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**IMPLEMENTATION OF AN ELECTRONIC HEALTH RECORD NOTIFICATION
SYSTEM FOR REDUCTION OF PESSARY COMPLICATIONS**

by

Margaret Hull, MSN

A DNP PROJECT

**Submitted in partial fulfillment of the requirements for the
Degree of Doctor of Nursing Practice**

to

The School of Graduate Studies

of

The University of Alabama in Huntsville

HUNTSVILLE, ALABAMA

2020

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Margaret Hull

4/23/2020

Student Signature

Date

DNP PROJECT APPROVAL FORM

Submitted by Margaret Hull in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the graduate faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

Susan Alexander Committee Chair

Elise D Adams DNP Program Coordinator

Karen Frith College of Nursing, Associate Dean, Graduate Programs

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ABSTRACT

The School of Graduate Studies

The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate:

Title: Implementation of an EHR Notification System for Reduction of Pessary Complications

While pessary use can be a safe and effective option for the management of pelvic organ prolapse, use of these devices is not without risk for complications and there is little information about development of complications when consistent care is not maintained. A quality improvement project designed to address reduction of complications by implementation of a tracking system within an electronic health record was used to improve follow-up communication and ensure consistency of care for patients who have pessaries placed. This project was completed at a large tertiary care center, in the outpatient gynecological specialties division. No patients were recruited for this project, as it served as a tracking system to maintain consistent follow up for patients who use a pessary to manage pelvic floor dysfunction. This system ensured current patient care standards were met. Much of the literature focuses on expert opinion with little randomized, controlled trials to define best practices. Success of the system was determined by improved consistency of pessary management and reduced complications once consistent management was implemented and maintained.

Keywords: pelvic organ prolapse, pessary, pessary complications, electronic medical records, tracking system

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Susan Alexander, DNP, ANP-BC, ADM-BC, Faculty Chair

Rony Adam, MD, MMHC Faculty Mentor

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Implementation of an Electronic Health Record Notification System for Reduction of Pessary Complications

Identification of the Problem

Pelvic floor dysfunction (PFD) can include many bothersome characteristics including prolapse and incontinence. Pelvic organ prolapse (POP), the descent of the pelvic organs toward, and in some cases, beyond, the vaginal introitus, is a quality of life (QoL) concern among many women, with some estimates defining a prevalence of 30% to 50% of the female population (O'Dell, Atnip, Hooper, & Leung, 2016; Rodriguez-Trowbridge & Fenner, 2005). This estimate is expected to rise as the U.S. population continues to grow and age (Colby & Ortman, 2014).

Stress urinary incontinence (SUI) is the loss of urine during physical exertion such as coughing, sneezing, laughing, exercising, or engaging in intercourse. Just like POP, SUI is a highly prevalent QoL-impacting condition with estimates as high as 40% among women 40 years of age and older (Older People, 2018; Simpson, Garbens, Dossa, Coyte, Baxter, & McDermott, 2019).

POP may encompass many different structures within the pelvis, involving the uterus, cervix, vagina, bladder, urethra, small bowel, large bowel, rectum, or any combination of these organs. However, it is important to understand the concern is reduced strength of the vaginal muscles, combined with connective tissue defects, making it difficult to support the heavy visceral structures (Corton, 2005; Sasso, 2003). Risk factors for both POP and SUI development include childbirth-related trauma; prolonged second stage of labor; chronic, refractory constipation; lifestyle habits from high intensity training or high impact careers; prior pelvic surgeries; increasing age and the menopausal transition; family history of POP; increasing body mass index (BMI); and tobacco use (Atnip & O'Dell, 2012; Jelovsek, Maher, & Barber, 2007).

Description of the Problem

As a QoL issue, women may not experience negative impacts or bother of POP, while other women may endure life-altering complications such as urinary and fecal incontinence, urinary and fecal obstruction, pelvic pressure and discomfort, sexual dysfunction, and vaginal bleeding from abrasion or erosion development when the vagina chafes against the undergarments (Atnip & O'Dell, 2012; Continence Foundation of Australia, 2012). Similarly, women suffering from SUI may limit their activities for fear of being embarrassed when leakage occurs, or they may experience vulvar skin irritation or breakdown when the skin is exposed to caustic urine or from irritation from pad use (McIntosh, Anderson, & Reekie, 2015; ACOG Practice Bulletin, 2017). Treatment options for PFD are varied and reflect each woman's goals. Options include observation, pelvic floor muscle (PFM) exercises or Kegels, placement of vaginal supportive and incontinence devices (pessaries), and pelvic floor reconstructive surgery (Lewthwaite, Staley, Girouard, & Maslow, 2013). A pessary may be a viable choice for women who wish to avoid or delay surgery yet want an effective, QoL- enhancing option for PFD (Cheung, Lee, Lee, Chung, & Chan, 2016).

Pessaries are flexible but durable devices made of a high-grade silicone that sit in the vagina and provide support to the pelvic structures and relief from vaginal protrusion or incontinence (Magali, Schulz, & Harvey, 2013; McIntosh, 2005). In a retrospective analysis, Lewthwaite et al. (2013) found that women who chose a pessary and continued with its long-term use were more likely to be postmenopausal, non-smoking, agreeable to vaginal hormone use, naïve to pelvic reconstructive surgery, or unable to undergo surgical repair due to life threatening co-morbidities. Additionally, in a prospective analysis, Schaffer et al. (2012) found that women who were more likely to be successfully fit with a continence pessary were

menopausal, more highly educated, naïve to prior incontinence surgery, and tended to experience fewer episodes of incontinence.

The pessary fitting procedure. Consideration of the use of a pessary must first involve extensive education about the device with the patient deciding to proceed with a fitting (Murray, Thomas, & Pollock, 2016). The goal of the pessary fitting procedure is to identify a style and size that is comfortable and effective (Atnip & O'Dell, 2012). During this process, the clinician and the patient must determine if self-management is an option, or, in the case of very frail, elderly women or women with physical or mental ailments, self-management of the pessary may not be possible.

Self-management of the pessary may entail nightly removal of the pessary with reinsertion in the morning, weekly removal for a one time per week overnight rest, or removal only for engaging in intercourse, defecating, showering, or using a vaginal preparation of estrogen (O'Dell & Atnip, 2012). Yet, there are no clear guidelines to define what is the best self-management strategy or protocol. Furthermore, no data exists requiring a self-management program as a definitive means for complication reduction compared to clinician only management, and there is no data to define a twice-weekly regimen of local vaginal estrogen to reduce problems with pessaries effectively.

Whether a patient can or cannot self-manage the pessary, the clinician must have a discussion regarding complications with pessary use, including the signs and symptoms for which to monitor, as there is little evidence stating that self-management reduces or negates the development of complications (O'Dell & Atnip, 2012). Potential complications include the development of vaginal abrasions, erosions, ulcerations, pessary incarceration, embedment into the vaginal epithelium, and fistulas, such as vesicovaginal fistulas (VVF) or rectovaginal fistulas

(RVF) (Abdulaziz, Stothers, Lazare, & Macnab, 2015; Rodriguez-Trowbridge & Fenner, 2007). Signs and symptoms may include vaginal bleeding or pain. Normal side effects of pessary use include an increase in vaginal discharge and some odor. While discharge and odor can be a normal side effect of pessary use, clinicians should instruct patients to notify the clinician if they experience discharge and odor that is also associated with bleeding or pain (O'Dell & Atnip, 2012).

A standard pessary management protocol. Most experts agree that the frequency of follow-up for women who do not self-manage the pessary be set for every six weeks to three months (Magali et al., 2013; O'Dell & Atnip, 2012; McIntosh, 2005). If patients demonstrate self-care, management may consist of less frequent evaluations of approximately every six to twelve months (O'Dell & Atnip, 2012; McIntosh, 2005). Pessary examination appointments follow a specific protocol for complication(s) detection and satisfaction management (O'Dell & Atnip, 2012). Each visit includes discussion of any developing concerns and/or a brief review of treatment goals and desires for continuation of the chosen treatment. The physical examination involves the removal and cleaning of the pessary with careful inspection of the vagina via a speculum examination to discern any development of ulcerations, erosions, or infection. If the provider detects an erosion, treatment may include the application of silver nitrate (AgNO_3) to cauterize the area and application of one gram of vaginal estrogen cream throughout the vagina. Upon completion of the exam, the clinician may choose to reinsert the pessary or, if a complication has developed, downsize the pessary, consider a different style of pessary, or provide the patient with a pessary holiday (O'Dell & Atnip, 2012; Sasso, 2003).

Little data exists to define a standardized protocol for pessary fittings and management with many of the recommendations for care delineated by expert opinion. Furthermore, there is

little data to direct clinicians on risks for complications when patients do not adhere to recommended maintenance protocols (Bugge, Adams, Gopinath, & Reid, 2013). This project will assess the risk of pessary complications when adequate follow-up is not maintained.

Project Objectives

The proposed project was a Quality Improvement (QI) project designed to maintain reliability of care among pessary-using patients. To achieve this consistency, the project investigators developed patient lists within a large electronic health record (EHR), EPIC, to track patients who received a pessary. These lists are generated monthly and include the pessary-fitting procedure list, the missed follow-up appointments list, and the complications list. With the help of the institution's health information technology (IT) colleagues, the assigned IT business analyst delivered the lists to the project developers on a monthly basis. The project included the following objectives: 1) reduced no-show rates and/or higher reschedule rates when appointments are missed, 2) decreased occurrences of complications when consistent care is properly maintained, and 3) improvement of care and greater consistency of care management.

