A DATA-BASED PRACTICE MODEL FOR PESSARY TREATMENT OF PELVIC ORGAN PROLAPSE: A QUALITY IMPROVEMENT PROJECT

by

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As members of the DNP Project Committee, we certify that we have read the DNP Project prepared by Denise Murray entitled "A Data-Based Practice Model for Pessary Treatment of Pelvic Organ Prolapse: A Quality Improvement Project" and recommend that it be accepted as fulfilling the DNP Project requirement for the Degree of Doctor of Nursing Practice.

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DEDICATION

I dedicate this work to my husband, Ian, who has been a source of support and motivation in keeping me focused so I could move forward to achieve this life goal. I know it has not been without its difficulties but I thank you and love you for it.

I also dedicate this work to my children: Matthew, Joshua and Desirae, and grandson Caden. To you I say: learn something new every day but keep in mind that the manner in which you learn may not be without struggle. However, the struggle may represent the significance of what is learned.

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ABSTRACT

Background: Pelvic organ prolapse (POP) can be treated surgically or, more conservatively, with use of a pessary.

Objective: To determine if the population of women treated for POP with the use of a pessary in one Nurse Practitioner's (NP) practice demonstrated health outcomes as better, same, or needing improvement through use of a data-based practice model from encounter data extracted from the electronic health record (EHR).

Design: The project design was a quality improvement (QI) project, descriptive in nature. One Plan Do Study Act (PDSA) cycle was conducted for this QI project.

Setting: NP managed specialty clinic in urban Southwestern Arizona that provides services to women with POP.

Patients: Ten randomly selected women who had been treated conservatively for POP with use of a pessary were identified as two subpopulations and evaluated: women who received professional management of the pessary and women who were patient managed.

Intervention: The intervention was the development of a data-based practice model, using patient profile data elements derived from the documented EHR encounters of the 10 women.

Measurements: Twelve scales were developed to evaluate the patient profile data elements, generating numeric scores for each encounter. Two Decision Rules were then used to evaluate numeric scores by encounter, creating primary and secondary health outcomes.

Limitations: Two limitations were identified. The QI project was limited by the small sample size of 10 patients. This is however, true to PDSA guidelines that recommend small scale cycles. The data were limited as only documented data were used.

Conclusions: In general, the expected outcome was the outcome observed; the provider was unaware of any women in this QI Project who were not successfully treated with use of a pessary for treatment of POP. The value of this data-based practice model is that outcomes can be aggregated across populations rather than relying on recall of individual outcomes and therefore has potential to be used regularly and systematically as a quality feedback loop, as well as on a larger scale in future PDSA cycles to determine other outcomes beyond a single provider in this or other similar clinical populations.

INTRODUCTION

The purpose of the DNP Project was to complete a quality improvement (QI) project developing a data-based practice model for evaluating population health outcomes. Specifically, the data-based practice model was used to determine if the population of women treated for pelvic organ prolapse (POP) with the use of a pessary in one nurse practitioner (NP) practice demonstrated health outcomes as better, same, or needing improvement.

Aggregating a provider's experience into population health outcomes is essential feedback for the provider; otherwise the provider considers health outcomes by individual patient. Focusing on population health outcomes, rather than individual health outcomes, also provides an opportunity to identify subpopulations with unique needs. Informed by population and/or subpopulation health outcomes, practices can be modified and care tailored to specific patient populations, subpopulations, and patient groups characterized by needs and level of risk.

Background Knowledge

This section will define and describe POP and identify the accepted manner of treatment. The intent of this QI project is not to recommend one type of treatment over another but to determine treatment and health outcomes from an actual practice where women are treated for POP with a pessary. Use of a pessary to treat POP was selected as a focus because of the prevalence of POP.

Pelvic Organ Prolapse (POP)

Pelvic floor disorders (PFD) develop in women when there is a loss or a weakening of anatomic pelvic support when muscles and connective tissue of the pelvic area have become weak or injured (NIH-NICHHD, 2013). Referred to as the "prolapse" of POP, this weakening

can cause organs of the pelvic area to fall or sag into the vaginal space or out of the vaginal opening. Multiple organs can be affected and may include the uterus, bladder, rectum, intestine, or vaginal wall structure itself (ACOG, 2011).

PFD has become an umbrella term for conditions of urinary incontinence (UI), over-active bladder (OAB), POP, and fecal incontinence. When providers address a woman's reported condition of UI, other co-occurring conditions and symptoms may be missed if the provider fails to inquire about additional symptoms. For example, Lawrence, Lukacz, Nager, Hsu, and Luber (2008) reported that women with UI, OAB, POP, or fecal incontinence were likely to have more than one occurring PFD. Research found this to be the case for: (a) 80% with UI or OAB, (b) 69% with POP, and (c) 48% with fecal incontinence (Lawrence et al., 2008). These findings demand providers broaden their diagnostic approach for women experiencing signs and symptoms of PFD and determine the exact nature and extent of the symptoms since more than one condition may be present (Maher, Feiner, Baessler, & Schmid, 2013).

Culligan (2012) described POP as a common condition that affects "millions of women" (p. 852). Women of all ages are affected but typically older women ranging in age from 57 to 84 years (Nygaard, Bradley, & Brandt, 2004; Tezelli-Borlolini, 2011). Sarma, Ying, and Moore (2009) reported POP to be present in half of all women over 50 years of age. Maher (2013) reported that POP occurs in as many as 50% of parous women (women who have had vaginal deliveries). POP can also occur in women who are pregnant and even in nulliparous women, (women who have never been pregnant) (Tezelli-Borlolini, 2011). Other contributing factors beyond pregnancy and vaginal births are: estrogen deficiency; connective tissue disorders, such as systemic lupus erythematosus (SLE) or osteogenesis imperfecta (brittle bone disease);

previous pelvic surgeries; obesity; aging; chronic cough; chronic constipation; running; or strenuous physical activity which increases abdominal pressure.

Symptoms of POP

Women with POP may experience symptoms of pelvic or vaginal pressure, pain, or a heaviness in the pelvic area; backache; bulging or a lump at or beyond the vaginal opening; stress or urge urinary incontinence; urinary frequency; an increase in urinary tract infections (UTI); incomplete bladder emptying (IBE); or difficulty with emptying or controlling the bowels (Reid, 2011). In addition, POP can affect the quality of life of women. Symptoms of depression are more common in women with POP when compared to those without POP (Ghetti, Lowder, Ellison, Krohn, & Moalli, 2010). Other symptoms of POP are sexual problems such as lack of libido, difficulty with vaginal intercourse, pain, lack of sensation and/or inability to achieve orgasm, and poor self-image—including fear of partner's perceptions (Ghetti et al., 2010).

Types of POP

POP is defined by the extent of the prolapse of the organ which is prolapsing. A uterine prolapse occurs when the uterus has come down into the vaginal space and may protrude from the vaginal opening; a cystocele is the prolapse of the bladder; a rectocele is a prolapse of the rectum; vaginal wall prolapse is when the vaginal wall no longer sustains its position and prolapses; and an enterocele is when a loop of bowel prolapses into the vaginal wall (Haylen et al., 2010).

Grades of POP

Several methods are accepted for grading or staging of POP. The POP-Q system is very common but difficult to use (Table 1) (Haylen et al., 2010). Nine measurements are taken from

the reference point of the hymeneal ring; and must be recorded in a grid prior to determining the corresponding stage (Persu, et al., 2011). The Baden-Walker staging of POP is a more common system for grading or staging POP and is less difficult to use than POP-Q because no numeric measurements are gathered because a visualization of the prolapse in relationship to the hymen is observed (Table 2) (Beckly & Harris, 2013).

TABLE 1. *Grades and Descriptions of Prolapse Defined by POP-Q.*

G0	No prolapse
G1	Descent of most distal portion of prolapse more than 1 cm above the level of the hymen
G2	Maximal descent of prolapse between 1cm above and 1 cm below the hymen
G3	Prolapse extends more than 1 cm beyond the hymen, but no more than 2 cm of total vaginal length
G4	Complete vaginal eversion of the prolapsing aspect

Note. G = Grade. Grade of prolapse based on POP-Q system (Haylen et al., 2010).

TABLE 2. *Grades and Descriptions of Prolapse Defined by Baden-Walker System.*

G0	No prolapse
G1	Halfway to the hymen or remnant of the hymen
G2	To the introitus (the vaginal opening)
G3	Halfway past the hymen or remnant of the hymen
G4	Maximum descent

Note. G = Grade. Grade of prolapse based on Baden-Walker system (Beckly & Harris, 2013).

Treatment for Pelvic Organ Prolapse

Women with POP face many challenges. One challenge is obtaining effective treatment. A pessary is a device made from medical-grade silicone that is manually inserted and designed to be worn inside the vagina to provide support to the vaginal walls and to help hold up the prolapsing aspect (Viera & Larkins-Pettigrew, 2000; Robert et al., 2013). Pessaries are cost-effective since no surgery is involved with insertion and should be considered as a minimally invasive treatment option for treating women with POP (Viera & Larkins-Pettigrew, 2000).

Surgical treatment of POP has been done on a large volume of women, in data, suggests in 1997 that 226,000 women had surgery for POP and costs for these surgeries were calculated to

be $1,012 million (Subak, Waetjen, van den Eeden, Thom, Vittinghoff, & Brown, 2001). This figure was calculated based on a total of 354,962 POP surgeries for more than 226,000 individual women (Subak et al., 2001). Of those 226,000 women, 15% experienced complications from the surgeries including hemorrhage and infections. More serious complications included: brain infarct, sepsis, and pulmonary embolism; these accounted for 1% of the complications and very few of these increased the length of stay in the hospital (Subak et al., 2001). Due to this, there was no change to the total calculated cost of the surgery (Subak et al., 2001). POP surgery was one of the most commonly performed surgeries in 1997 (Subak et al., 2001).

Surgery for the repair of POP is not always successful and often requires additional surgeries (Maher et al, 2013). Advantages and disadvantages to using a pessary or surgical intervention for POP are listed in Table 3.

TABLE 3. *Comparing Advantages and Disadvantages for Treatment of POP.*

Pessary	**Surgery**

• Advantages:
  • Noninvasive
  • Inexpensive
  • No down time
  • Not permanent
• Disadvantages:
  • Not permanent
  • Ongoing management
  • Cost of insurance copays for ongoing management
	• Advantages:
	  • Permanent
	  • No ongoing management
	  • No ongoing cost of insurance copays since there is no ongoing management
	• Disadvantages:
	  • Invasive
	  • Expensive
	  • Permanent
	  • Down time

Note. Maher, Feiner, Baessler, & Schmid, C. (2013).

In 2010, 57 women with preoperative POP and occult stress urinary incontinence (OSUI) were studied and followed longitudinally for two to eight years after having had surgical prolapse repair to reduce the prolapse (Ennemoser, Schönfeld, von Bodungen, Dian, Friese, &

Jundt, 2012). The prevalence of OSUI was tested for preoperatively and was present when there was urinary incontinence that occurred when the prolapse was supported by use of a vaginal speculum (Ennemoser et al., 2012). At an average of 5.7 years, 16 (28.1%) of the 57 women who had prevalence for OSUI, prior to surgical prolapse repair, developed subjective and/or objective stress urinary incontinence postoperatively; 17 (29.8%) of the 57 women had recurrence of POP, 5 of whom also had OSUI (Ennemoser et al., 2012).

The Cochrane Incontinence Group completed four systematic reviews for the Cochrane Database of Systematic Reviews, collecting and analyzing data to objectively determine effects of all surgeries done for the management of pelvic organ prolapse (Maher et al., 2013). The most recent review revealed data specific to 56 trials involving a total of 5,954 women who had surgical repair of POP (Maher et al., 2013). The systematic review provided the findings of the 56 trials addressing the type of surgery, the type of prolapse, the reduction in patient's awareness of POP, failed surgical outcomes, and reoperation findings (Maher et al., 2013). Women were more aware of the recurrence of a prolapse if having undergone anterior repair (28%) while those who had polypropylene mesh repair were less aware of the recurrence of prolapse (18%). Types of failed surgical outcomes were: de novo stress UI (new urinary incontinence), recurrence of prolapse, and risk of repeat of surgical repair which may have been dependent on products used in the surgical repair (Maher et al., 2013).

The need for better understanding this health problem is evident as predictions have been made that the number of women who will choose surgery for UI will increase from 210,700 in 2010 to 310,050 in 2050; and for POP, the number of women expected to choose surgery will increase from 166,000 in 2010 to 245,970 in 2050 (Wu, Kawaski, Hundley, Dieter, Myers, &

Sung, 2010). It is therefore recommended that women be informed of the use of pessary for conservative treatment; the majority of women with POP can be treated successfully with use of a pessary (Culligan, 2012).

Treatment of POP with a Pessary

A pessary is a silicone device designed to be worn inside the vagina to provide support to vaginal walls and to help hold up the prolapsing organ (Viera & Larkins-Pettigrew, 2000). The style and size of pessaries vary by manufacturer (Viera & Larkins-Pettigrew, 2000). The most commonly used pessaries are made of silicone and come in a variety of styles such as: open ring, ring with support, open oval, oval with support, Shaatz, Gellhorn, cube, and donut (Robert, Schulz, & Harvey, 2013).

The southwest specialty clinic uses the following approach for the initial fitting a pessary: During the initial fitting at the specialty clinic, women were provided with standard pessary education to become prepared for adjusting to the pessary. Women were educated by verbal communication about side effects of pessary use, such as: pessary falling out, pelvic pain, vaginal odor and/or discharge, vaginal blood spotting or bleeding caused by vaginal irritation or erosion, leaking urine, or difficulty having bowel movements. Women who received this education were expected to be more successful with the pessary.

