD	Vaginal dilator
VS	Vaginal Stenosis
vs	versus
w	with
wks	Weeks
y.o.	Years old

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