The first objective was measured by reviewing the pre-implementation no-show rates and comparing these with post-implementation no-show rates. The second project objective was evaluated by examining use of the ICD-10 code: N89.8 (vaginal erosion secondary to pessary use). The project investigator made comparisons by looking at the number of complications coded pre- and post-implementation. The third objective was measured as the investigators closely tracked the patients through evaluation of scheduled appointments and kept appointments. The project offered important information that could be used to define a standard of care for pessary management. Other questions that were answered with the completion of the project included a determination of need for changes to routine management, as there is little

data to support the pessary maintenance schedules as described in the literature, and supported the need for self-management by patients, regardless of the consistency of clinician management (Bugge et al., 2013; O'Dell & Atnip, 2012; Wu, Farrell, Baskett, & Flowerdew, 1997).

PICOT Question

Among female patients using a vaginal pessary for pelvic organ prolapse, how does the development and implementation of an electronic health record tracking system compared to routine follow-up without a tracking system affect the reduction of pessary complications during a five-month period?

Synthesis of Evidence

Identification of the need for a greater definition for pessary management and monitoring of patient adherence to a program of care drove the direction for the review of the relevant literature. The search of the pertinent literature will be divided into two questions: 1) What are the rate of complications among pessary users and what are the recommended practices for pessary care? 2) What are the available EHR processes and implemented tracking systems? The Project investigators conducted a search of various databases, including PubMed, CINAHL, Cochrane Database of Systematic Reviews, and Medline using the search terms “pessary complications,” “pessary risks,” “pessary management,” “pessary follow-up,” “pessary plan of care,” “pessary program,” “pessary best practices,” “EHR implementation,” “EHR alert systems,” “EHR tracking and monitoring systems,” “mechanisms of EHR functionalities,” “integration of EHR and pessary management,” and “integration of EHR and practice change.”

Complication Rates and Pessary Practice

Complication rates. Pessaries are relatively non-invasive devices yet are not without some risk. Evaluation of the literature revealed a paucity of large randomized, controlled trials

addressing pessary management protocols and risks of complications, with much of the data consisting of small numbers and case studies or case series (Bugge et al., 2013). Literature addressing pessary management emphasizes the need for a patient-centered focus. However, a significant discrepancy of the recommendations of timelines for follow-up demonstrates the lack of evidence-based guidance (O'Dell & Atnip, 2012). A lack of information exists to determine if higher complication rates occur among patients who self-manage versus patients who do not self-manage the pessary, patients who use a vaginal estrogen preparation versus patients who do not, and patients who do not maintain consistent clinician management.

Abdulaziz et al. (2015) attempted to review the relevant literature by completing a systematic review of pessary complication rates with a gradation of the severity. The authors evaluated 61 studies that consisted of case reports and case series and found that the most commonly reported complications included vaginal discharge, bleeding, VVF, erosion, ulceration, and odor (Abdulaziz et al., 2015).

In a long-term evaluation of complication rates from pessary use, Sarma, Ying, and Moore (2009) reported a 56% occurrence of concerns. However, there is wide variation in the description and report of the complications as well as unclear determinations on the reasons for the development.

Pessary practice. Sasso (2003) discusses a case study that describes a pessary follow-up program for one patient who underwent pessary treatment for greater than seven years. During this extended period, the management recommendations changed as the patient aged, trialed different types of pessaries due to worsening POP, or chose to cease self-management of the pessary.

Wu, Farrell, Baskett, and Flowerdew (1997) developed and evaluated a pessary management protocol for 110 women who the study authors successfully fit with one of three different types of pessaries. The authors determined that the stage of POP, style of the pessary, use or non-use of vaginal estrogen, or inability to self-manage the pessary did not necessitate shorter interval follow-up and described a follow-up protocol of every three to six months.

In an evaluation of pessary practices among nurse providers, O'Dell et al. (2016) surveyed 216 nurse providers and found that, regardless of the style of the pessary, most practicing nurses recommended a follow-up frequency interval of three months. In an attempt to measure the quality of care provided to women with POP, Alas et al. (2015) noted that 98% of the pessary users followed up for a vaginal exam every six months.

EHR Alert Systems

The advent of EHR systems has greatly revolutionized and changed the charting of patient encounters forever. However, EHR utilization does not simply mean a replacement of the paper system of patient documentation as implementation has created opportunities for greater functionalities and efficiencies for patient care and safety, as well as research and protocol development and quality improvement initiatives (Keshavjee et al., 2006).

This portion of the review highlights the use of alert and tracking systems across multiple health care settings. Much like the pessary literature review, this review has also revealed a dearth of data to address or answer the question regarding the development and implementation of an alert or tracking system for pessary management. Information does exist evaluating the general design and implementation of best practice advisories (BPA), alert systems, and patient tracking systems for other specialty concerns.

Vartak, Crandall, Brokel, Wakefield, and Ward (2009) developed a system of tracking patients in the emergency department (ED) of a busy 35,000 visits-per-year hospital. The goal of the tracking system was to address the high length of stay (LOS) with the hopes that LOS would be reduced with the advent of the tracking system. Interestingly, the IT personnel and authors saw an increase in the LOS, not due to inefficiencies of the alert and tracking system, but due to other exposed inefficiencies when the alert system went live. Information gleaned from this research allowed the authors to implement other workflows within the ED to reduce those inefficiencies (Vartak et al., 2009).

Krist (2015) cited evidence addressing the use of prompts in EHR systems, stating these functionalities are complementary to EHRs and aid patient care by serving as important reminders about needed services or treatments and allowing for better engagement among the healthcare team. Turchin et al. (2010) saw an increase in clinician use of additional EHR functionalities when alert systems were in place.

Implementation

Conceptual Framework

The theory chosen to guide this project is Duffy's Middle Range Theory of Quality Caring. While several of the middle-range theories are appropriate for consideration, the Quality Caring Model (QCM) has a strong focus on high-quality patient care that includes the engagement of the patient as a partner in her treatment. The theory's overarching goal is the patient's positive sense of care (Smith & Parker, 2015). To this end, Duffy has worked to highlight the professional, caring relationship between the nurse and the patient, stating that this is a different type of caring than the care administered by a friend or family member (Smith & Parker, 2015). This distinction fully integrates the nurse into the caring relationship, which drives

the formation of “human connections...with patients and families that influence future interactions and positively influence intermediate health outcomes” (p. 395).

Duffy’s QCM incorporates the family or other caregivers into the patient care focus, which may serve to reduce the risk of loss to follow-up. Alternatively, the theory allows for close, consistent collaboration between the family member and the nurse, creating a ladder of care between the patient, the community, the nurse, and the family member/members, with the patient always at the center of the process (Smith & Parker, 2015).

The QCM also demonstrates great promise for utilization and implementation when developing an EHR tracking system designed to minimize lost patients. While this is not an intuitive part of the act of caring, it is part of the process which will enable the pessary provider to furnish higher quality and more effective care. Even though it does not indicate an outward or obvious appearance of correspondence with the QCM, full implementation and effectiveness of care cannot occur without the creation and effective use of the EHR tracking system. Finally, Duffy’s model is well-measured and researched, which will be an important piece for consideration when working to develop the pessary EHR tracking system (Figure 1). With its emphasis on nursing contributions to the quality and improved patient care, patient outcomes can be measured through Duffy’s defined components of structure and process (Duffy & Hoskins, 2003).

Methodology

This is a quality improvement (QI) project, which will be implemented within a large tertiary care center. Institutional Review Board (IRB) approval will be requested through the Vanderbilt IRB. As a large referral-based urogynecology practice within this tertiary care center, clinicians evaluate and treat patients for pelvic floor dysfunction (PFD) who present from the

larger state and regional area. Some of the patients referred to the practice have experienced significant complications due to inconsistent, minimal, or no pessary management.

Complications treated among this population include VVF, RVF, incarcerated pessaries, as well as large ulcerations and erosions. Observation of these serious pessary complications, along with a recognition that clinician practices and departmental guidelines within the institution may not be fool proof, served as the motivation for project completion. Participants included for evaluation in this project will be women who choose a pessary for POP or SUI management and undergo a successful pessary fitting procedure.

The project investigators will identify the ten providers (attending physicians, nurse practitioners, and research fellows) within the urogynecology division who place and manage pessaries. The investigators will provide a list of the names of these clinicians to the IT personnel who will create three patient lists within the EHR and provide these to the project developer on a monthly basis. The first list generated will reflect the pessary fitting procedure; any patient who undergoes the procedure fitting, as identified by the procedure code 57160, and any patient who receives a pessary during that appointment, as identified by the supply code A4562, will be added to this list. The second list will contain any missed follow-up or pessary maintenance appointments among the women who underwent the pessary fitting procedure. The third list will contain the most common complication code with pessary use, N89.8, vaginal erosion secondary to pessary use. Upon generation each month, the health IT personnel will send the patient lists to the project investigators for review and management.

Furthermore, each list will grow as patients are added to the new pessary fitting procedure list. Ideally, the complication and the missed appointments list will remain small as patients receive consistent management. The health IT personnel will provide these lists to the

project developer at the beginning of each month for the previous month's totals. Patients who routinely make the scheduled maintenance appointments but who develop a complication despite the regularity of management will also be included on the patient alert list.