The review by Robert et al. (2013) stated that women able to remove the pessary were instructed to do on a regular basis in order to clean the pessary with soap and water. If during follow-up visits these women were noted to have vaginal erosion, the provider would decide to remove the pessary and leave it out for an extended period of time, allowing vaginal erosions to heal with or without use of vaginal estrogen (Robert et al., 2013). Kuncharapu, Majeroni, and

Johnson (2010) indicated that fitting a patient with a pessary involves trial and error that is facilitated with clinical experience.

During the initial encounter at the specialty clinic, an evaluation and assessment was obtained and an abdominal, rectal, and pelvic exam with vaginal speculum was performed. If atrophy of vaginal tissues was noted, use of vaginal medications (creams, rings, or tablets), including those containing estrogen, were discussed. During the pessary fitting, a number of pessaries were tried in order to fit a suitable pessary into the vagina. Fitting a pessary is not a surgical procedure (Robert et al., 2013). Fittings were time consuming and required patience on the part of the patient, the NP provider, and staff. *Mygyne* (2013) also reported that pessary fittings take time and patience. The experience can be uncomfortable as well as embarrassing for the patient to undergo the awkwardness of pelvic exam and manipulation of the prolapsing pelvic organ(s) during the pessary fitting (Mygyne, 2013). As recently as 2010, there were no randomized trials which provided evidence to help providers select the most appropriate pessary (Kuncharapu et al., 2010). Lamers, Broekman, and Milani (2011), reported most women were able to be fit successfully 85% of the time; and only on rare occasions were women unable to be fit with a pessary for POP.

At the specialty clinic, new patients who were fit with a pessary were scheduled to return in two weeks for the first follow-up encounter. They were instructed to call the NP provider's office for questions or concerns, such as pain, bleeding, or inability to urinate. Calls to the specialty clinic sometimes necessitated verbally directing the women how to remove the pessary should there be such problems.

During the follow-up encounters at the specialty clinic, the NP provider and patient discussed the effectiveness of the pessary as well as any questions or concerns. The patient and provider discussed the patient's desire to be taught how to manage the pessary independently. If the patient did not want to or was unable to manage the pessary, the patient was instructed to return for a pessary follow up for professional management once every three months. Women who were able to successfully remove and reinsert the pessary independently were seen once every six months and were expected to remove the pessary at least once monthly, or more frequently as desired, in order to clean it with soap and water. In the study by Kuncharapu et al. (2010), they also reported that consideration for vaginal medication was discussed with the patients during follow-up visits if there were signs of vaginal irritation or erosions.

Pessary Side Effects

Use of a pessary is not without side effects or risks. Although serious complications from use of a pessary are rare, complications have been associated with patient nonadherence to pessary management education (Culligan, 2012). Pessaries left neglected without management oversight may cause fistulous communication from vaginal placement of the pessary to now protruding into the bladder (Arias, Ridgeway, & Barber, 2008). Another complication of nonadherence to management caused a recto-vaginal fistula to have formed after a woman had forgotten she had a pessary in place (Hanavadi, Durham-Hall, & Aston, 2004). Women may require surgery for repair of a fistula. There is little information as to the long-term use with regards to adverse events associated with use of pessary treatment for POP, despite the many practitioners who treat POP with a pessary (Sarma et al., 2009). Unfortunately, there is little

information as to adverse events with long-term use of pessary treatment for POP, despite the many practitioners who treat POP with a pessary (Sarma et al., 2009).

However, there was a reported concern that initiating treatment of POP with use of a pessary for young and healthy women may preclude a woman from having surgery when she is older and perhaps no longer a good surgical candidate (Sarma et al., 2009).

Common side effects from use of a pessary included: the pessary was not retained or fell out; or moves about inside the vagina; vaginal blood spotting developed; the provider had difficulty removing the pessary during an encounter; the pessary caused vaginal irritation and/or erosion to the vaginal walls, and if so, the patient may have been prescribed vaginal medication to be used as directed (Atnip & O'Dell, 2012). Consensus on use of vaginal estrogen cream is lacking due in part to limited evidence supporting the concurrent use of vaginal estrogen creams in those who use a pessary (Cundiff, Weidner, Visco, Bump, & Addison, 2000). However, there is evidence indicating menopausal women have higher success rates with use of a pessary when prescribed a vaginal estrogen cream (Hanson, Schulz, Flood, Cooley, & Tam, 2006). Side effects and risks can be mitigated by properly fitting a pessary, watchful oversight, patient education, use of vaginal estrogen creams, and regular pessary management by experienced providers (Hanson et al., 2006).

Sarma et al. (2009) reported less favorable results of pessary use by limiting patients to two styles of pessaries: a Protex ring pessary for women with POP and an Introl pessary for women with POP and UI. Vaginal estrogen creams were only used in postmenopausal women (Sarma et al., 2009).

Some pessaries can remain in the vagina during intercourse and others must be removed. If a woman is unable to remove the pessary for intercourse, patient is less likely to use the pessary (Lamers, Broekman, & Milani, 2011). Unfortunately, the inability to engage in intercourse is a side effect of a pessary that is oftentimes overlooked and can have long lasting effects on women's quality of life (QOL) as well as the partner's QOL (Lamers et al., 2011). There is a gap in the literature regarding QOL of women where a pessary is used for long-term treatment of POP (Lamers et al., 2011).

Local Problem

The local problem is a national problem. In the United States, women with POP number 3.3 million (Wu, Hundley, Fulton, & Myers, 2009). This is expected to increase to 4.9 million by the year 2050— an increase of 46% (Wu et al., 2009). The National Association For Continence (NAFC) corroborates these figures (NAFC, 2014). POP is made complex due to two important diagnostic concerns common in the women seen at the specialty clinic. First, it was rare for women to be specific in describing their symptoms to their providers and second, help is sought to address the issue in various care settings or with various types of providers such as: gynecologists, urologists, primary care providers (PCP), urgent care providers, long-term care providers, as well as providers in hospitals and emergency departments. Women shared with the NP provider that they realized something didn't feel or look normal but because symptoms were minor, vague, or occurred randomly, women would choose to tolerate the symptoms and postpone discussing symptoms with any provider.

In a study involving 223 women with symptoms of UI, only 10-20% sought help but not until their symptoms increased, threatening their QOL; the increase in symptoms was the

primary reason women sought help (Krissi, Ram, & Peled, 2012). Embarrassment, fear of social stigma, and a “belief that pelvic dysfunction is a normal part of aging, or ability to cope” were cited as reasons why women did not seek help sooner (Krissi et al., 2012, p. 102). Krissi et al. (2012) reported that women sought help was because they had heard of new information or treatment for the symptoms (Krissi et al., 2012).

Providers may have failed to inquire or evaluate for co-existing conditions when women present with UI; and POP may have been missed or not accurately diagnosed (Lawrence et al., 2008). Providers may also be uncomfortable examining and diagnosing POP and may refer women to gynecology or urology. Not all gynecologists or urologists routinely manage POP conservatively with use of a pessary. Therefore, women are not always informed about use of a pessary as a nonsurgical option for treatment of POP (Culligan, 2012).

Of the 223 women in the study by Krissi et al. (2012), 137 women had discussed symptoms of UI or POP with their PCP but were not offered the opportunity for further evaluation. Explanations for this were: no referral was made; the women were told the symptoms were not severe enough; they were told the symptoms were a natural experience at their age; women were afraid of surgery; there was a system delay; or there was shame (Krissi et al., 2012). Of the 223 women in the study, 96 had a main complaint of POP; the average delay in obtaining further evaluation in the women with POP was 41.2 months (Krissi et al., 2012).

Krissi et al. (2012) recommended the following: PCPs should become informed about diagnosing and managing PFDs; referrals should be made in a timely manner to those that specialize in PFDs such as POP; and PCPs should also help their patients become more comfortable in opening up about their symptoms and complaints. This provides the women with

the opportunity to obtain self-help or other therapy and spares them some preventable misery (Krissi et al., 2012).

Intended Improvement

The purpose of the DNP Project was to complete a QI project developing a data-based practice model for evaluating population health outcomes. Specifically, the data-based practice model was used to determine if the population of women treated for POP with the use of a pessary in one NP practice demonstrated health outcomes as better, same, or needing improvement.

At the specialty clinic, women with POP represented 23% of the total number of unique patients seen from January 1, 2011, to July 31, 2014. It was further anticipated that the developed data-based practice model would be used to gather data for other health outcomes for the NP. For example, health outcomes from the use of biofeedback for pelvic floor therapy for UI would be accumulated and help determine if the condition of urinary incontinence was better, same, or needing improvement. Aggregating evidence from individual patient encounters would enable the NP to consider practice patterns for the caseload in terms of overall populations, subpopulations, and outliers, rather than just approach practice patterns by individual patient. Treatment, informed by evidence and best practices could be modified based on the health outcomes.

Study Question

What existing EHR data can be used to develop a data-based practice model for determining if pessary use for treatment of pelvic organ prolapse leads to better, same, or needs improvement health outcomes at the population level for the provider?

Methods

Ethical Issues

This section will address the ethical aspects of developing this data-based practice model as a QI project. The author was the provider, and the author's documentation created data used to develop the data-based practice model over the period of time of January 11, 2011, to July 31, 2014, from which the data was extrapolated. In adherence to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Sections 164.514(a), 164.514(b), and(c) of the privacy rule, all protected health information (PHI) was removed (HHS, 2010). This de-identified data were not otherwise modified. Only documented data were used. The author had no known conflicts of interest other than being the provider for the patients. The Project was reviewed by the Internal Review Board (IRB) and was approved as a QI Project.

Setting

Data used to develop the data-based practice model were accumulated from an NP-managed specialty clinic for men and women. The specialty clinic opened in 1998 in an urban area of southwest Arizona and included two satellite locations. Multiple services are provided by the NPs and staff of the specialty clinic which included evaluation and non-surgical treatment for urinary and fecal incontinence, voiding dysfunction, pelvic pain, pelvic organ prolapse, bowel problems, and female sexual health disorders.

Eight employees provided service for the specialty clinic: two NPs, five medical assistants, and a lead urodynamic study technician. The small specialty clinics provided a comfortable atmosphere for patients who presented with highly personal conditions. Patients

were seen on a self-referral basis or were referred by primary care, urology, gynecology, urogynecology, or gastroenterology providers.

The focus of this DNP project was an NP's clinical population of women with POP and use of a pessary as conservative POP treatment. From January 1, 2011, to June 30, 2014, the specialty clinic saw a total of 2,782 individual patients. Encounters during this timeframe for the specialty clinic numbered 10,899. Of the total patients seen, 631 were diagnosed with POP and treated with a pessary. Over this 3½ year period, a total of 5,840 encounters were pessary management. From these total encounters, the NP author saw 206 women with POP to initiate pessary treatment or for pessary management for a total of 1,424 encounters.

Planning the Quality Improvement Project

The NP author applied a PDSA cycle as a means of implementing and completing this QI project (IHI, 2014). A PDSA cycle is a quality improvement method which is used to test change on a small scale, allowing for fine tuning changes and re-testing before it is implemented on a larger scale (IHI, 2014). There are four steps to one cycle. Step 1 is "Plan." This step involves planning the test, including a plan for data collection; a plan to test changes is also involved (IHI, 2014). Step 2 is "Do." This step involves conducting the test on a small scale, documenting and observing for problems, and the initial analysis of data. Step 3 is "Study." This step involves completing the data analysis and noting comparisons of the data to any predictions made, as well as studying and summarizing the results of the analysis (IHI, 2014). Step 4 is "Act." This step involves preparation of a plan for further testing after determining any changes to be made in the test (IHI, 2014). This section overviews the general plan for a PDSA cycle.

Quality Improvement Project Intervention

Providers assess and document health outcomes for individual patients in the EHR. Then, from this data, EHRs offer providers an opportunity to aggregate individual patient data as a data-based practice model to provide ongoing feedback about population health outcomes. Using this same hypothesis, the NP author can determine if quality and safety are optimal with current practice, and view data to determine the need to change practice. Based on the potential for a data-based practice model to inform practice, a QI project was planned to provide population feedback to the NP author. Specifically, the QI project plan was to develop a database that could be queried to determine health outcomes as better, same, or needing improvement for the population of women using pessaries for POP.

Development of subpopulations was necessary because two groups of pessary patients were identified: professionally managed and patient managed. Professionally managed patients were unable to remove or reinsert the pessary independently and were required to be seen once every three months by the NP provider for cleaning the pessary and for pelvic exam. Patient managed patients were able to remove and reinsert the pessary independently in order to clean the pessary, at least once monthly, and as desired. They were required to be seen once every six months by the NP provider for cleaning the pessary and for pelvic exam. The sample for the QI project was comprised of 10 randomly selected women from these two subpopulations who received treatment by the NP with a pessary for POP.

Key Intervention Factors

The main factor that contributed to this intervention was the EHR, which provided accessible data for developing the data-based practice model. The EHR used in the specialty

clinic consisted of two integrated systems: administrative and patient management. Diagnostic codes from the administrative system of the EHR were used to identify the pool of women from which the ten women were randomly selected. Inclusion criteria were also developed to identify which women met the criteria for inclusion. Women excluded from the QI project were also identified, as well as the reason for exclusion identified. Data from the patient management system included written text which consisted of notes having been entered as either phone notes or encounter notes. Details about the selection process are described in Project Design.

Initial Plan of Intervention Implementation

The initial plan represents step one, “plan,” of a PDSA cycle. To start model development, the first task of the initial intervention implementation plan was identifying relevant data elements contained in the EHR. Patient profiles comprised of these data elements were created for the 10 women. The profiles included data about pessary use for treatment of POP, as well as associated potential complaints of side effects caused by use of a pessary.

The second task in the initial intervention implementation plan was development of scales to evaluate the patient profile data elements. Use of the scales generated a numeric score for each encounter. The scale score sum of the most recent encounter was compared to that of the initial encounter.

The third task in the initial intervention implementation plan was the development of two Decision Rules. The decision rules were used to analyze scale scores of the most recent encounter compared to the initial encounter.

Following the PDSA guidelines of small scale, the fourth task, and final task in the initial intervention implementation plan, was to use the data-based practice model based on the

encounter data of 10 women patients who used a pessary for POP treatment. These 10 women were categorized into one of two subpopulations: women who rely on professional management of the pessary or women who were patient managed. Development of subpopulations was necessary because two groups of pessary patients were identified: professionally managed and patient managed. Professionally managed patients were seen once every three months; and patient managed patients were seen once every six months. Encounter data for 10 women were used to develop the practice model.

The findings of this QI project allowed for modification of treatment and tailoring of healthcare interventions by subpopulation (professionally managed or patient managed) or by clusterings of other groups within subpopulations or populations.

Planning the Study of the Quality Improvement Intervention

Planning the QI data-based practice model intervention and small-scale use of the intervention was the first step of the project. Planning the study of the QI intervention involved more specific planning and was a continuation of PDSA Step 1 from the initial plan of the intervention implementation (IHI, 2014).

Assessment Plan of Intervention Implementation

To complete the QI project, and assess intervention implementation, the data-based practice model was developed and then used to evaluate health outcomes data for 10 women using a pessary as treatment of POP in the NP author's practice at a specialty clinic. The total number of women seen by the NP author for treatment for POP with use of a pessary during the time frame of January 1, 2011, to July 31, 2014, was 206. Following PDSA small-scale guidelines, 10 women were randomly selected for the evaluation of health outcomes. Once this

first PDSA cycle was analyzed for the model's effectiveness for determining health outcomes as better, same or needing improvement, additional PDSA cycles would be repeated for continued testing until the intervention had been fully developed and used across the entire population of women using pessary as treatment for POP for one NP. Results from each PDSA cycle set up opportunity for consideration of practice change to improve health outcomes addressed in Standards for Quality Improvement Reporting Excellence (SQUIRE) Guidelines as mechanisms for causing change. This also provided the opportunity to evaluate the results of the data-based practice model which SQUIRE Guidelines addressed as testing mechanisms for effectiveness.

Project Design

The project design was a QI project, descriptive in nature, although small in scope. The population was women treated for POP with a pessary and seen by one NP at one specialty clinic. Only 10 random women patients were selected. Seventeen data elements were selected to comprise the patient profiles; two of which were included in the label of each patient profile. Twelve scales were developed and used to evaluate the patient profile data elements. Numeric scale scores were calculated for each of the twelve scales per encounter and then summed as a total score for each encounter. The difference was used to answer decision rules as a determination of health outcome being better, same, or needing improvement.

Random Selection of Patients

All of the POP patients (206) were assigned a random number using the random number function in Microsoft Excel (Excel). The women were placed in ascending order based on the assigned random number. The first woman on the list was then evaluated to see if inclusion criteria were met. If 'yes,' the woman was included in the total of 10 women. If 'no,' the reason

for exclusion was described. This process was repeated until 10 women were selected with representatives from the two subpopulations.

Inclusion Criteria

The demographic and encounter data for each woman was analyzed to determine suitability for inclusion in this QI project. The following criteria were established in order for a woman to be included in the QI Project:

- Patient must have had at least four encounters during the timeframe from January 1, 2011, to July 31, 2014.
- Patient must not have a pattern of two or more no-calls and/or no-shows for scheduled encounters, as this was considered nonadherent for pessary management.
- Patient must currently be using a pessary for treatment of POP.
- Patient must have been seen solely for pessary management by the NP author of the specialty clinic who is conducting the DNP Project and not by another provider within the specialty clinic or at another clinic.
- Patient must be eligible to be seen at the specialty clinic with an insurance plan that is accepted by the clinic or be a cash-pay patient. There are some payers which do not pay for visits to the specialty clinic (i.e., Arizona Health Care Cost Containment System [AHCCCS]).
- Patient's pessary management type must either be professionally managed or patient managed in order to avoid mixed data.

Women who met the inclusion criteria were placed into subpopulation categories of either professionally managed or patient managed for pessary care. A total of ten women were randomly selected who met the inclusion criteria of the QI project.

Exclusion of Patients

Women who did not meet the inclusion criteria were excluded and the information as to the exclusions was categorized for reference (Table 4).

TABLE 4. *Categories and Totals of Excluded Patients.*

Exclusion Categories	Number of Patients Excluded
Too few encounters	64
Nonadherent with pessary management	21
Not using a pessary:	
▪ Diagnosis of POP but elected no pessary for treatment	16
▪ Formerly used a pessary but had surgery for POP	2
No longer a patient of the specialty clinic or of the author of this PI:	
▪ Changed to provider nearer to residence	3
▪ No longer eligible to be seen at the specialty clinic due to a change in insurance	3
▪ Terminally ill & no longer being seen	2
▪ Moved out of state	2
▪ Changed to different provider within practice	1
▪ Deceased	1
Not all data accessible due to multiple providers providing pessary management	5
Changed pessary management type causing mixed data	2
Total	122

Sixty-four patients were excluded because there were less than four encounters. Four encounters were deemed necessary to provide sufficient data from which to draw conclusions. A large number of patients were determined to be nonadherent (21) with pessary care. For example, patients who had two or more no-calls and/or no-shows for scheduled encounters were excluded. The EHRs did not contain sufficient data and/or the patient was deemed nonadherent with pessary management for failure to have regularly scheduled encounters for pessary management.

Of the 84 remaining patients, 62 patients (73%) were professionally managed and 22 patients (26%) were patient-managed for pessary care.

Database Development

Microsoft Access was used to create the database for model development by extracting data from the administrative and patient management EHR systems. Patients were de-identified and an alphanumeric coding system was used to organize and categorize the extracted data for each patient. This was done in adherence to HIPAA to keep the data de-identifiable (HHS, 2010).

Within Microsoft Access, queries were performed to mine the relevant data needed for development of the data-based practice model. Specifically, the database allowed for aggregation of the unique patients and patient encounters in the clinic from January 1, 2011, to July 31, 2014, for POP treated with a pessary by the NP (See Appendix A – Table A1). The relevant data were then exported into Microsoft Excel. Microsoft Excel was used to analyze patient profile data elements. Based on these data elements, scale scores, and use of decision rules, health outcomes were determined to be better, same, or needing improvement for women being treated for POP with use of a pessary.

Internal Validity

For this QI project, data integrity was the primary concern for internal validity. Data integrity was required to create a valid data-based practice model. In this QI project, the integrity of the data being analyzed was dependent on the quality of the data entered by the NP at the time of the encounters. The NP author's training and experience with POP, pessary fitting, and pessary management, benefitted data integrity.

Although extracting data from the EHR data fields was an effective means to collect data directly from each encounter, this extraction approach would have been jeopardized if data fields had been left incomplete (Moran, Burson, & Conrad, 2014). The infrastructure of the specialty clinic's EHR did not prevent the NP from skipping fields prior to signing the encounter note. However, the NP author had responsibility to ensure completeness of the encounter note prior to signature. There was no missing data.

External Validity

The purpose of the QI project was to develop a data-based practice model to determine if population health outcomes of women treated with a pessary for POP by the specialty clinic NP author were better, same, or needing improvement. The NP author was interested in the feedback that the QI project would provide for the practice and for the specialty clinic. Given the nature of QI projects, the NP author did not generalize findings beyond the practice of the specialty clinic initially. Rather, based on findings of individual women and the development of the data-based practice model at a population level, the NP author considered continued use of the data-based practice model, as well as implementation of ongoing measures to determine health outcomes of those being treated for POP with use of a pessary. Much of the existing research and recommendations in literature regarding use of pessaries as conservative treatment for POP has been extrapolated from other aspects of women's health, i.e., pelvic floor disorders (O'Dell & Atnip, 2012). Therefore, analyzing data available from one's own practice was used to ensure quality and safe care when determining health outcomes for women who received treatment of POP with use of a pessary when there was very little evidence available.

Methods of Evaluation

This section evaluates the data from the administrative and patient management systems to identify the relevant data which was ultimately used to determine if health outcomes related to use of a pessary for treatment of POP were better, same, or needed improvement. Specifically, this section represents the “do” of PDSA, step 2 (IHI, 2014). The method of identification of data, development of the database, and analysis will be addressed here.

Electronic Health Record

The EHR was the means by which the intervention, of developing a data-based practice model, was carried out. The EHR consisted of two integrated systems: administrative and patient management. The administrative system is where the patient demographics, insurance, billing information, and appointment scheduling had been entered and were maintained. Relevant specific fields available in the administrative system were identified and downloaded into Access (Table 5).

TABLE 5. *Administrative Management System Data.*

Fieldname	Data Type
Appointments.Appointment_UID	Number
Appointments.StartDateTime	Date/Time
AppointmentTypes.AppointmentType_UID	Number
AppointmentTypes.Name	Text
ChargeCodes.ChargeCode	Text
ChargeCodes.ChargeCode_UID	Number
ChargeDetail.ChargeDetail_UID	Number
DiagnosisCode.DiagnosisCode	Text
DiagnosisCode.DiagnosisCode_UID	Number
PatientInfo.FirstName	Text
PatientInfo.LastName	Text
PatientInfo.Patient_UID	Number
Providers.FirstName	Text
Providers.LastName	Text
Providers.PGProvider_UID	Number

The relevant data selected for analysis from the administrative system fields were:

- patients seen at the specialty clinic;
- patient encounters at the specialty clinic;
- patients seen by the specialty clinic NP provider;
- patient encounters with the specialty clinic NP provider;
- POP patients seen at the specialty clinic;
- POP patient encounters at the specialty clinic;
- POP patients seen by the specialty clinic NP provider; and
- POP patient encounters with the specialty clinic NP provider.

Patient data was annualized and aggregated to identify randomized patients who had been assigned a diagnosis code of at least one type of POP. This was accomplished by extracting diagnoses codes from the administrative system. In order to establish the provider population, the

data was analyzed to identify the POP patients and the POP patient encounters. The query was specific to one NP.

The steps taken to aggregate this patient data were: (a) determining the number of total encounters for the specialty clinic during the specified time frame, (b) identifying POP patients with a diagnosis of a type of POP seen during the specified time frame, and (c) identifying the POP patients who had encounters with the designated NP during the specified time frame.

From the patient management system data, the NP identified what type of encounter the women had: new, follow-up, or problem. Each note template had been customized to meet the specialty clinic's needs. The ability for ongoing customization continues to be supported. The patient management system also included medications and information regarding prescriptions and electronic prescriptions.

Relevant specific fields available in the patient management system were identified (Table 6). This data was downloaded into Microsoft Excel for further analysis.

TABLE 6. *Patient Management System Data.*

Field Name	Data Type	Static Choices
Appointments.Appointment_UID	Number	
Bladder Scan	Text	
Can Patient remove or insert pessary	Yes/No	
Irritation of vaginal mucosa:	Yes/No	
Irritation of vaginal mucosa: C/O	Text	
No complaints; routine pessary check C/O	Text	
No complaints; routine pessary check	Yes/No	
Pessary is removed:	Text	*Without difficulty*, *With difficulty*, or *None Present*
Pessary well tolerated by patient?	Yes/No	
Patient encounter notes	Text	

The relevant data selected for analysis from the patient management system fields were

- encounter dates;

- management type: patient or professionally;
- type of encounter;
- type of [patient] complaint(s);
- difficulty by the provider to remove the pessary;
- post void residual (PVR) bladder scan;
- vaginal irritation;
- type(s)/grade(s) of prolapse;
- pessary in use;
- change in pessary; and
- vaginal treatment

Patient profile data elements. Data from the identified data fields were collected for each patient from both the administrative and patient management systems. These patient data were used to create a patient profile for every encounter for each of the ten randomly selected women. The patient profile data elements were used to create the data-based practice model. Patient profile data elements of the data-based practice model and use of the scales allowed for generating a numeric score for each encounter. The sum of the scale scores for the most recent encounter and the initial encounter were determined and compared (Appendix C – See Figures C1 through C10); (Appendix D – See Figures D1 through D10). The comparison of the scale score sums between the most recent encounter and the initial encounter provided the difference in the scores for these two encounters. This difference was evaluated by decision rules in order to determine whether the women's health outcome was better, same, or needed improvement with conservative treatment of POP with use of a pessary.

Patient profile data elements were organized into tables for the data-based practice model. The tables were then labeled by pessary management type (either professionally managed or patient managed) and a de-identified patient number. The tables included 11 types of data for a total of 15 unique data elements. The elements included those dependent on use of a pessary for treatment of POP. These data elements are described in Tables 7, 8, and 9.