The N89.8 complication code is not necessarily unique to pessary use and can be attributed to other sources, such as vaginal mesh erosion or ulcerative vaginitis. Therefore, to control for complications unrelated to pessary use, the project investigators will review the electronic encounters via the appointment date of the patients included on the complications list and verify that there are no inaccuracies. Patients inadvertently included on the list will be deleted. As an additional measure of control, the leader for this QI project will be the primary person who will receive the alerts. However, all providers within the division will be educated about the protocol to ensure consistency of care and accuracy of coding. If patients cease to use the pessary, the project developer will remove the patients from the notification list. There will be no recruitment of subjects for this QI project as the focus will be on the list generation using CPT and ICD-10 codes, and all patient maintenance appointments are part of the routine care delivered to women who use vaginal pessaries.

Once IRB approval has been obtained, the project personnel will discuss the plan with the EHR IT business analyst to develop the lists needed each month. The timeframe for the evaluation of the effectiveness of the EHR tracking system and potential reduced complications will be during a five-month period. This will allow for the collection of data from the initial fitting as well as two follow-up appointments after the initial placement.

Evaluation

The project was assessed according to its stated objectives.

Configuration of EHR Reporting Workbench

IT personnel developed three patient lists within the Epic EHR (EStar) system and provided these to the investigators via a secure “reporting workbench” communication system at the beginning of the month. The first list generated reflected the pessary fitting procedure; any patient who underwent the procedure fitting, as identified by the procedure code 57160, and any patient who received a new pessary at that visit, as identified by the supply code A4562, was added to this list. The second list contained any missed maintenance appointments after the fitting procedure. The third list contained the most commonly used complication code identified with pessary use, N89.8, vaginal erosion secondary to pessary use. These three lists were used to alert the investigator when patients missed an appointment or received a diagnosis of N89.8, even if the appointment was maintained.

Staff Education on Workflow Process Change

Before the implementation of the project, the QI investigator educated the division personnel and outpatient staff nurses about the tracking system and the new workflow during the weekly FPMRS division meeting. Any follow up questions were addressed as needed. Project objective 2 was measured by IT personnel instituting a test to identify errors in the tracking system and the nurses ran a test of communication utilizing the new workflow to ensure accuracy of the lists and efficiency of the process. (Figure 2)

Adherence to follow-Up Care

Project objective 3 was measured as patients were closely tracked with scheduled appointments and kept appointments. Patients who received a new pessary and who received care for that pessary were tracked. After the five-month protocol period, project investigators evaluated the effectiveness of this QI project by measuring the rescheduled and kept appointments. The investigators also compared these data to the complication list to determine if

a complication occurred because of inconsistent follow-up. Conversely, the information was also collected from the lists among the consistently returning patients to ascertain if a complication developed despite consistent management.

After removal of patients who were not successfully fit with a pessary, who were inaccurately duplicated, or who were diagnosed with N89.8 for erosions from other causes, such as mesh erosion or ulcerative vaginitis (and in the absence of pessary use), the investigators included a total of 105 pessary fitting encounters in the database for the baseline or “pre-tracking” evaluation and 110 pessary fitting encounters for the “tracking” evaluation period.

Demographic characteristics of the two groups show the similarities of this patient population. Most of the patients identified as either white (81.4%) or African American (7.4%) and there was a relatively large cohort who classified themselves as other/unknown (8.4%). Women in both groups tended to be older (80% of the patients were >50) with an average age of 65. A greater number of women were agreeable to use of a local estrogen preparation (53.5%) than not (46.5%) and chose to self-manage the pessary (61.9%) versus clinician only management (38.1%) (Table 1).

The baseline or pre-tracking complication rate among these fittings was 4 out of the 105 identified encounters or 3.8%, and the complication rate among the tracked patients was 12 out of 110 fittings for a 10.9% rate and this was statistically significant ($p = 0.0474$, Fisher’s exact test). The investigators expected this finding, given the increased number of erosions diagnosed as the patients were actively tracked and returned for consistent management.

Use of an annotated run chart (Figure 3) allows for better visualization of this phenomenon as a function of time. The increased rate of complications is noted relative to the point of implementation of the tracking system, as well as the variability from month to month,

before and after the system was launched. The orange line indicates the mean rate (7-8%) of N89.8 complications with only the month of May noted to have a higher number prior to initiation of tracking. The blue line represents the percent of erosions per month in relation to the average. It is easy to see the increased number of erosions reported once the tracking system began. This is represented by the rapid rise of the blue line that, primarily in the second month and beyond, occurred when the phone calls from the nurses began and patients were scheduled to return to the office for evaluation.

During the 10-month time period of evaluation for this cohort, the project personnel saw no statistically significant association between age and complication development with age cut off used ≤ 50 and > 50 years of age ($p=.4356$, Fisher's exact test). Rate for erosion development, while seemingly higher as women age (4.7 % for women ≤ 50 compared to 8.1 % for women over 50), was not statistically significant as determined by paired-samples t-test to determine the effect of age on complication development, $t(213) = -0.905, p = 0.367$. Furthermore, the investigators saw no differences when comparing age to the pre and post tracking groups, $t(213) = 0.936, p = 0.350$ and there was no difference in development of erosions among women who used a local estrogen preparation and women who did not by Chi square analysis $X^2(2, N = 215) = 0.5642, p = 0.4525$.

The rate for development of an erosion when the patient scheduled the first follow up appointment after completion of the fitting procedure was 7.7% and the risk for the development of an erosion when the patient did not schedule the first follow up appointment prior to leaving the office was 6.9%. There was no association for erosion development whether a patient scheduled an appointment after the completion of the fitting and when checking out with the front office personnel prior to leaving the office versus not scheduling the follow up appointment

with the front office personnel prior to leaving the office $X^2 (2, N = 215) = 0.0388, p = 0.8436$.

Additionally, there was no association for development of an erosion when the patient missed the first follow up appointment after the initial fitting $X^2 (2, N = 215) = 0.0183, p = 0.8922$. Rates for the development of a complication were 7.7% and 7.2% among patients who missed the first follow up and patients who did not miss the first follow up.

When looking at subsequent follow up appointments among the tracking group, it appeared the total number of unscheduled and missed appointments seemed to improve over time. That is, as time progressed the patients in this group, seemed less likely to forget to schedule a follow up appointment and it appeared they were more likely to maintain the appointment once scheduled. When comparing the pre and post tracking groups, the percentage of 0-1 missed appointments was 69.5 % among the non-tracked group and 83.6 % among the tracked group. This is interesting, as it appears the tracked group was more likely to miss up to one appointment. However, when looking at >2 missed appointments, (as time passed and pessary management became more routine for patients in both groups) the pre and post tracking groups saw further reductions of missed appointments (30.5 % among the pre-tracking group and 16.4 % among the tracked group) with the tracked cohort seeing a greater reduction of >2 missed appointments. This finding was statistically significant ($p=0.0143$, Fisher's exact test).

Evaluation of subsequent scheduled appointments showed the same progression with patients forgetting to schedule up to one appointment prior to leaving the office 71.4% among the pre-tracking group and 87.3% among the tracking group. When the project personnel looked at > two unscheduled appointments, this number was greatly reduced between both groups, with the greater reduction seen in the tracking group (28.5 % among pre-tracked patients and 12.7 % among tracked patients, $p=0.0039$, Fisher's exact test) (Table 2). To further prove the validity

that surveillance was associated with a decrease in missed appointments, the project personnel used the t-test and found the mean number of missed appointments went from 1.22 pre-tracking to 0.91 tracking and this was statistically significant $t(213)=-2.118, p=0.035$.

Application to Practice

The investigators did not set out to address or determine the accurate timing of pessary management. However, this project did highlight the paucity of knowledge and evidence-based guidelines for pessary care (Bugge et al., 2013; O'Dell & Atnip, 2012; Wu, Farrell, Baskett, & Flowerdew, 1997). Furthermore, the project yielded important information to reassure the adequacy of the division's defined standard of care for pessary management. With little existing data to dictate management of pessary use, with most recommendations for routine maintenance and management of complications provided via expert opinion, it was important to learn that outlined practices at this institution were satisfactory. It is possible this project may inspire others to develop high quality, randomized controlled trials to lay a foundation for best pessary practices.

The investigators did not design this project to answer questions regarding use of estrogen and patient self-management of the pessary. However, they did capture valuable data regarding these questions noting there were more women using estrogen in the tracking group than in the pre-tracking group (49.5 % versus 57.3 %). This may be an indication of the greater communication between nurses and patients who were in the tracked group, but this analysis did not reach statistical significance by Chi square $X^2(p=0.2548)$. Additionally, the investigators saw no differences in erosions among women who self-managed the pessary and women who chose to have the clinician manage the pessary ($p=0.3921$, Fisher's exact test). Despite initiation of the tracking system, and the presumed greater communication between nurses and patients,

the project personnel did note a reduced number of women in the tracking group who self-managed the pessary (64.8 % pre-tracking and 59.1 % tracking). Gathering this data may trigger additional questions regarding estrogen use and self-management and empower other clinicians to design high quality trials to investigate the benefits of estrogen use and self-management for prevention of erosions.

As stated previously, concern for potential lost patients served as motivation for the development of a tracking system as pessaries, while relatively benign, are not without risk. The stated project timeline was a 5-month implementation period with a goal to have this tracking system become the standard for practice within this specialty division and serve as the basis for care well beyond the completion of the project. Furthermore, as this division practices in a large academic setting, the faculty and staff have a dedication and commitment to the learners, the next generation of nurses, Advanced Practice Providers (APP), and doctors, who will attend and care for patients who choose a pessary for PFD. Therefore, it is paramount to provide a sound, safe educational, and management system designed to minimize complications and loss to follow up. It is possible these future providers, while learning to provide safe and consistent pessary management, will also find the value of a tracking system and plan to implement such a system into future practice settings. Such a system may enable these future clinicians and scholars determine specific guidelines for management.

This project utilized a well-known EHR system. As the healthcare industry strives to improve upon current EHR capabilities, it is possible this and other EHR projects will highlight weaknesses of the system and drive development and improvement of systems to improve the delivery of care for patients. One area of weakness, which may not be an EHR concern, and is more likely an institutional or departmental concern, is the discrepancy and variation among

provider documentation. This was apparent by the inability of the project investigator to gather pessary style information, time to erosion development, interventions utilized for pessary erosion treatment, and time to erosion resolution. It is possible this project will enlighten the experts who can develop a process of standardization of notes.

The use of EHR systems has the potential to drive robust QI initiatives and improve patient care. To date, there are no documented surveillance systems for pessary management. The development of this monitoring system has the potential to answer many questions regarding pessary practices, and may further the knowledge to better care for patients who choose a pessary for PFD.

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TABLES

Table 1: *Demographic Characteristics*

	Pre-tracking		Tracking		Total	
	n	%	n	%	n	%
Race						
White	83	79	92	84	175	81.4
African Amer.	9	8.6	7	6.4	16	7.44
Asian	3	2.9	1	0.9	4	1.9
Hispanic	1	0.95	0	0	1	0.46
Native Amer.	0	0	1	0.9	1	0.46
Unknown/other	9	8.6	9	8.2	18	8.4
Age						
≤ 50	22	21	21	19.1	43	20
> 50	83	79	89	81.0	172	80
Estrogen						
Yes	52	49.5	63	57.3	115	53.5
No	53	80.9	47	42.7	100	46.5
Self-manage						
Yes	68	64.8	65	59.1	133	61.9
No	37	35.2	45	40.9	82	38.1

Note. N = 215 (105 in the pre-tracking group and 110 in the tracking group)

Table 2: *Follow up Patient Appointments Scheduled or Not Kept in the Project (N=105)*

Appointments Not <u>Scheduled</u>	0-1 <u>Appointments</u> <u>n</u>	<u>%</u>	<2 <u>Appointments</u> <u>n</u>	<u>%</u>	<u>X²</u>
Prior to implementation tracking system	75	71.4	30	28.5	
Post implementation Tracking system	96	87.3	14	12.7	8.285*
Appointments Scheduled but Not Kept					
Prior to implementation tracking system	73	69.5	32	30.5	
Post implementation tracking system	92	83.6	18	16.4	5.994*