TABLE 7. *Patient Profile Data Element Types and Descriptions.*

Data Element Types	**Data Element Descriptions**
Encounter number	Identifies the unique encounter.
Days from initial encounter	Initial patient encounter identified by day "0." Each encounter thereafter was identified by a number which is the number of days from the initial patient encounter.
Encounter type	Represents the type of encounter the patient was scheduled for: - New patient – patient has never been seen at the specialty clinic or it has been more than 2 years since the last encounter at the specialty clinic - Follow-up – An encounter for follow up for the purpose of managing the pessary - Problem – An encounter for which the patient has expressed a problem. Examples: pessary fell out, spotting of blood, leaking/UI, pain/discomfort, a feeling of IBE, or difficulty removing the pessary (if the patient is managing the pessary).
Complaint type	Represents the type of complaint the patient reports: - Pessary fell out since previous encounter - Spotting since previous encounter - Leaking/incontinence since previous encounter - Pain/discomfort since previous encounter - Feeling of IBE
Difficulty by the provider to remove the pessary	Indicates if the provider had difficulty removing the pessary during an encounter.
Post void residual (PVR) bladder scan	Bladder scan indicates the amount of urine, expressed in milliliters, that remains after patient voids.
Vaginal irritation	Indicates if the provider finds presence of vaginal irritation when performing exam at an encounter.
Type(s)/grade(s) of prolapse	Indicates the type(s) of prolapse and the grade(s) of any prolapse patient is diagnosed as having at the initial encounter as defined in Tables 5 & 6.
Pessary in use	Identifies the type and size of the pessary the patient is fit with at the first encounter or at a follow-up encounter.
Change in pessary	Indicates if a change was made in the type and size of the pessary the patient is fit with at the first encounter or at a follow-up encounter.
Vaginal treatment	Indicates if vaginal treatment in the form of a vaginal cream has been prescribed or is in use. Examples may include: Estrace, compounded estradiol, Natural Base Cream (NBC), Premarin, Femring vaginal ring, Estring vaginal ring, Vagifem (vaginal tablet), Replens, Trimo-San, Luvena, or Neogyn

TABLE 8. *Types and Descriptions of Prolapse.*

Types of Prolapse	Description of Prolapse
Uterine	Prolapse of uterus
Cystocele	Prolapse of bladder
Rectocele	Prolapse of rectum
Vaginal wall prolapse	Prolapse of vaginal wall
Enterocele	Prolapse of a loop of bowel into the vaginal wall

TABLE 9. *Grades and Descriptions of Prolapse.*

Grades of Prolapse	Descriptions of Grade of Prolapse
G0	No prolapse
G1	Descent of most distal portion of prolapse more than 1 cm above the level of the hymen
G2	Maximal descent of prolapse between 1cm above and 1 cm below the hymen
G3	Prolapse extends more than 1 cm beyond the hymen, but no more than 2 cm of total vaginal length
G4	Complete vaginal eversion of the prolapsing aspect

Note. G = Grade. Grade of prolapse based on POP-Q system (Haylen et al., 2010).
(Appendix B – See Tables B1 through B10).

Analysis

The data-based practice model was used to aggregate patient profile data elements from 10 women patients using a pessary for POP treatment. Scales were used to evaluate 12 types of data elements initially. Scale score sums of the most recent encounter were compared to those of the initial encounter to determine the difference between the two encounters. Decision rules were used to interpret the difference in the scores to determine if health outcomes were better, same, or needed improvement for treatment of POP with use of a pessary. The primary outcome was determined using the 12 scales. A secondary outcome was determined using 4 of the 12 scales. This section represents step 3 of PDSA, “study” (IHI, 2014).

Scales

Scales were established for 12 of the patient profile data elements. All scales are described below.

Type of encounter. A New Patient encounter type will be equal to zero. A follow-up encounter will be equal to zero. A Problem encounter type will be equal to one (Table 10).

TABLE 10. *Encounter Type.*

	New Patient	**Follow-up**	**Problem**
What is the type of the encounter?	0	0	1

Patient complaints. A scale was used to represent each of the five types of patient complaints. If a patient's pessary had not fallen out since the previous encounter, this was a score of zero. If a patient's pessary had fallen out since the previous encounter, this was a score of one (Table 11).

TABLE 11. *Pessary Fell Out.*

	No	**Yes**
Has the pessary fallen out since the previous encounter?	0	1

If a patient had not had vaginal blood spotting since the previous encounter, this was a score of zero. If a patient had spotting since the previous encounter, this was a score of one (Table 12).

TABLE 12. *Spotting.*

	No	**Yes**
Has there been spotting since the previous encounter?	0	1

If a patient had no change in urination, which included leaking of urine and/or incontinence of urine, as well as frequency of urination since the previous encounter, this was a score of zero. If a patient did have leaking or incontinence since the previous encounter, this was a score of one (Table 13).

TABLE 13. *Leaking/Incontinence.*

	No	**Yes**
Has there been leaking and/or incontinence since the previous encounter?	0	1

If a patient had no pain or discomfort in the pelvic or vaginal regions and/or had no discomfort with urination and/or defecation since the previous encounter, this was a score of zero. If a patient had pain or discomfort in the pelvic or vaginal regions and/or had discomfort with urination and/or defecation since the previous encounter, this was a score of one (Table 14).

TABLE 14. *Pain/Discomfort.*

	No	**Yes**
Has there been pain or discomfort since the previous encounter?	0	1

If a patient had no feeling of IBE since the previous encounter, this was a score of zero. If a patient had a feeling of IBE since the previous encounter, this was a score of one (Table 15).

TABLE 15. *Feeling of Incomplete Bladder Emptying.*

	No	**Yes**
Has there been a feeling of IBE since the previous encounter?	0	1

Note. IBE = Incomplete Bladder Emptying

Pessary removal. A scale was used to represent if the provider had difficulty removing the woman's pessary during an encounter. If the provider had no difficulty removing the

woman's pessary, this was a score of zero. If the provider had difficulty removing the woman's pessary, this was a score of one. An initial patient encounter was scored a zero as the woman was not yet fit with a pessary. If a new patient, at the initial patient encounter was already using a pessary, this was scored a zero, provided that no change was made in the pessary, or this would have been equal to one (Table 16).

TABLE 16. *Difficulty Removing Pessary by Provider.*

	No	**Yes**
Does the provider have difficulty removing the pessary at the encounter?	0	1

Post-void residual measure. A scale was used to represent a score for the amount of PVR urine as determined by the bladder scan done at the encounter (Table 17).

TABLE 17. *Post-Void Residual (PVR)Bladder Scan in ml.*

	Acceptable (0-60)	**Above Acceptable (61-150)**	**More than Most (151-249)**	**Much More Than Most (>250)**
What is the amount of PVR on bladder scan at this encounter?	1	2	3	4

Note. PVR = Post-Void Residual

Vaginal mucosa irritation. A scale was used to represent a score for irritation of vaginal mucosa as determined by the NP provider during an encounter. The size of the area of irritation or erosion were described in terms of common objects, dime-size, quarter-size, and silver dollar size for ease of explaining this to the patient.

- A score of zero represented that there was no vaginal irritation.
- A score of one represented that there was mild vaginal irritation. Mild was defined as: some vaginal redness with intact tissue and not bleeding at the time of the exam.

- A score of two represented that there was moderate vaginal irritation. Moderate was defined as: small area(s) of superficial vaginal tissue erosion, with or without active bleeding, which was treated with cautery using AgN03. The size of the area was described in the data; dime-sized was considered small.
- A score of three represented that there was severe vaginal irritation. Severe was defined as: large area(s) of superficial vaginal erosion and/or ulceration of vaginal tissue, with or without active bleeding. Quarter-sized to Silver-dollar sized were considered large and were treated with cautery using AgN03 (Table 18).

TABLE 18. *Irritation of Vaginal Mucosa.*

	None	**Mild**	**Moderate**	**Severe**
What is the appearance of any vaginal irritation at this encounter?	0	1	2	3

Grade of prolapse. A scale was used to represent a score for the grade(s) of the prolapse as determined by the NP provider during the patient's initial encounter during Valsalva.

- A G0 was not be scored
- A G1 was equal to a score of 1
- A G2 was equal to a score of 2
- A G3 was equal to a score of 3
- A G4 was equal to a score of 4 (Table 19).

TABLE 19. *Grade of POP.*

	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
What is the grade of the diagnosed POP at the initial encounter	1	2	3	4

Note. G = Grade

Change in pessary. A scale was used to represent a score for whether or not there was a change in the pessary during an encounter. If no change was made in the pessary that the patient was using, the score was zero. If a change was made in the type of pessary that the patient was using, the score was one (Table 20).

TABLE 20. *Change in Pessary.*

	No	**Yes**
Was there a change in pessary during this encounter?	0	1

Change in vaginal treatment. A scale was used to represent whether or not there was initiation or change in vaginal treatment for the woman during an encounter. If no vaginal treatment was initiated or changed, the score was zero. If vaginal treatment was initiated or changed, the score was one (Table 21).

TABLE 21. *Vaginal Treatment.*

	No	**Yes**
Was vaginal treatment initiated or changed during the encounter?	0	1

Scales were used to generate a numeric score for the data elements. The sum of the scale scores for the most recent encounter and the initial encounter were determined. These sums were compared to derive the difference in the encounter scores. Decision Rules were then applied to these differences to determine an outcome.

Decision Rules

Two decision rules were created for this PDSA cycle using the data-based practice model to evaluate health outcomes for 10 women who used a pessary as treatment for POP. These decision rules were used to interpret the difference between the scale score sums of the most

recent encounter with the initial encounter as a means to determine the health outcome as being better, same, or needed improvement.

Decision Rule 1 included all data elements and all 12 scales to attain a score for the most recent encounter and the initial encounter. This included elements related to side effects from use of a pessary in order to achieve the primary outcome (Table 22).

TABLE 22. *Scales Used to Calculate Sum of Scores for Encounters Using All 12 Scales.*

Encounter type	Pessary fell out	Spotting
Leaking/incontinence	Pain/discomfort	Feeling of IBE
Difficulty removing pessary by provider	Post void residual (PVR) bladder scan	Irritation of vaginal mucosa
Grade/type of prolapse	Change in pessary	Vaginal treatment

Note. IBE = Incomplete Bladder Emptying

Decision Rule 1 states:

- if the sum of the total scale scores for the most recent encounter was less than the sum of the scale scores for the initial encounter, the patient was better;
- if the sum of the total scale scores for the most recent encounter was the same for the initial encounter, the patient was the same;
- if the sum of the total scale scores for the most recent encounter was more than the sum of the scale scores for the initial encounter, the patient needed improvement.

The total scales score sum for Decision Rule 1 was generated by evaluating the patient profile data elements (Appendix C – See Tables C1 through C10). The total scale score sum for each encounter was graphed and included line indicating the least squares analysis (Appendix C – See Figures C1 through C10).

Decision Rule 2 included seven data elements and four scales to attain a score for the most recent encounter and the initial encounter. Decision Rule 2 did not include those elements

or scales which are related to side effects from use of a pessary to achieve the secondary outcome (Table 23).

TABLE 23. *Scales Used to Calculate Sum of Scores for Encounters Using Four of the 12 Scales.*

Leaking/incontinence	Pain/discomfort	Feeling of IBE	PVR bladder scan

Note. IBE = Incomplete Bladder Emptying. PVR = Post Void Residual

Decision Rule 2 states:

- if the sum of the four identified scales scores for the most recent encounter was less than the sum of these scale scores for the initial encounter, the patient was better;
- if the sum of the four identified scale scores for the most recent encounter was the same for the initial encounter, the patient was the same;
- if the sum of the four scale scores for the most recent encounter was more than the sum of these scale scores for the initial encounter, the patient needed improvement.

The total scales score sum for Decision Rule 2 was generated by evaluating the patient profile data elements (Appendix D – See Tables D1 through D10). The total scale score sum for each encounter was graphed and included a line indicating the least squares analysis (Appendix D – See Figures D1 through D10).

RESULTS

This section reports the results of the QI project in which a data-based practice model was developed as an intervention for a specialty clinic practice, specifically using a pessary to treat POP. A data-based practice model uses data from practice to create a feedback loop to describe the effectiveness of delivering a specific treatment or services and determining if health

outcomes are better, same, or needing improvement. This section represents part of the "study" of PDSA, step 3 (IHI, 2014).

The QI project population consisted of 10 women who used a pessary for the treatment of POP. Two subpopulations had been identified from this population, woman who rely on professional management of the pessary and women who are patient managed.

Primary Outcome

Seven women were professionally managed and three women were patient managed. In utilizing Decision Rule 1, six of the seven (86%) professionally managed women were found to have better outcomes when using a pessary for treatment of POP. One of the seven (14%) professionally managed women was found to be the same when using a pessary for treatment of POP (Table 24).

TABLE 24. *Results of Professionally Managed Patients.*

			Sum of 12 Scale Scores for Encounters	
	Health Outcome	**Change in Sum**	**Initial**	**Most Recent**
Patient 1	Better	7	12	5
Patient 2	Better	6	12	6
Patient 3	Better	1	7	6
Patient 4	Better	5	9	4
Patient 5	Better	5	9	4
Patient 6	Same	0	8	8
Patient 7	Better	2	6	4

All three (100%) of the patient managed women were found to have better health outcomes when using a pessary for treatment of POP (Table 25).

TABLE 25. *Results of Patient Managed Patients.*

			Sum of 12 Scale Scores for Encounters	
	Health Outcome	**Change in Sum**	**Initial**	**Most Recent**
Patient 1	Better	1	7	6
Patient 2	Better	3	10	7
Patient 3	Better	5	9	4

Secondary Outcome

A subscale score for the same population of 10 women was calculated to express the results without consideration of side effects from use of a pessary. When a woman was fit with a pessary, an adjustment period was expected for becoming accustomed to the pessary. The pessary may have caused side effects and/or caused the woman to have complaints. During adjustment time, a patient may have been found as “improvement needed” until they became accustomed to the pessary as well as more informed and comfortable about the use and management of the pessary. Decision Rule 2 allowed the comparison of scale scores without weighing the nature and magnitude of side effects associated with use of a pessary.

In utilizing Decision Rule 2 for the subscale, all seven (100%) of the professionally managed women were found to have better health outcomes when using a pessary for treatment of POP (Table 26).