* $p < .05$

FIGURES

Figure 1: A program of caring

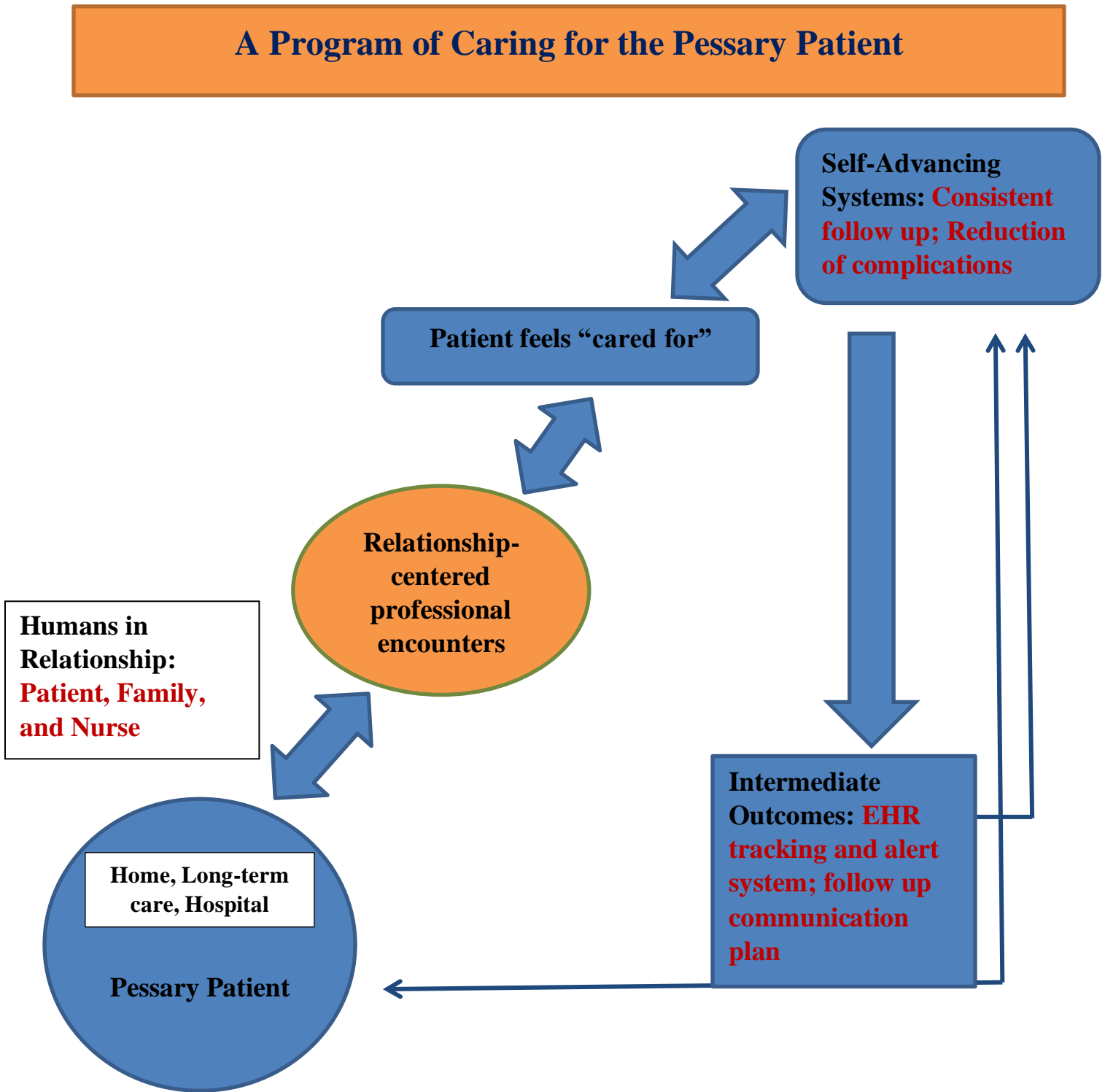


Figure 2: Communication Process Map

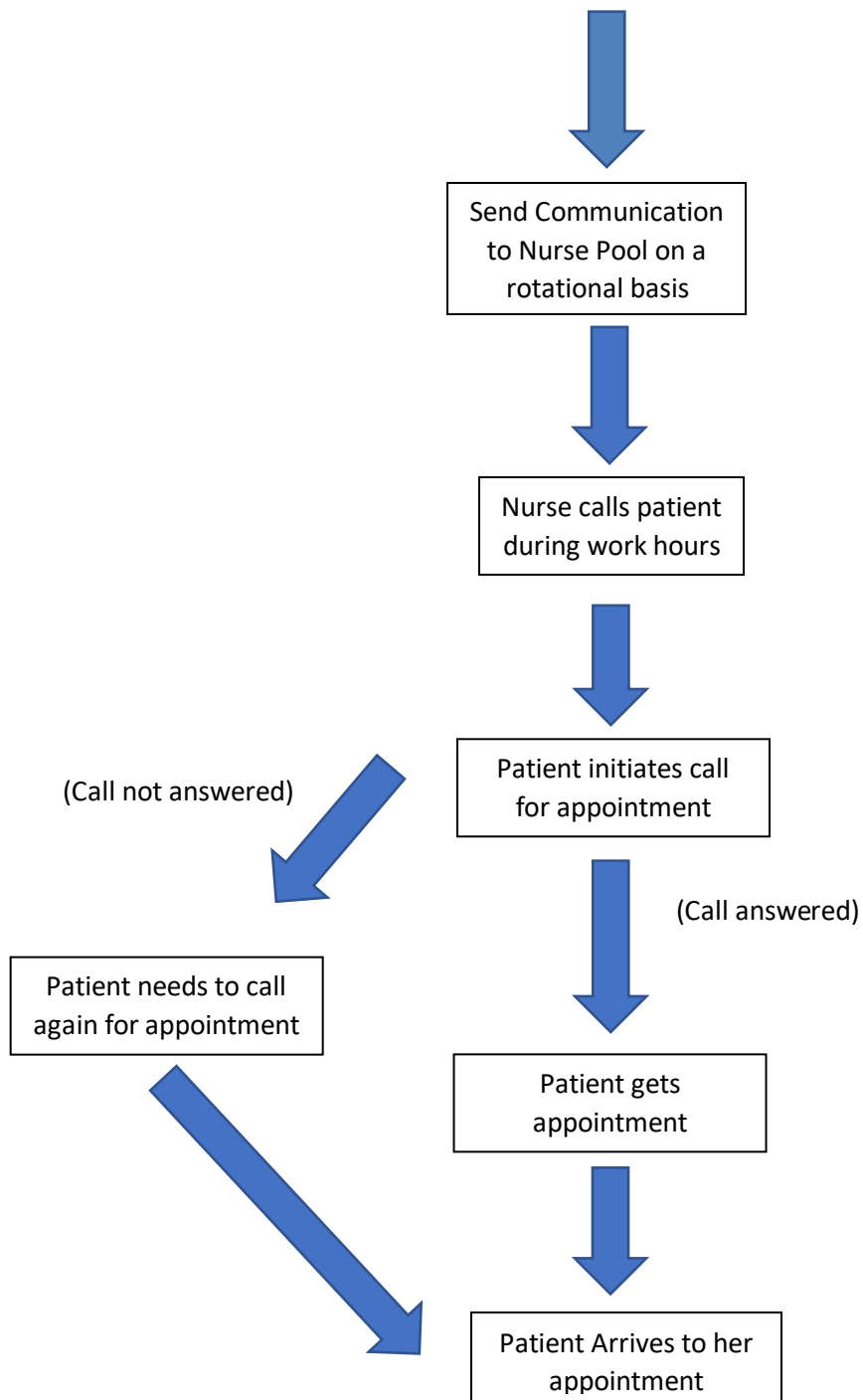
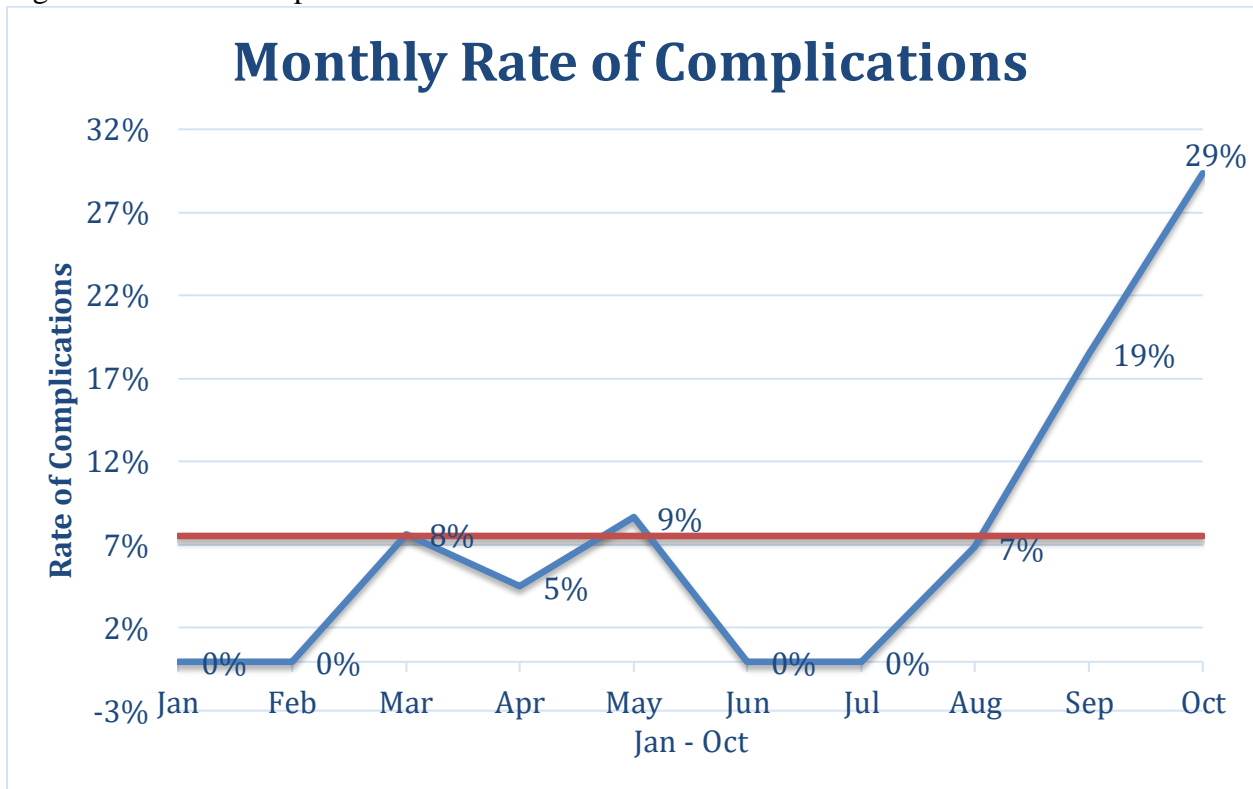


Figure 3: Rate of Complications



Appendix A



<input checked="" type="checkbox"/> Expedited (see pg 2)
<input type="checkbox"/> Exempted (see pg 3)
<input type="checkbox"/> Full Review
<input type="checkbox"/> Extension of Approval

December 6th 2018

Margaret Hull
Department of Nursing
University of Alabama in Huntsville

Dear Mrs. Hull,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Development and Implementation of an Electronic Health Record Alert System for Reduction of Pessary Complications*, and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,



Bruce Stallsmith
IRB Chair
Professor, Biological Sciences

Expedited:

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Appendix B

Human Research Protections Program – HRPP Supporting the work of the IRB and Providing HRPP Oversight



RE: IRB #180736 "Implementation of an EHR alert system for the reduction of pessary complications, a quality improvement project" Dear Margaret A Hull:

A designee of the Institutional Review Board reviewed the research study identified above. The designee determined the project does not qualify as "research" per 45 CFR §46.102(d).

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

This project aims to develop an alert system within the electronic health record with a goal to achieve consistency of care, avoid a “lost to follow-up” concern, and reduce potential pessary complications.

As this does not meet the "criteria for research" as described in 45 CFR §46.102(d), **IRB approval is not required.**

Please note: Any changes to this proposal that may alter its” non-research” status should be presented to the IRB for approval prior to implementation of the changes. In accordance with IRB Policy III.J, amendments will be accepted up to one year from the date of approval. If such changes are requested beyond this time frame, submission of a new proposal is required.

Sincerely, Shannon Smith BS Institutional Review Board Health Sciences Committee #3

Electronic Signature: Shannon Smith/VUMC/Vanderbilt:

(d9cd4c907f6795ba6bd79a33b62141b1) Signed On: 05/11/2018 10:31:30 AM CDT

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Appendix C

Guidelines for Authors

Send your query or manuscript to Urologic Nursing today!

Urologic Nursing, the official journal of the Society of Urologic Nurses and Associates, Inc. (SUNA), is a peer-reviewed journal that welcomes the submission of original manuscripts pertinent to the practice of urologic health care professionals. Unless clearly specified, the views expressed in articles, editorials, and letters published in Urologic Nursing represent the opinions of the authors and do not reflect the official policies of SUNA.

The journal accepts original articles: case study, clinical practice, continuing education, patient education, systematic review of the literature, quality/performance improvement, and research. Specific templates for many types of manuscripts are available online (www.suna.org/unj). Query letters are welcomed, but not required.

Material must be original and never published before. Material is submitted for review with the understanding that it is not being submitted to any other journal simultaneously. An electronic copy of the manuscript should be submitted to the editorial office.

Urologic Nursing is a refereed journal. All manuscripts submitted undergo review by the editor and blind review by members of the manuscript review panel and/or editorial board. Each manuscript is evaluated on its timeliness, importance, accuracy, clarity, and applicability to urologic nursing. Upon acceptance of the manuscript, the author will yield copyright to Urologic Nursing. Manuscripts accepted are subject to copy editing. The author will receive proofs for review prior to publication.

Tables: Construct tables using the “Draw Table” tool in MS Word or create tables in an Excel spreadsheet. Do NOT place tables inside a separate text box, and do not use tabs to create columns of text.

Photographs: Camera-ready photographs may be black and white or color. Photos should be glossy, 5 x 7 inches. Electronic files (JPGs) must be in high resolution, 300 dpi. Please note: Images found on Google, Bing, or other Internet search engines are not public domain; permission from the original source must be provided.

References: List all references (only those cited within the text) in alphabetical order. All citations should reference primary sources. The use of secondary sources (material analyzed or interpreted from the primary source) is discouraged. If necessary, locate a copy of the original work and credit it as such. Authors are encouraged to provide the digital object identifier (DOI) number for all references when possible directly after the citation. Manuscripts must NOT contain reference software codes.

Citing Multiple Authors: In-text citations with six or more authors should include the first author followed by et al., even in the first citation. In the list of References, if there are eight authors or more, list the first six, then an ellipsis, then the last author. If there are seven authors, list all seven.

Websites: It is not necessary to include the date a site was accessed, unless the material will change

over time.

Samples Periodical:

Lamb, B., Jalil, R., Shah, S., Brown, K., Allchorne, P., Vincent, C., ... Sevdalis, N. (2014). Cancer patients' perspectives on multidisciplinary team working: An exploratory focus group study. *Urologic Nursing*, 34(2), 83-91, 102.

Book:

American Psychological Association (APA). (2010). *Publication Manual of the American Psychological Association* (6th ed.). Washington, DC: Author.

Chapter in a Book:

Gray, M. (2009). Management of men with reproductive disorders. In J. Black, & J. Hawks (Eds.), *Medical-surgical nursing: Clinical management for positive outcomes* (8th ed., pp. 873-911). Philadelphia: Elsevier.

Manuscript Preparation

Manuscripts must be typed and double-spaced. Style should follow the *Publication Manual of the American Psychological Association* (6th ed.). As a general rule, manuscripts should be saved as MS Word documents. Use the author-date method of citation within the text, e.g., (Doe, 2017) or "Doe (2017) states..." With multiple authors, the first citation must list all authors, and subsequent citations should list only the last name of the first author and et al. (Doe et al., 2017). Acquiring permission to reprint previously published materials is the responsibility of the author.

Format of Manuscript

Title Page: Include the manuscript title, authors' names, credentials, and job titles and affiliations. Also include a brief abstract of 40 words or less along with an address for correspondence, day and evening phone numbers, fax number, and email address.

Text: Double-space all typing, using 1-inch margins. Include the title or a short descriptor on top of each page, but do not include the author's name. Use Times Roman and avoid complex font attributes such as outline.

Subheadings: Include subheadings in the manuscript where possible. The first three levels use bold font. Italics are not used unless there are more than 3 levels of headings:

Level 1 Example

Centered, Boldface, Uppercase and Lowercase Heading

Level 2 Example

Flush Left, Boldface, Uppercase and Lowercase Heading

Level 3 example

Flush left, boldface, lowercase heading ending with a period.

Level 4 example

Flush left, italicized, lowercase heading ending with a period.

Figures: These include line drawings, photographs, diagrams, and graphs. Each figure should be numbered, and the number must correspond to a statement in the manuscript directing the reader to see such figure (see Figure 1). Include a separate legend sheet with captions. When using figures reprinted or adapted from another source, the author must obtain written permission for both print and

electronic use from the original publisher.

Conflict of Interest: Urologic Nursing requires authors, editorial board members, and reviewers to disclose any conflicts of interest related to their submission and involvement with the journal. Urologic Nursing endorses and subscribes to the definition of Conflict of Interest by the International Committee of Medical Journal Editors (2006), “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” which states:

Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author’s institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflict of interest. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion. Authors should identify individuals who provide writing assistance and disclose the funding source for this assistance.

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When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in

2000. If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should be asked to indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

Submit manuscripts or queries to:

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SECTION II

DNP Project Product

I. Urologic Nursing Journal

A. Scope of Journal

Peer reviewed original manuscripts including case reports, education protocols, quality improvement projects, and original research.

B. Aims of Journal

Advance nursing education and research with a focus on growth of the sub-specialty of urologic nursing. Provide continuing education credits and expand evidence-based practice to improve patient care and outcomes.

Implementation of an Electronic Health Record Notification System for Reduction of Pessary Complications

Implementation of an Electronic Health Record Notification System for Reduction of
Pessary Complications

Margaret Hull, DNP

Susan Alexander, DNP

Rony Adam, MD, MMHC

Biography

Margaret is an advanced practice registered nurse and assistant professor at Vanderbilt University Medical Center in Nashville, TN. She received her Doctor of Nursing practice from the University of Alabama, Huntsville. Recent publications include “Urologic Nursing: Scopes and Standards of Practice” (2020), “50 Years of Pessary Use” (2019), and “The Impact of Genitourinary Syndrome of Menopause on Quality of Life” (2017).

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Abstract

Use of a pessary, a vaginal support device, is a low risk option to improve symptoms associated with pelvic floor dysfunction. However, little data exists to define follow up recommendations to minimize potential complications. This quality improvement project involved implementation of a tracking system utilizing an electronic health record to maintain consistency of care and possible reduction of more serious complications.

Introduction

Pelvic floor dysfunction (PFD) may include many bothersome characteristics, including pelvic organ prolapse (POP) and urinary incontinence (UI). POP, the descent of the pelvic organs toward, and in some cases, beyond the vaginal introitus, is a quality of life (QoL) concern among many women, with some estimates defining a prevalence of 30% to 50% of the female population (O'Dell, Atnip, Hooper, & Leung, 2016; Rodriguez-Trowbridge & Fenner, 2005). This estimate is expected to rise as the U.S. population continues to grow and age (Colby & Ortman, 2014).

Stress urinary incontinence (SUI) is the loss of urine during physical exertion, such as coughing, sneezing, laughing, exercising, or while engaging in intercourse. Just like POP, SUI is a highly prevalent QoL-impacting condition with estimates as high as 40% among women 40 years of age and older (Older People, 2018; Simpson, Garbens, Dossa, Coyte, Baxter, & McDermott, 2019).

Symptoms of POP may include urinary and fecal incontinence, urinary and fecal obstruction, pelvic pressure and discomfort, sexual dysfunction, and vaginal bleeding from abrasion or erosion development when the vaginal wall chafes against itself and/or with undergarments (Atnip & O'Dell, 2012; Continence Foundation of Australia, 2012). Similarly, women suffering from SUI may limit their activities for fear of being embarrassed when leakage occurs or experience vulvar skin irritation or breakdown when the skin is exposed to caustic urine or irritating and constrictive pads (McIntosh, 2015; ACOG Practice Bulletin, 2017).

Women who choose pessaries are more likely to be postmenopausal, non-smoking, agreeable to vaginal hormone use, naïve to pelvic reconstructive surgery, or unable to undergo surgical repair due to life-threatening co-morbidities (Lewthwaite et al., 2013). Additionally,

women who choose a continence pessary for SUI are more likely to be menopausal, more highly educated, naïve to prior incontinence surgery, and less prone to incontinence (Schaffer et al., 2012).

Pessary use is not without risks for the development of complications, and recommendations for routine pessary and problem management emphasize the need for a patient-centered focus. Complications can include vaginal abrasions, erosions, ulcerations, pessary incarceration (or embedment into the vaginal epithelium), and fistulas, such as vesicovaginal fistulas (VVF) or rectovaginal fistulas (RVF) (Abdulaziz, Stothers, Lazare, & Macnab, 2015; Rodriguez-Trowbridge & Fenner, 2007).

Providers may suggest a strategy of pessary self-management for the prevention of concerns. This may entail nightly removal of the pessary with reinsertion in the morning, weekly removal for a one time per week overnight rest, or removal only for engaging in intercourse, defecating, showering, or using a vaginal preparation of estrogen (O'Dell & Atnip, 2012). Yet, there are no clear guidelines to define what is the best self-management strategy or protocol. Furthermore, no data exists requiring a self-management program as a definitive means for complication reduction compared to clinician only management, and there is no data to define a twice-weekly regimen of local vaginal estrogen to effectively reduce problems with pessaries.

Significant discrepancy of recommendations for timing of follow-up to prevent complications prove a lack of evidence-based guidance, and timelines can vary from 3 to 6 months (O'Dell & Atnip, 2012; Gorti, Hudelist, & Simons, 2009; Pott-Grinstein & Newcomer, 2001). Recent efforts to better define the timeline for scheduling of routine maintenance and monitoring of erosions have been helpful and showed that a 24-week follow-up interval was noninferior to a 12-week interval for prevention of erosions (Propst, Mellen, O'Sullivan, &

Tulikangas, 2020). However, most described protocols for pessary fittings and surveillance continue to be delineated by expert opinion (Bugge, Adams, Gopinath, & Reid, 2013). To determine if complications develop when routine management is not maintained, the study authors developed a tracking system within the electronic health record (EHR) to track patients who received a pessary for PFD to determine if the risk for complications was greater when consistent management was not maintained.

Methods

This is a quality improvement (QI) process implemented within a large tertiary care center. The project investigators designed and reported on this project using Squire 2.0 guidelines for QI projects (Ogrinc et al., 2015). The Vanderbilt Institutional Review Board (IRB) granted approval. The project investigators identified ten providers (attending physicians, nurse practitioners, and fellows) within the Female Pelvic Medicine and Reconstructive Surgery (FPMRS) division, who place and manage pessaries and provided the names of these individuals to the Vanderbilt IT personnel for use when developing the pessary fitting and management encounter lists.

IT personnel developed three patient lists within the Epic EHR (EStar) system and provided these to the primary project investigator via a secure “reporting workbench” communication system at the beginning of the month. The first list generated reflected the pessary fitting procedure; IT added to the list any patient who underwent the procedure fitting, as identified by the procedure code 57160, and any patient who received a new pessary at that visit, as identified by the supply code A4562. The second list contained any missed maintenance appointments after the fitting procedure. The third list contained the most commonly used complication code identified with pessary use, N89.8, vaginal erosion secondary to pessary use.

These three lists alerted the project investigators when patients missed an appointment or received a diagnosis of N89.8, even if the patient maintained the appointment.

Before the implementation of the tracking system, the project investigators determined the baseline complication rates among the identified pessary providers through a retrospective chart analysis of pessary fittings during a five-month period beginning January 1, 2019, to May 31, 2019. The investigators used Excel to create a database and the QI Macros 2019 Add On to conduct the statistical analyses for this project. The investigators included the following information in the database: the CPT code (57160) for pessary fitting procedures, the device code (A4562) for the pessary, and the ICD-10 code (N89.8) for the pessary complication of vaginal erosion secondary to pessary use. Additional data collection included patient age, self-management versus clinician management of the pessary, use or non-use of vaginal estrogen, missed pessary appointment after the initial procedure, unscheduled pessary maintenance appointment with office staff after the initial procedure, maintained appointment after the initial fitting, all other maintained maintenance appointments, and all other missed maintenance appointments. The investigators did not collect data to define the treatment intervention when a complication was identified due to documentation inconsistencies among the providers.