TABLE 26. *Results of Professionally Managed Patients.*

			Sum of Four Scale Scores for Encounters	
	Health Outcome	**Change in Sum**	**Initial**	**Most Recent**
Patient 1	Better	6	7	1
Patient 2	Better	5	7	2
Patient 3	Better	2	3	1
Patient 4	Better	5	6	1
Patient 5	Better	3	4	1
Patient 6	Better	2	3	1
Patient 7	Better	2	3	1

Likewise, in utilizing Decision Rule 2 for the subscale, all three (100%) of the patient managed patients were found to have better health outcomes when using a pessary for treatment of POP (Table 27).

TABLE 27. *Results of Patient Managed Patients.*

			Sum of Four Scale Scores for Encounters	
	Health Outcome	**Change in Sum**	**Initial**	**Most Recent**
Patient 1	Better	2	3	1
Patient 2	Better	4	5	1
Patient 3	Better	3	4	1

Incidental Finding

Review of the patient profile data elements determined there had been 8 different styles and sizes of pessaries used by the 10 randomly selected women patients (Table 28). One woman did require the use of two pessaries to support the existing POP.

TABLE 28. *Styles and Sizes of Pessaries Fit for Randomly Selected Patients.*

Styles and Sizes of Pessary	No. of Patients
6 Ring with support	1
5 Donut	1
5 Oval with support	2
3 Ring with support Evacare	1
2 Gellhorn	3
5 Cube	1
5 Ring with support	1
8 Oval with support	1

Note. No. = Number. One patient required two pessaries.

DISCUSSION

Summary

The purpose of the DNP Project was to develop a data-based practice model that would be used in conducting QI projects to determine population health outcomes and then consider practice changes to improve outcomes. The specific development of the database is considered the intervention for this QI project. This data-based practice model was initially used for conducting a QI project to determine if the population of women treated for POP with the use of a pessary in one NP practice demonstrated health outcomes as better, same, or needed improvement. Use of the results to determine what next action would be taken describes step 4, "act" of the PDSA cycle (IHI, 2014).

Two subpopulations were identified for the initial QI project: women who received professionally managed pessary care and women who received patient managed pessary care. The initial QI project was one PDSA cycle, using the data-based practice model with 10 women who opted for pessary as treatment of POP. Population health outcome results supported the development and utilization of the data-based practice model and demonstrated that population health outcomes were better with use of a pessary for treatment of POP.

A difficulty for this QI project was the time required completing the project. Review of the EHR to extrapolate data electronically and then manually evaluate the data was an effective process but not efficient. The development of the data-based practice model would have to become automated to be a useful tool for a busy NP with little free time.

A project strength was the EHR and the availability and accessibility of the data used to create the data-based practice model. Storage of the data in an electronic format allowed data to be identified and extracted in an effective manner to develop the data-based practice model. Had the data been stored in paper charts, the identification and extraction of the patient data elements would have been difficult, if not impossible, to conduct the QI project in a timely manner. The capability to organize these data for the data-based practice model, specific to the needs and interests of the specialty clinic, provided the opportunity to view and analyze health outcomes of a population and not just an individual patient.

This summary represents step 4 of the PDSA cycle, “act” (IHI, 2012). The QI intervention was planned, collection and the analysis of the data achieved, results studied, and then the NP author must act upon what was learned. Translating the summary into action would be accomplished by making changes to practice if indicated, as well as set into motion another PDSA cycle to evaluate a different aspect of the NP author’s practice. For example, a change may be needed in how women are educated regarding the use of vaginal medication for treating vaginal irritation. The planned change in educating women would be implemented and would be evaluated. Reduction in vaginal irritation would be the anticipated result of the change.

Relation to Other Evidence

This QI project provides evidence about the practice experience of one NP without intent to generalize about women in this practice to women of other practices. The specialty clinic where the QI took place is a private practice where women are seen for the treatment and management of POP with use of a pessary. There are no known similar practices in the local area to compare the practice or the population. There are few literature-based benchmarks by which to compare the practice of the NP author or the health outcomes of the women of this specialty clinic. The NP author engages with a colleague with whom she works and who shares her expertise and knowledge of treatment of POP with use of a pessary with the NP author.

There is also limited evidence of the effects of QOL in women who use a pessary for treatment of POP. Review of the literature for development of this DNP Project found there was lack of evidence about the overall management of pessaries, e.g., who should be responsible for removing and washing the pessary, or should vaginal estrogen cream be prescribed or not (Cundiff et al., 2000).

Hanson et al. (2006) reported factors contributing to successful pessary use in 71% of the patients studied, these were: experience of provider, support with education, use of vaginal cream, and use of various styles and sizes of pessaries. Based on these factors, Hanson et al. (2006) concluded that use of a pessary is a viable and conservative treatment for POP and UI.

Sarma et al. (2009) questioned whether pessaries should be used as initial treatment for POP because a patient may become a higher surgical risk in the future. Sarma et al. (2009) also stated that surgery should be done earlier rather than later. Thus, Sarma et al. (2009) concluded that “based on the sobering results” of their study they do not support long-term use of pessary

treatment (p. 1720). The types of pessaries used in that study of pessary for long-term use were limited to two.

Evidence from this literature (Hanson et al., 2006; Sarma et al., 2009; Cundiff et al., 2000), is compared to results from this QI project. First, the focus of this QI project was only on the use of a pessary for treatment of POP and not on the background and experience of the NP author for treating women for POP, use of vaginal creams, or the selection process of a pessary. Second, despite concern about long-term use of a pessary for treatment of POP, the women in the first PDSA cycle had health outcomes that were better at their most recent encounter when compared to their first encounter. These health outcomes are not consistent with the literature, as a gap exists in the literature about long-term use of a pessary.

While reporting results of their survey intended to discover trends in pessary use for POP, Cundiff et al. (2000) stated that 231 (64%) of 359 surveyed members of the American Urogynecologic Society considered “hypoestrogenism” (p.934) a contraindication for pessary use. Yet, researchers also reported 337 (94%) members surveyed recommended use of a vaginal estrogen cream for women who are receive treatment of POP with use of a pessary

Hanson et al. (2006) supports having well educated and experienced providers educate patients about use of a pessary, reporting that this contributed to women having more success with treatment of POP with use of a pessary. This QI’s author agrees with this; however, another cycle in the future would have to be done to focus on health outcomes in women being treated for POP with use of a pessary by comparing the education and experience of several providers within the same practice, or from one practice to another.

Conflicting with literature, in this QI project, eight different styles and sizes of pessaries were used to fit 10 women, with one woman requiring the use of two different styles of pessaries to support the POP. In addition, when not including scale scores reflective of side effects of pessary use (Decision Rule 2), 100% of the 10 women were found to be better with use of a pessary for treatment of POP from January 1, 2011, to July 31, 2014. Sarma et al. (2009) limited their study to testing only two styles of pessaries for treatment of women with POP. Their study included 273 women who were seen from 1992 to 2002 and treated for POP with use of a pessary; as of their published date of 2009, only 23 (8%) of those women had continued to use one of the two pessaries.

Limitations

This QI project was limited by the small sample size of 10 patients for the first PDSA cycle. This sample was reduced even more when separated into two subpopulations, seven professionally managed patients and three patient managed patients. In the future, a larger sample size would be used.

The data were limited as only documented data were used. Data, which were de-identified, were taken directly from the data sources documented in the EHR during an encounter. There was no modification of the data taken from the EHR. There was no bias introduced because documented data were used. However, the EHR does not have an automated method to verify the completion of all fields at the time the NP documents the encounter and encounter notes can be signed without verification of all fields being completed.

Several factors of limitations do not apply to this QI project: generalizability and variability of gains. With respect to generalizability, there was no intent to generalize from a QI

project about women in this practice to women of other practices. There is little likelihood that gains, or positive results, will lessen over time. In fact, with continued feedback provided by keeping a pulse on health outcomes, it would be anticipated that the gains would continue to be represented by successful findings of use of a pessary for treatment of POP in future cycles.

Interpretation

Prior to conducting this QI Project, the specialty clinic focused on individual patient outcomes. The results of the QI allow for aggregating outcomes across populations. The expected outcome was the outcome observed, because the provider was unaware of any women in this QI project who were not successfully treated with use of a pessary for treatment of POP. The findings were positive based on objective data for 10 randomly selected women. This QI was done on a small scale initially with one provider's practice. This allowed for testing without great consequence to the specialty clinic as a whole and is the small-scale approach advocated by PDSA (IHI, 2014).

Because of the ability to aggregate outcomes, a provider has the opportunity to study health outcomes of subpopulations and not just of an individual. For example, if a patient has elected to be patient managed but begins to have vaginal irritation or erosion, the provider may decide that the patient must have more frequent encounters to monitor the vaginal irritation until it is improved or it may be necessary for the patient to become professionally managed. If a trend of vaginal irritation is identified in a population of women, it may be reasonable to consider prescribing a vaginal medication (creams, rings, or tablets), for all women who use a pessary for treatment of POP.

Intervention Effectiveness

Interventions are inherently associated with cause and effect, meaning there is an intervention that leads to an outcome. In this QI project the intervention was the development of the data-based practice model. The outcome was the use of the model to evaluate health outcomes

Improving Future Performance

In order to create the model, the data were extracted from the EHR into Microsoft Access for formatting that would allow data analysis. Further analysis was done using Microsoft Excel, which was both a manual and time intensive process. In order to make analysis of health outcomes more efficient, software modifications of the EHR would be required. This would include automated reporting and tools to allow comparisons of patient data elements across multiple encounters. Since the EHR is designed for widespread use, having the EHR developer create custom software for a single clinic may outweigh the costs of the manual extraction of the manual process. Modifications to the EHR may be cost prohibitive for a small specialty clinic to undertake.

Cost

The initial cycle of this QI project was developed and conducted at no expense to the specialty clinic. It was also advantageous that the EHR note templates had previously been customized by the specialty clinic to meet the clinic's needs. This helped with ease of identifying relevant data.

Conclusions

The results of this DNP Project may be of benefit to both potential research as well as other similar practice settings where women are treated for POP with use of a pessary. As this was the first cycle of the QI project, future test cycles will need to be completed in order to better understand the benefits for research and other clinical settings. The value of this data-based practice model is that it has the potential to be used on a larger scale in future PDSA cycles to determine other outcomes in this or other similar clinical populations.

The results of this data-based practice model are from one provider's practice. It would be beneficial to have all providers of the same practice reach consensus on the approach to treatment of POP with the use of a pessary or treatment of other related conditions. This would allow for the data-based practice model to be utilized for the entirety of practice of one specialty clinic. Results could be used to evaluate other outcomes of patient populations of the specialty clinic. Results could be used to guide a provider in making changes to practice to effect change in patient populations as well as their practice operations. Overall, results can be used to enhance health outcomes.

Changes may need to be made within the EHR templates to support capturing additional information that the specialty clinic may use for regularly conducting QI projects. The current EHR does allow the specialty clinic to make limited changes to the existing templates that may help facilitate this but larger changes may be cost prohibitive.

The results determined from this project would also be beneficial in educating other practice providers about treatment of POP with a pessary. This would assist women to get obtain

help from their PCP or to avoid a delay to be seen by a trained specialist for treatment of POP with use of a pessary.

APPENDIX A:

NUMBER OF PATIENTS AND PATIENT ENCOUNTERS

TABLE A1. *Patients and Patient Encounters*

	2011	**2012**	**2013**	**2014**
Specialty clinic unique patients	1,275	1,158	1,162	822
NP unique patients	190	223	393	272
Specialty clinic unique patient encounters	2,907	2,935	3,401	1,656
NP unique patient encounters	208	535	966	476
Specialty clinic POP patients	298	376	544	520
Specialty clinic POP patient encounters	1,048	1,429	2,226	1,137
NP POP patient encounters	153	306	648	317

Note. The data in 2014 represents January 1, 2011, through July 31, 2014.

APPENDIX B:

PATIENT PROFILE DATA ELEMENTS

TABLE B1. *Professionally Managed Patient 1 Encounter Data*

			Patient Complaints											
Enc No.	Days from Initial Enc	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	Yes	No	522	None	• G4 Rect • G4 Cyst • Vag Wall	5 ring with support Evacare	Yes	None
2	14	Follow Up	Yes [a]	No	No	No	No	No	138	None	• G4 Rect • G4 Cyst • Vag Wall	6 ring with support	Yes	None
3	105	Follow Up	No	No	No	No	No	No	55	None	• G4 Rect • G4 Cyst • Vag Wall	6 ring with support	No	None
4	196	Follow Up	No	No	No	No	No	No	21	None	• G4 Rect • G4 Cyst • Vag Wall	6 ring with support	No	None

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.
[a] Pessary moves about.

TABLE B2. *Professionally Managed Patient 2 Encounter Data*

			Patient Complaints											
Enc No.	Days from Initial Enc	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	Yes	No	657	None	• G4 Uterine • Vag Wall	5 donut and 5 oval with support	Yes	None
2	17	Follow Up	No	No	No	No	No	No	0	None	• G4 Uterine • Vag Wall	5 donut and 5 oval with support	No	None
3	115	Follow Up	No	No	No	No	No	Yes [a]	0	None	• G4 Uterine • Vag Wall	5 donut and 5 oval with support	No	None
4	210	Follow Up	No	No	Yes [b]	No	No	No	0	None	• G4 Uterine • Vag Wall	5 donut and 5 oval with support	No	None

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.
[a] Large amount of stool in rectum.
[b] Urinary incontinence. Bladder irritants discussed.