The investigators implemented the tracking system on June 1, 2019 through October 31, 2019, for a 5-month time period of evaluation. This allowed for data collection from the initial fitting as well as two follow-up appointments after the initial placement. The standard management protocol within the FPMRS division defines a 1-2-week follow-up appointment after the initial pessary placement with surveillance appointments occurring every three months for patients who are unable to self-manage the pessary, and every 4-6 months for patients who do self-manage the pessary. During the tracking period, the project investigators received the lists

from the IT department at the beginning of each month. These lists did not include any patient names or other personal data. The only identifying data included was the uniquely assigned medical record number (MRN) and date of the encounter.

Once received, the project investigators, in collaboration with the four staff nurses in the outpatient clinic setting who were educated about the alert system and trained on the pessary management protocol contacted patients who were listed as having missed a planned follow-up appointment and offered an appointment within the week. Figure 1 details the process of communication with the patient once the project investigators received the missed appointment alert. The project investigators included patients listed as having the diagnosis of N89.8 on the second list, whether they missed an appointment or did not miss scheduled maintenance. The project investigators used this list to ensure that a pending appointment existed. The office nurses then called the patients on the N89.8 list who missed the scheduled follow-up appointment and offered an “overbooking, next day” appointment.

Results

After removal of patients who were not successfully fit with a pessary, who were inaccurately duplicated, or who were diagnosed with N89.8 for erosions from other causes, such as mesh erosion or ulcerative vaginitis (and in the absence of pessary use), the investigators included a total of 105 pessary fitting encounters in the database for the baseline or “pre-tracking” evaluation and 110 pessary fitting encounters for the “tracking” evaluation period.

Demographic characteristics of the two groups show the similarities of this patient population. Most of the patients identified as either white (81.4%) or African American (7.4%) and there was a relatively large cohort who classified themselves as other/unknown (8.4 %). Women in both groups tended to be older (80% of the patients were >50) with an average age of

65. A greater number of women were agreeable to use of a local estrogen preparation (53.5%) than not (46.5%) and chose to self-manage the pessary (61.9%) versus clinician only management (38.1%) (Table 1).

The baseline or pre-tracking complication rate among these fittings was 4 out of the 105 identified encounters or 3.8%, and the complication rate among the tracked patients was 12 out of 110 fittings for a 10.9% rate and this was statistically significant ($p = 0.0474$, Fisher's exact test). This finding was expected, given the increased number of erosions diagnosed as the patients were actively tracked and returned for consistent management.

Use of an annotated run chart (Figure 2) allows for better visualization of this phenomenon as a function of time. The increased rate of complications is noted relative to the point of implementation of the tracking system, as well as the variability from month to month, before and after the system was launched. The orange line indicates the mean rate (7-8%) of N89.8 complications with only the month of May noted to have a higher number prior to initiation of tracking. The blue line represents the percent of erosions per month in relation to the average. It is easy to see the increased number of erosions reported once the tracking system began. This is represented by the rapid rise of the blue line that, primarily in the second month and beyond, occurred when the phone calls from the nurses began and patients were scheduled to return to the office for evaluation.

During the 10-month time period of evaluation for this cohort, the project personnel saw no statistically significant association between age and complication development with age cut off used ≤ 50 and > 50 years of age ($p=.4356$, Fisher's exact test). Rate for erosion development, while seemingly higher as women age (4.7 % for women ≤ 50 compared to 8.1 % for women over 50), was not statistically significant as determined by paired-samples t-test to determine the

effect of age on complication development, $t(213) = -0.905, p = 0.367$. Furthermore, the investigators saw no differences when comparing age to the pre and post tracking groups, $t(213) = 0.936, p = 0.350$ and there was no difference in development of erosions among women who used a local estrogen preparation and women who did not by Chi square analysis $X^2(2, N = 215) = 0.5642, p = 0.4525$.

The investigators saw no differences in erosions among women who self-managed the pessary and women who chose to have the clinician manage the pessary ($p=0.3921$, Fisher's exact test). Despite initiation of the tracking system, and the presumed greater communication between nurses and patients, the project personnel did note a reduced number of women in the tracking group who self-managed the pessary (64.8 % pre-tracking and 59.1 % tracking).

The rate for development of an erosion when the patient scheduled the first follow up appointment after completion of the fitting procedure was 7.7% and the risk for the development of an erosion when the patient did not schedule the first follow up appointment prior to leaving the office was 6.9%. There was no association for erosion development whether a patient scheduled an appointment after the completion of the fitting and when checking out with the front office personnel prior to leaving the office versus not scheduling the follow up appointment with the front office personnel prior to leaving the office $X^2(2, N = 215) = 0.0388, p = 0.8436$. Additionally, there was no association for development of an erosion when the patient missed the first follow up appointment after the initial fitting $X^2(2, N = 215) = 0.0183, p = 0.8922$. Rates for the development of a complication were 7.7% and 7.2% among patients who missed the first follow up and patients who did not miss the first follow up.

When looking at subsequent follow up appointments among the tracking group, it appeared the total number of unscheduled and missed appointments seemed to improve over

time. That is, as time progressed the patients in this group, seemed less likely to forget to schedule a follow up appointment and it appeared they were more likely to maintain the appointment once scheduled. When comparing the pre and post tracking groups, the percentage of 0-1 missed appointments was 69.5 % among the non-tracked group and 83.6 % among the tracked group. This is interesting, as it appears the tracked group was more likely to miss up to one appointment. However, when looking at >2 missed appointments, (as time passed and pessary management became more routine for patients in both groups) the pre and post tracking groups saw further reductions of missed appointments (30.5 % among the pre-tracking group and 16.4 % among the tracked group) with the tracked cohort seeing a greater reduction of >2 missed appointments. This finding was statistically significant ($p=0.0143$, Fisher's exact test).

Evaluation of subsequent scheduled appointments showed the same progression with patients forgetting to schedule up to one appointment prior to leaving the office 71.4% among the pre-tracking group and 87.3% among the tracking group. When the project personnel looked at > two unscheduled appointments, this number was greatly reduced between both groups, with the greater reduction seen in the tracking group (28.5 % among pre-tracked patients and 12.7 % among tracked patients, $p=0.0039$, Fisher's exact test) (Table 2). To further prove the validity that surveillance was associated with a decrease in missed appointments, the project personnel used the t-test and found the mean number of missed appointments went from 1.22 pre-tracking to 0.91 tracking and this was statistically significant $t(213)=-2.118, p=0.035$.

Discussion

Evaluation of this QI project shows the system worked and underscores the number of potential complications missed prior to the initiation of a tracking system. Furthermore, the results lend credibility that the QI personnel and staff "did their part" through identifying, contacting, and scheduling patients who required care. It is also possible that identification of

these erosions, and the subsequent erosion management, will have further reduced the risk of serious complications over time, such as fistula development. The consistent surveillance and enhanced contact with patients likely produced a greater understanding of the need for routine or structured management and may have served as a means of empowerment to patients by serving as an opportunity to enable personal ownership and collaboration in pessary management. This is most evident by the reduced number of >2 missed appointments (1.22 pre-tracking to .91 tracking) among the tracking group. As the project personnel achieved greater communication with the patients, greater, more consistent follow up was realized.

There are limitations to the process that require discussion. The first list generated by the IT personnel, the pessary fitting procedure list, may have been better utilized to determine if a follow-up appointment had been scheduled by the patient before leaving the office. This could have been easily and quickly completed when the project investigators received this list each month by utilizing through the MRN and identifying within the EHR, any upcoming scheduled appointments. The use of the list in this way may have assisted the investigators, and the nursing staff identify and contact the patients who failed to schedule an appointment prior to leaving the office after the initial procedure was completed. This intervention, while perhaps not a definitive means for reducing no-shows, may have encouraged the patient to understand the importance of consistency in management.

The project personnel did not maintain data in the lists regarding the shape of pessary placed, so the project investigators cannot make associations between type of pessary and erosion development. Future iterations of this tracking system should include the shape and size of pessary used as this may aid the clinicians to determine more objectively greater or lesser risk of complications among different pessary styles. This information could also possibly be used to

provide greater understanding and customization of the timing of pessary maintenance based on the style of pessary used.

Little information exists on the development of erosions with or without estrogen use or in the presence or absence of patient management of the pessary (O'Dell & Atnip, 2012). While the investigators collected information on estrogen use and self-management of the pessary, an evaluation of the interventional options for preventative management to reduce the occurrence of erosions was not performed for this project, as this was not the defined goal. Future collection of this data may prove helpful for future pessary recommendations. Comparisons could be made to address this question by evaluating the risk of a complication among women who 1) self-manage the pessary and use estrogen 2) do not self-manage and use estrogen 3) self-manage and do not use estrogen and 4) do not self-manage and do not use estrogen.

The project investigators did not collect information on the intervention provided to manage the erosion, once diagnosed. Most recommendations are based on expert opinion with few randomized controlled trials to define the most appropriate management of erosions. Management options are varied and include pessary holidays, pessary downsizing, application of silver nitrate (AgNO_3) to the erosion, and addition or initiation of local estrogen (Magali, Schulz, & Harvey, 2013; O'Dell & Atnip, 2012; Wu et al., 1997). This information may have been helpful to determine what worked best to treat the erosion once identified. While not part of a tracking system per se, data collection on time to erosion development as well as time to resolution of the erosion after implementation of the intervention may have been helpful to see what worked best to reduce the number of erosions and resolution of the erosions over time.