TABLE B3. *Professionally Managed Patient 3 Encounter Data*

Enc No.	Days from Initial Enc	Enc Type	Patient Complaints: Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	No	No	15	None	• G3 Cyst • G1 Rect • G2 Uterine • Vag Wall	5 oval with support	Yes	None
2	18	Follow Up	No	No	No	No	No	No	16	None	• G3 Cyst • G1 Rect • G2 Uterine • Vag Wall	5 oval with support	No	Estradiol
3	109	Follow Up	No	No	No	No	No	No	6	None	• G3 Cyst • G1 Rect • G2 Uterine • Vag Wall	5 oval with support	No	Estradiol
4	151	Follow Up	No	No	Yes	No	No	No	0	Mild	• G3 Cyst • G1 Rect • G2 Uterine • Vag Wall	5 oval with support	No	Estradiol [a]

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

[a] Patient indicates not using cream. Patient counseled to use cream as directed.

TABLE B4. *Professionally Managed Patient 4 Encounter Data*

			Patient Complaints											
Enc No.	Days from Initial Enc	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	Yes	No	195	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	Yes	No
2	14	Follow Up	Yes	No	No	No	No	No	225	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	No	NBC
3	28	Follow Up	No	No	No	No	No	No	101	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	No	NBC
4	87	Problem	No	No	No	No	No	No	249	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	No	NBC
5	185	Follow Up	No	No	No	No	No	No	117	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	No	NBC
6	297	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	No	NBC
7	367	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • Vag Wall	3 ring with support - Evacare	No	NBC

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

TABLE B5. *Professionally Managed Patient 5 Encounter Data*

			Patient Complaints											
Enc No.	Days from Initial Enc	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	Yes	No	0	No	• G2 Cyst • G2 Rect	2 Gellhorn	Yes	Estrace
2	20	Follow Up	No	No	No	No	No	No	0	No	• G2 Cyst • G2 Rect	2 Gellhorn	No	Estrace
3	45	Problem	Yes [a]	No	No	No	No	No	0	No	• G2 Cyst • G2 Rect	2 Gellhorn	No	Estrace
4	118	Follow Up	No	No	No	No	No	No	6	No	• G2 Cyst • G2 Rect	2 Gellhorn	No	Estrace
5	227	Follow Up	No	No	No	No	No	No	0	No	• G2 Cyst • G2 Rect	2 Gellhorn	No	Estrace
6	318	Follow Up	No	No	No	No	No	No	0	No	• G2 Cyst • G2 Rect	2 Gellhorn	No	Estrace
7	412	Follow Up	No	No	No	No	No	No	0	No	• G2 Cyst • G2 Rect	2 Gellhorn	No	Estrace

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

[a] Feels like coming down.

TABLE B6. *Professionally Managed Patient 6 Encounter Data*

			Patient Complaints											
Enc No.	Days from Initial Enc	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	Yes	No	51	None	• G3 Cyst • G1 Rect • Vag Wall	2.75 Gellhorn	No	NBC
2	3	Problem	Yes [a]	No	No	No	No	No	0	None	• G3 Cyst • G1 Rect • Vag Wall	4 donut	No	NBC
3	7	Problem	Yes	No	No	No	No	No	80	None	• G3 Cyst • G1 Rect • Vag Wall	4 donut	No	NBC
4	14	Problem	Yes	No	No	No	No	No	0	None	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
5	42	Follow Up	No	Yes	No	No	No	No	32	None	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
6	91	Follow Up	No	Yes	No	No	No	No	19	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
7	133	Follow Up	No	Yes	No	No	No	No	26	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
8	196	Follow Up	No	Yes	No	No	No	No	11	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
9	287	Follow Up	No	Yes	No	No	No	No	17	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
10	336	Follow Up	No	Yes	No	No	No	No	63	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
11	378	Follow Up	No	Yes	No	No	No	No	29	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC
12	483	Follow Up	No	Yes	No	No	No	No	28	Moderate	• G3 Cyst • G1 Rect • Vag Wall	5 cube	No	NBC

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.
[a] The pessary did not fall out, but the patient feels prolapsing around the pessary.

TABLE B7. *Professionally Managed Patient 7 Encounter Data*

Enc No.	Days from Initial Enc	Enc Type	Patient Complaints					Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
			Pess Fell Out	Spotting	Leaking	Pain	IBE							
1	0	New	No	No	No	Yes	Yes	No	59	None	• G2 Cyst • G1 Rect	3 Ring with Support	Yes	None
2	13	Follow Up	Yes [a]	No	No	No	No	No	202	None	• G2 Cyst • G1 Rect	5 Ring with support	Yes	None
3	49	Follow Up	No	No	No	No	No	No	22	None	• G2 Cyst • G1 Rect	5 Ring with support	No	None
4	140	Follow Up	No	No	No	No	No	No	5	None	• G2 Cyst • G1 Rect	5 Ring with support	No	None
5	231	Follow Up	No	No	No	No	No	No	0	Mild	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
6	322	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
7	427	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
8	510	Follow Up	No	No	No	No	No	No	0	Mild	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC [b]
9	601	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
10	692	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
11	783	Follow Up	No	No	No	No	No	No	0	Mild	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
12	874	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
13	965	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
14	1056	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC
15	1147	Follow Up	No	No	No	No	No	No	20	None	• G2 Cyst • G1 Rect	5 Ring with support	No	NBC

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

[a] The pessary did not fall out, but the patient feels prolapsing around the pessary.

[b] The pessary did not fall out, but the patient feels prolapsing around the pessary. The patient was not using the NBC as directed and was re-educated.

TABLE B8. *Patient Managed 1 Encounter Data*

Enc No.	Days from Initial Enc	Enc Type	Patient Complaints: Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	No	No	0	None	• G3 Rect • G1 Cyst • Vag Wall	2 Gellhorn	Yes	None
2	18	Follow Up	No	No	No	No	No	No	34	Mild	• G3 Rect • G1 Cyst • Vag Wall	2 Gellhorn	No	Estrace
3	109	Follow Up	No	No	No	No	No	No	4	None	• G3 Rect • G1 Cyst • Vag Wall	2 Gellhorn	No	Estrace
4	305	Follow Up	Yes [a]	No	No	No	No	No	0	None	• G3 Rect • G1 Cyst • Vag Wall	2 Gellhorn	No	Estrace

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.
[a] Fell out twice.

TABLE B9. *Patient Managed 2 Encounter Data*

Enc No.	Days from Initial Enc	Enc Type	Patient Complaints: Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	0	No	Yes	Yes	Yes	0	62	None	• G4 Cyst • Vag Wall	6 ring with support	New fitting	None
2	4	Problem	No	No	Yes [a]	Yes [b]	No	No	0	None	• G4 Cyst • Vag Wall	6 ring with support	No	NBC [c]
3	17	Follow Up	No	No	Yes [d]	No	No	No	0	None	• G4 Cyst • Vag Wall	6 ring with support	No	NBC [c]
4	53	Follow Up	No	No	No	No	No	No	0	None	• G4 Cyst • Vag Wall	6 ring with support	No	NBC [c]
5	200	Follow Up	Yes [e]	No	No	No	No	No	53	None	• G4 Cyst • Vag Wall	8 oval with support	Yes	NBC [f]

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.
[a] Increased urination.
[b] Increased urination and pain with urination.
[c] To assist with tissue health.
[d] Increased urination. Patient educated on biofeedback to help with urinary incontinence. The patient was also taught how to remove and insert the pessary.
[e] Patient indicated that it feels like the prolapse is going over the pessary. A new pessary was fit.
[f] Patient stopped using the NBC. Patient was directed to use the NBC as directed (2-3x per week).

TABLE B10. *Patient Managed 3 Encounter Data*

			Patient Complaints											
Enc No.	Days from Initial Enc	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan (ml)	Vag Irr	Prolapse Grade & Type	Pess in Use	Pess Changed	Vag Tx
1	0	New	No	No	Yes	Yes	Yes	No	0	None	• G2 Cyst • Vag Wall	4 Ring with support	Yes	None
2	19	Follow Up	Yes	No	No	No	No	No	0	None	• G2 Cyst • Vag Wall	2 Gellhorn	Yes	None
3	145	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • Vag Wall	2 Gellhorn	No	None
4	392	Follow Up	No	No	No	Yes	No	Yes	0	Mild	• G2 Cyst • Vag Wall	2 Gellhorn	No	None
5	480	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • Vag Wall	2 Gellhorn	No	None
6	676	Follow Up	No	No	No	No	No	No	0	None	• G2 Cyst • Vag Wall	2 Gellhorn	No	None
7	830	Follow Up	No	Yes	No	No	No	No	0	Mild	• G2 Cyst • Vag Wall	2 Gellhorn	No	None

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; V Tx = Treatment; Vag = Vaginal.

APPENDIX C:

DECISION RULE 1 – SCALE TABLES AND GRAPHS

TABLE C1. *Professionally Managed Patient 1 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	12	0	0	0	1	1	1	0	4	0	4	1	0
2	14	8	0	1	0	0	0	0	0	2	0	4	1	0
3	105	5	0	0	0	0	0	0	0	1	0	4	0	0
4	196	5	0	0	0	0	0	0	0	1	0	4	0	0

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Tx = Treatment; Vag = Vaginal.

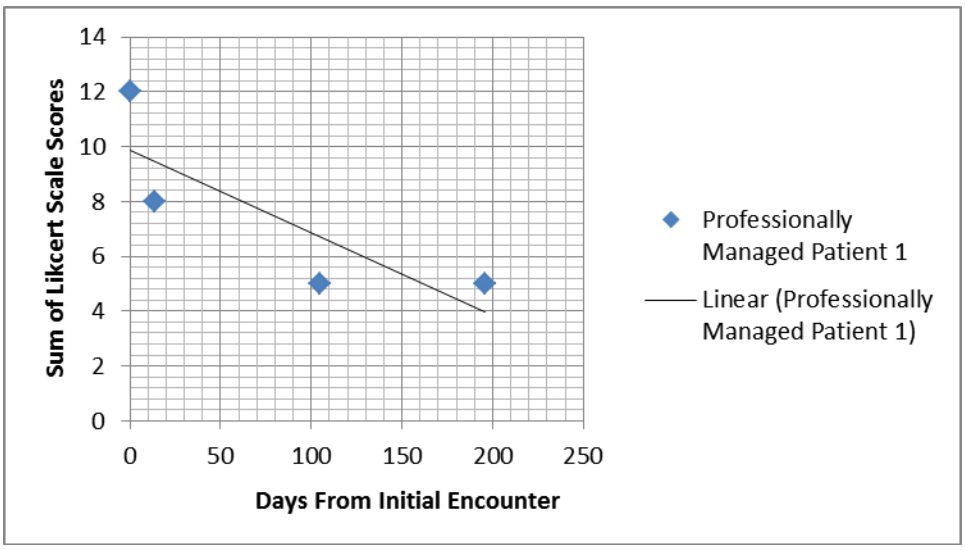

FIGURE C1. *Graph of Professionally Managed Patient 1 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C2. *Professionally Managed Patient 2 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	12	0	0	0	1	1	1	0	4	0	4	1	0
2	17	5	0	0	0	0	0	0	0	1	0	4	0	0
3	115	6	0	0	0	0	0	0	1	1	0	4	0	0
4	210	6	0	0	0	1	0	0	0	1	0	4	0	0

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

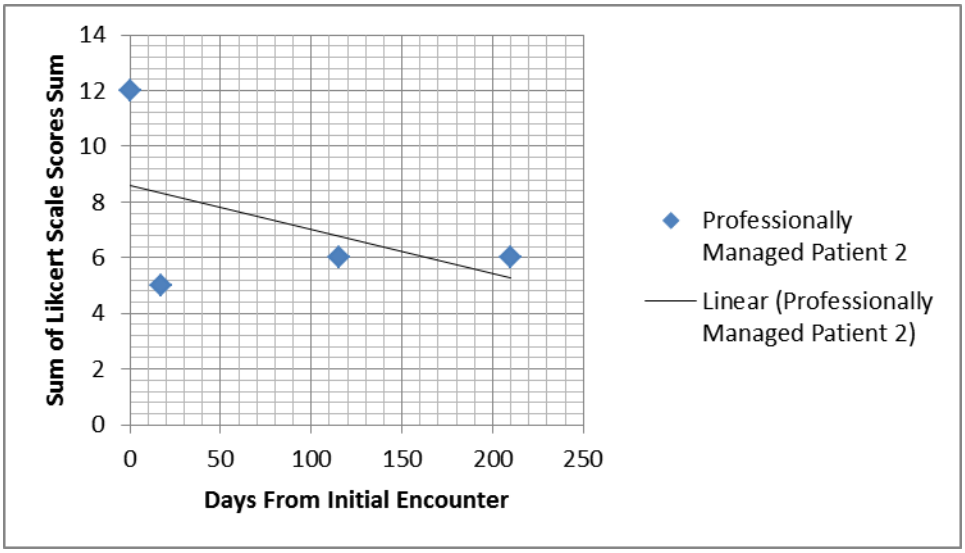

FIGURE C2. *Graph of Professionally Managed Patient 2 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C3. *Professionally Managed Patient 3 Scale Scores (Decision Rule 1)*

					Patient Complaints									
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irritation	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	7	0	0	0	1	1	0	0	1	0	3	1	0
2	17	5	0	0	0	0	0	0	0	1	0	3	0	1
3	115	5	0	0	0	0	0	0	0	1	0	3	0	1
4	210	6	0	0	0	0	0	0	0	1	1	3	0	1

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

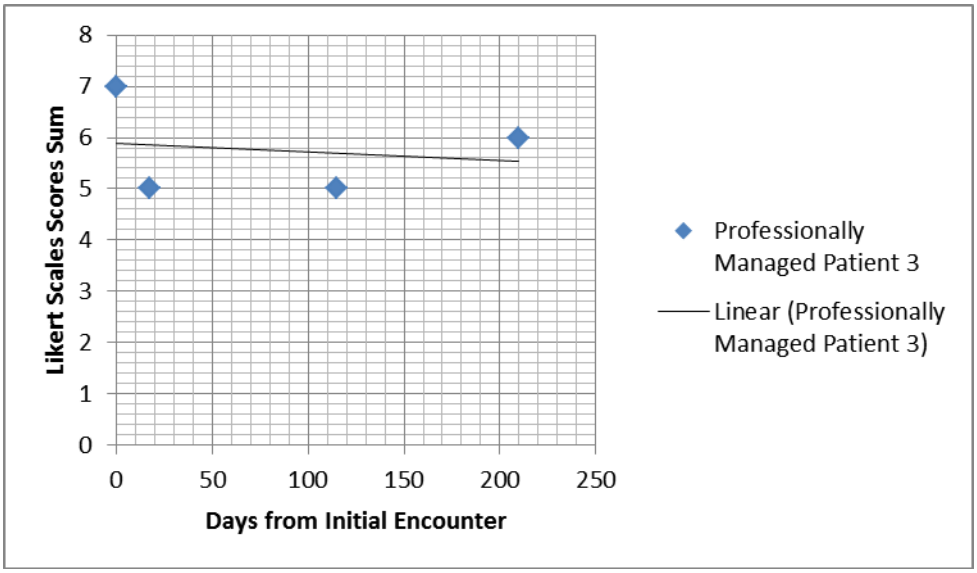

FIGURE C3. *Graph of Professionally Managed Patient 3 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C4. *Professionally Managed Patient 4 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	9	0	0	0	1	1	1	0	3	0	2	1	0
2	14	7	0	1	0	0	0	0	0	3	0	2	0	1
3	28	5	0	0	0	0	0	0	0	2	0	2	0	1
4	87	7	1	0	0	0	0	0	0	3	0	2	0	1
5	185	5	0	0	0	0	0	0	0	2	0	2	0	1
6	297	4	0	0	0	0	0	0	0	1	0	2	0	1
7	367	4	0	0	0	0	0	0	0	1	0	2	0	1

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; TX = Treatment; Vag = Vaginal.

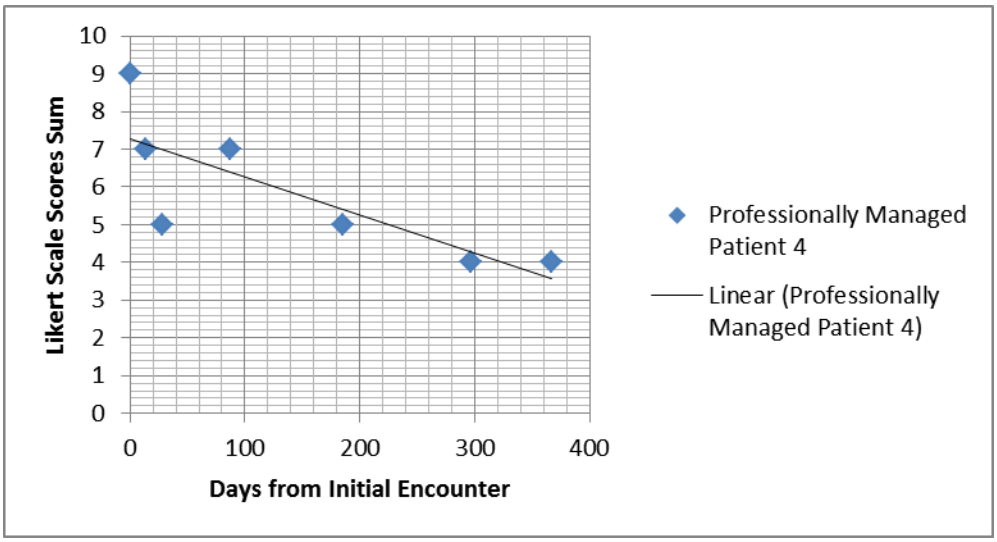

FIGURE C4. *Graph of Professionally Managed Patient 4 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C5. *Professionally Managed Patient 5 Scale Scores (Decision Rule 1)*

Enc No.	Days	Scale Scores Sum	Enc Type	Patient Complaints: Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	9	1	0	0	1	1	1	0	1	0	2	1	1
2	20	4	0	0	0	0	0	0	0	1	0	2	0	1
3	45	5	0	1	0	0	0	0	0	1	0	2	0	1
4	118	4	0	0	0	0	0	0	0	1	0	2	0	1
5	227	4	0	0	0	0	0	0	0	1	0	2	0	1
6	318	4	0	0	0	0	0	0	0	1	0	2	0	1
7	412	4	0	0	0	0	0	0	0	1	0	2	0	1

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Vag = Vaginal.

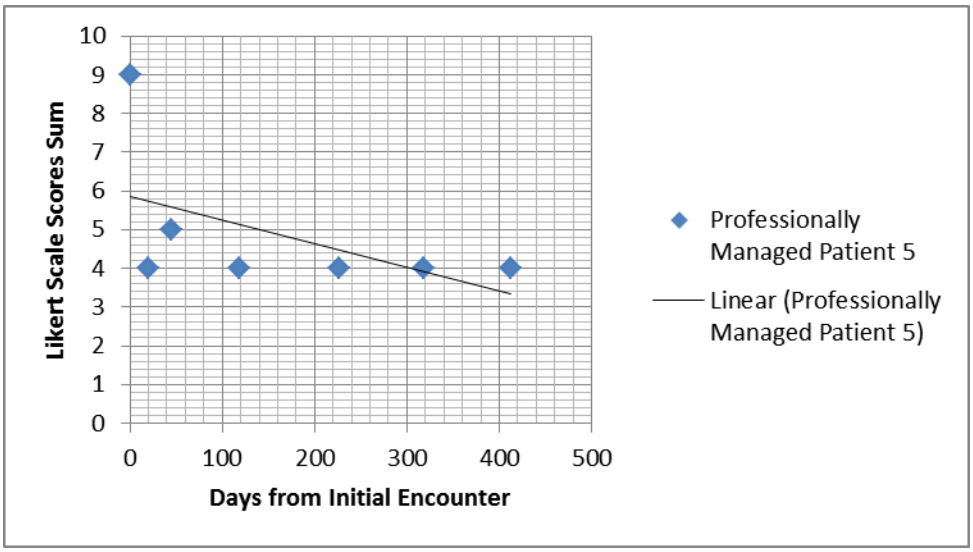

FIGURE C5. *Graph of Professionally Managed Patient 5 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C6. *Professionally Managed Patient 6 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	8	0	0	0	1	1	0	0	1	0	3	1	1
2	3	9	1	1	0	0	0	0	1	1	0	3	1	1
3	7	9	1	1	0	0	0	0	0	2	0	3	1	1
4	14	8	1	1	0	0	0	0	0	1	0	3	1	1
5	42	6	0	0	0	0	0	0	1	1	0	3	0	1
6	91	7	1	0	0	0	0	0	0	0	2	3	0	1
7	133	7	1	1	0	0	0	0	0	1	0	3	0	1
8	196	5	0	0	0	0	0	0	0	1	0	3	0	1
9	287	6	0	0	0	1	0	0	0	1	0	3	0	1
10	336	10	0	1	1	0	0	0	0	2	2	3	0	1
11	378	8	0	0	1	0	0	0	0	1	2	3	0	1
12	483	8	0	0	1	0	0	0	0	1	2	3	0	1

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

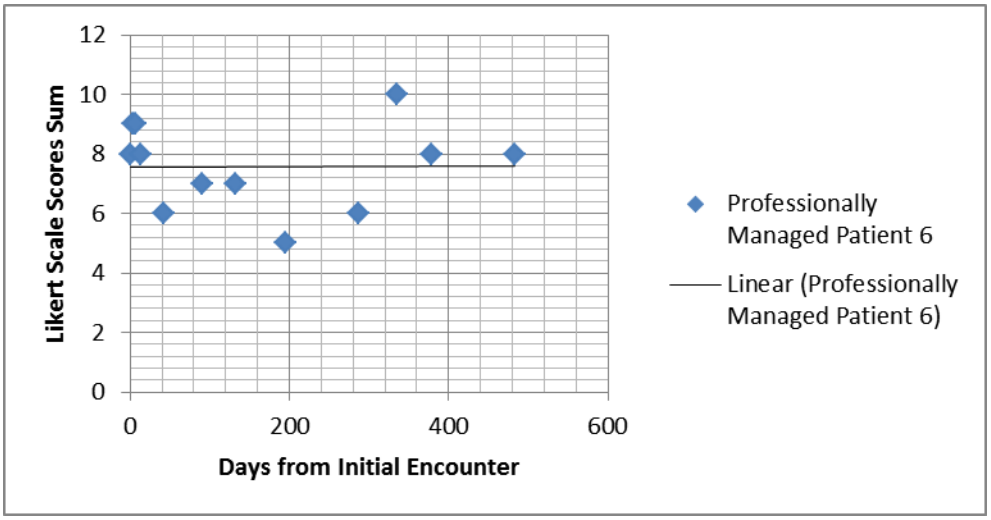

FIGURE C6. *Graph of Professionally Managed Patient 6 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C7. *Professionally Managed Patient 7 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	6	0	0	0	0	1	1	0	1	0	2	1	0
2	13	7	0	1	0	0	0	0	0	3	0	2	1	0
3	49	3	0	0	0	0	0	0	0	1	0	2	0	0
4	140	3	0	0	0	0	0	0	0	1	0	2	0	0
5	231	5	0	0	0	0	0	0	0	1	1	2	0	1
6	322	4	0	0	0	0	0	0	0	1	0	2	0	1
7	427	4	0	0	0	0	0	0	0	1	0	2	0	1
8	510	5	0	0	0	0	0	0	0	1	1	2	0	1
9	601	4	0	0	0	0	0	0	0	1	0	2	0	1
10	692	4	0	0	0	0	0	0	0	1	0	2	0	1
11	783	5	0	0	0	0	0	0	0	1	1	2	0	1
12	874	4	0	0	0	0	0	0	0	1	0	2	0	1
13	965	4	0	0	0	0	0	0	0	1	0	2	0	1
14	1056	4	0	0	0	0	0	0	0	1	0	2	0	1
15	1147	4	0	0	0	0	0	0	0	1	0	2	0	1

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

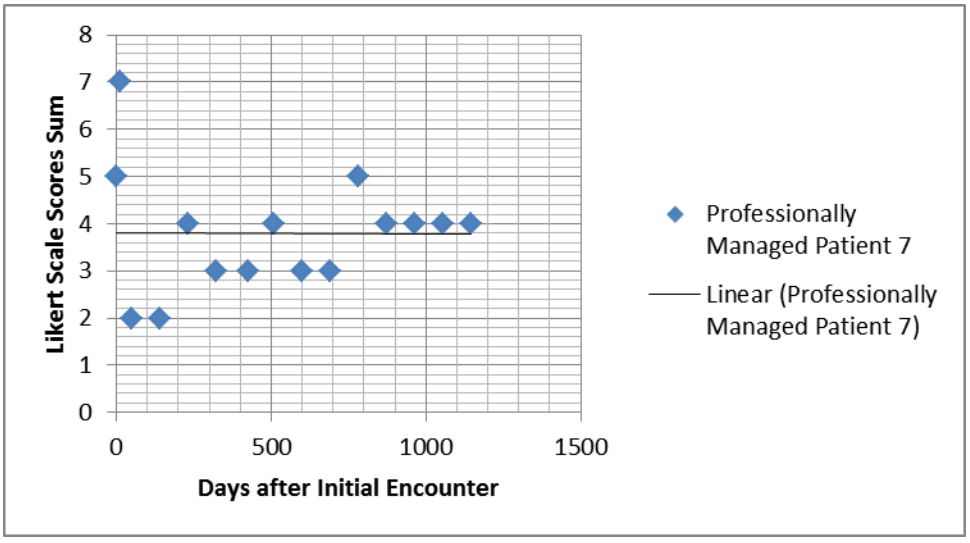

FIGURE C7. *Graph of Professionally Managed Patient 7 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C8. *Patient Managed 1 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	7	0	0	0	1	1	0	0	1	0	3	1	0
2	18	6	0	0	0	0	0	0	0	1	1	3	0	1
3	109	5	0	0	0	0	0	0	0	1	0	3	0	1
4	305	6	0	1	0	0	0	0	0	1	0	3	0	1

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Vag = Vaginal.