This project utilized a well-known EHR system. As the healthcare industry strives to improve upon current EHR capabilities, it is possible this and other EHR projects will highlight

weaknesses of the system and drive development and improvement of systems to improve the delivery of care for patients. One area of weakness, which may not be an EHR concern, and is more likely an institutional or departmental concern, is the discrepancy and variation among provider documentation. This was apparent by the inability of the project investigators to gather pessary shape information, time to erosion development, interventions utilized for pessary erosion treatment, and time to erosion resolution. It is possible this project will enlighten the experts who can develop a process of standardization of notes within the EHR.

The use of EHR systems has the potential to drive robust QI initiatives and improve patient care. To date, there are no documented surveillance systems for pessary management. The development of this monitoring system has the potential to answer many questions regarding pessary practices, and may further the knowledge to better care for patients who choose a pessary for PFD.

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Figure 1. Communication Process Map

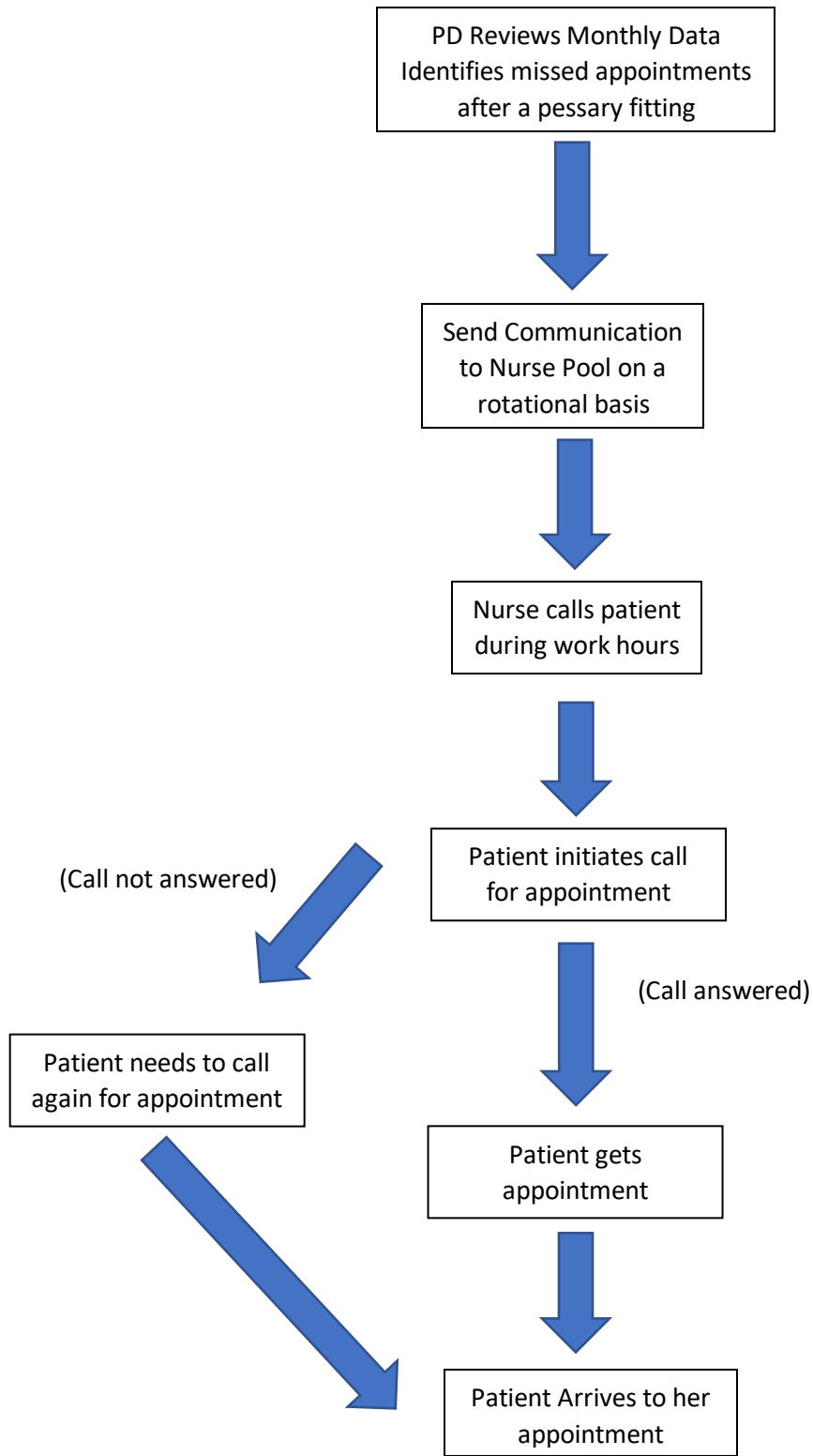


Figure 2: Monthly Rate of Complications

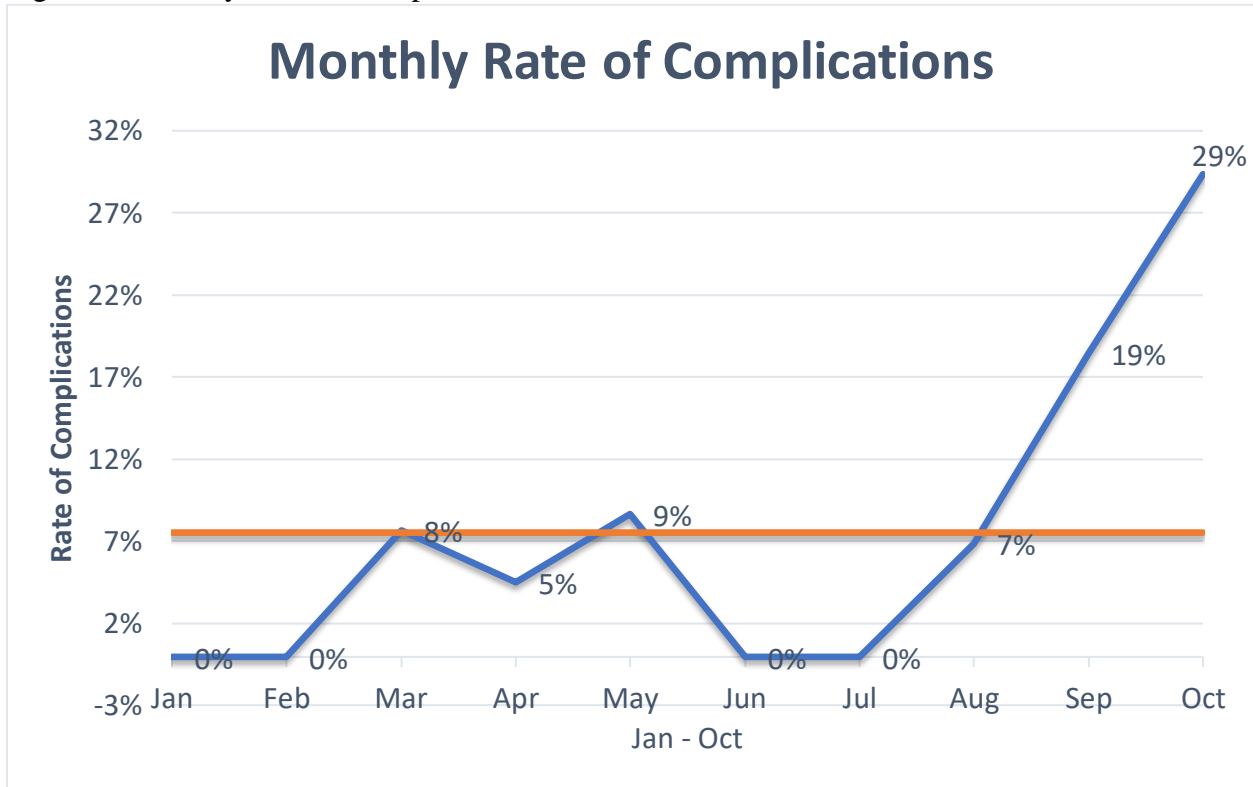


Table 1: *Demographic Characteristics*

	Pre-tracking		Tracking		Total	
	n	%	n	%	n	%
Race						
White	83	79	92	84	175	81.4
African Amer.	9	8.6	7	6.4	16	7.44
Asian	3	2.9	1	0.9	4	1.9
Hispanic	1	0.95	0	0	1	0.46
Native Amer.	0	0	1	0.9	1	0.46
Unknown/other	9	8.6	9	8.2	18	8.4
Age						
≤ 50	22	21	21	19.1	43	20
> 50	83	79	89	81.0	172	80
Estrogen						
Yes	52	49.5	63	57.3	115	53.5
No	53	80.9	47	42.7	100	46.5
Self-manage						
Yes	68	64.8	65	59.1	133	61.9
No	37	35.2	45	40.9	82	38.1

Note. N = 215 (105 in the pre-tracking group and 110 in the tracking group)

Table 2: *Follow up Patient Appointments Scheduled or Not Kept in the Project (N=105)*

Appointments Not <u>Scheduled</u>	0-1 <u>Appointments</u> <u>n</u>	<u>%</u>	<2 <u>Appointments</u> <u>n</u>	<u>%</u>	<u>X²</u>
Prior to implementation tracking system	75	71.4	30	28.5	
Post implementation Tracking system	96	87.3	14	12.7	8.285*
Appointments Scheduled but Not Kept					
Prior to implementation tracking system	73	69.5	32	30.5	
Post implementation tracking system	92	83.6	18	16.4	5.994*

* $p < .05$