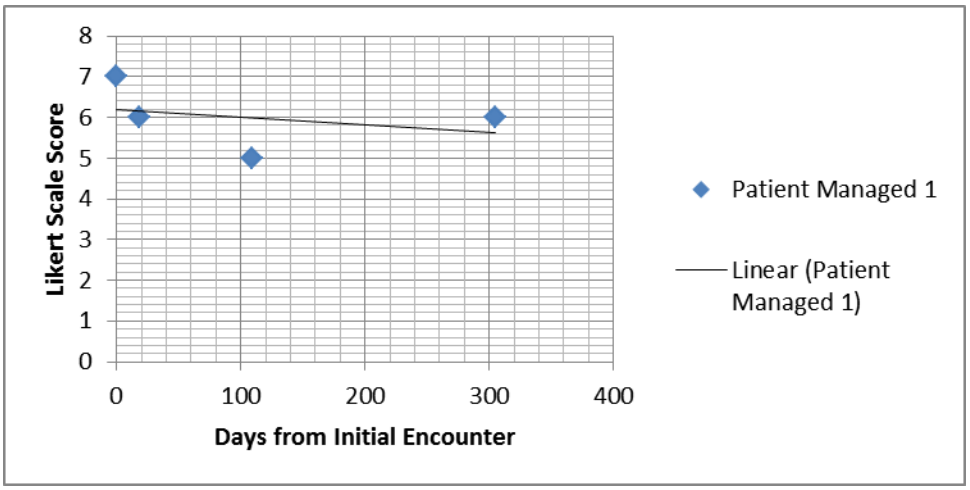

FIGURE C8. *Graph of Patient Managed 1 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C9. *Patient Managed 2 Scale Scores (Decision Rule 1)*

				Patient Complaints										
Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	10	0	0	0	1	1	1	0	2	0	4	1	0
2	4	8	1	0	0	1	0	0	0	1	0	4	0	1
3	17	7	0	0	0	1	0	0	0	1	0	4	0	1
4	53	6	0	0	0	0	0	0	0	1	0	4	0	1
5	200	7	0	0	0	0	0	0	0	1	0	4	1	1

Note: Cyst = Cystocele; Enc = Encounter; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

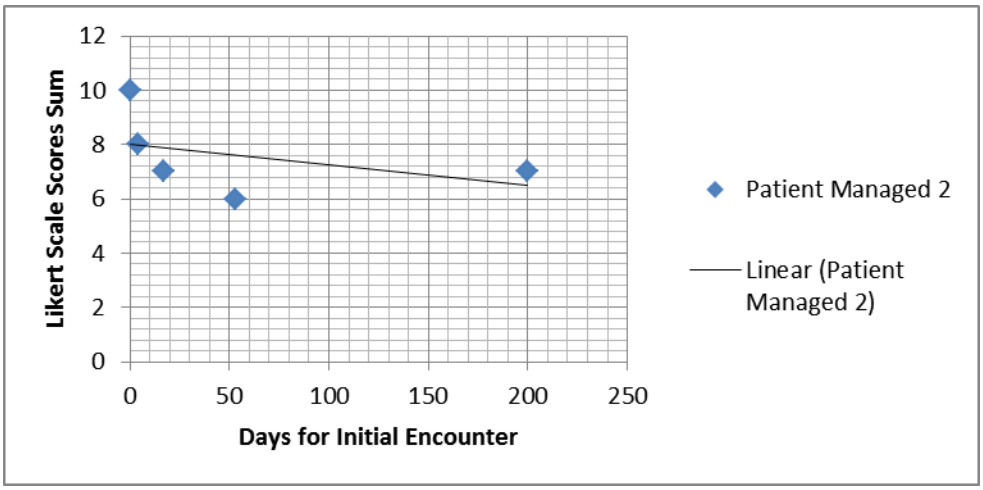

FIGURE C9. *Graph of Patient Managed 2 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

TABLE C10. *Patient Managed 3 Scale Scores (Decision Rule 1)*

Enc No.	Days from Initial Enc	Scale Scores Sum	Enc Type	Patient Complaints: Pess Fell Out	Spotting	Leaking	Pain	IBE	Pess Difficult to Remove	PVR Bladder Scan	Vag Irr	Prolapse Grade & Type	Pess Changed	Vag Tx
1	0	9	0	0	0	1	1	1	0	0	0	2	2	2
2	19	7	0	1	0	0	0	0	0	0	0	2	2	2
3	145	6	0	0	0	0	0	0	0	0	0	2	2	2
4	392	6	0	0	0	0	1	0	1	1	1	2	0	0
5	480	3	0	0	0	0	0	0	0	1	0	2	0	0
6	676	3	0	0	0	0	0	0	0	1	0	2	0	0
7	830	4	0	0	0	0	0	0	0	1	1	2	0	0

Note: Cyst = Cystocele; G=Grade; IBE = Incomplete Bladder Emptying; Irr = Irritation; No. = Number; Pess = Pessary; PVR = Post Void Residual; Rect = Rectocele; Tx = Treatment; Vag = Vaginal.

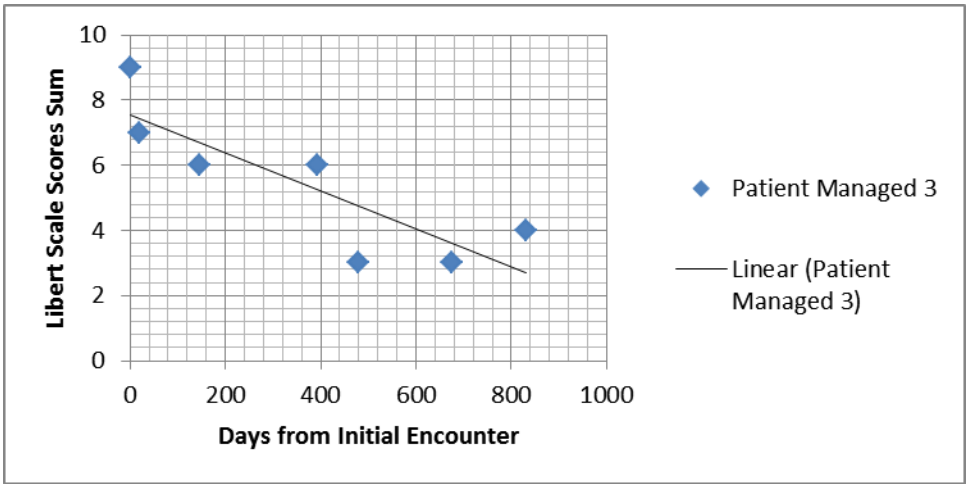

FIGURE C10. *Graph of Patient Managed 3 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 1)*

APPENDIX D:

DECISION RULE 2 – SCALE TABLES AND GRAPHS

TABLE D1. *Professionally Managed Patient 1 Scale Scores (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	7	1	1	1	4
2	14	2	0	0	0	2
3	105	1	0	0	0	1
4	196	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual; Tx = Treatment.

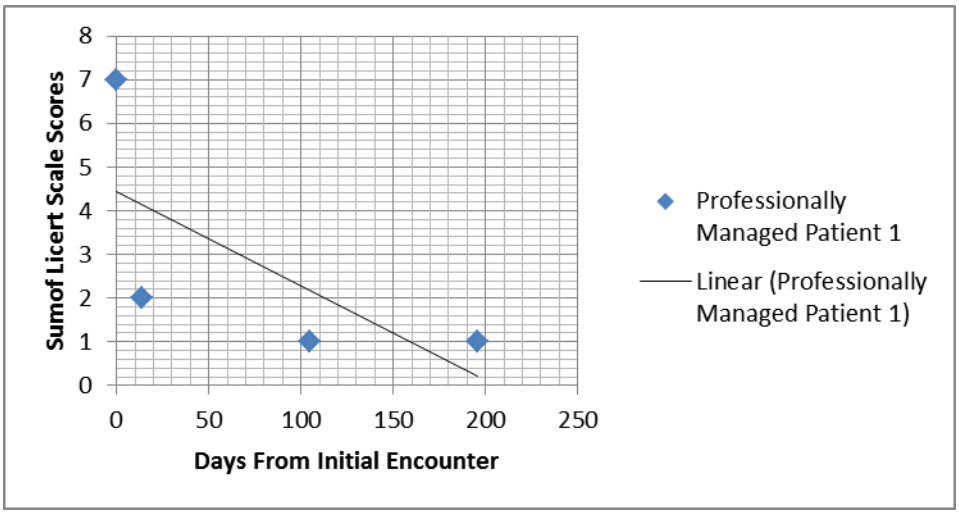

FIGURE D1. *Graph of Professionally Managed Patient 1 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D2. *Professionally Managed Patient 2 Scale Scores (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	7	1	1	1	4
2	17	1	0	0	0	1
3	115	1	0	0	0	1
4	210	2	1	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual; TX=Treatment.

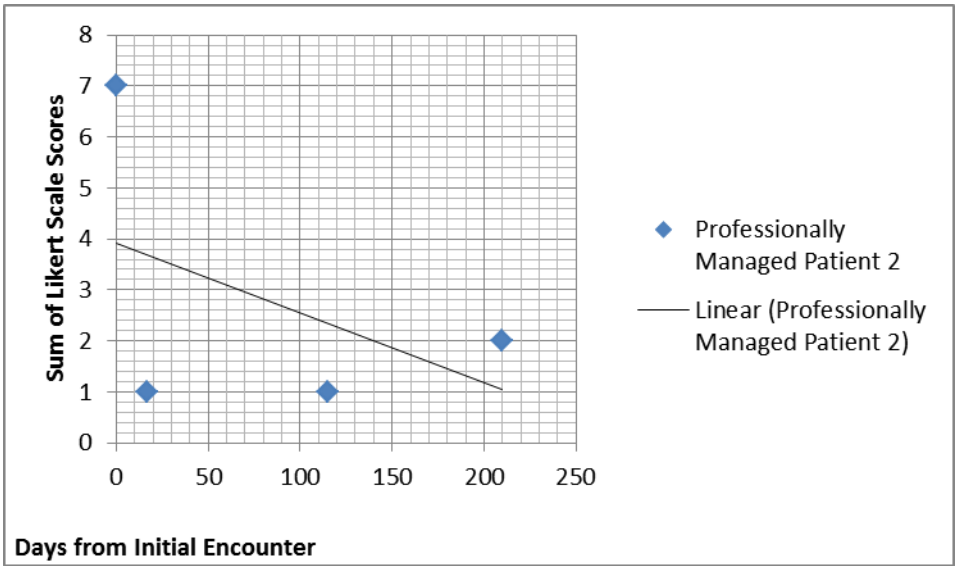

FIGURE D2. *Graph of Professionally Managed Patient 2 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D3. *Professionally Managed Patient 3 Scale Scores (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	3	1	1	0	1
2	17	1	0	0	0	1
3	115	1	0	0	0	1
4	210	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

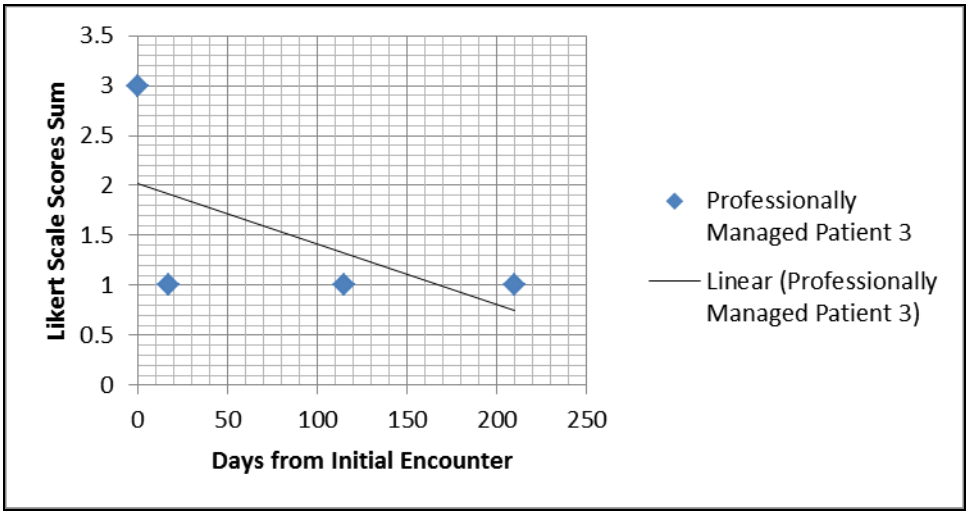

FIGURE D3. *Graph of Professionally Managed Patient 3 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D4. *Professionally Managed Patient 4 Scale Scores (Decision Rule 2)*

			Patient Complaints			
Enc No	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	6	1	1	1	3
2	14	3	0	0	0	3
3	28	2	0	0	0	2
4	87	3	0	0	0	3
5	185	2	0	0	0	2
6	297	1	0	0	0	1
7	367	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

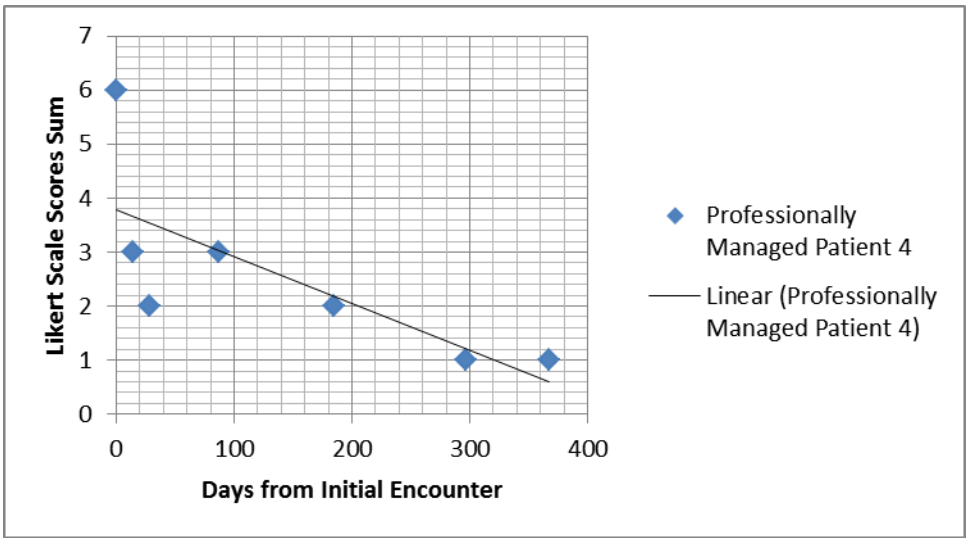

FIGURE D4. *Graph of Professionally Managed Patient 4 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D5. *Professionally Managed Patient 5 Scale Scores (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	4	1	1	1	1
2	20	1	0	0	0	1
3	45	1	0	0	0	1
4	118	1	0	0	0	1
5	227	1	0	0	0	1
6	318	1	0	0	0	1
7	412	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

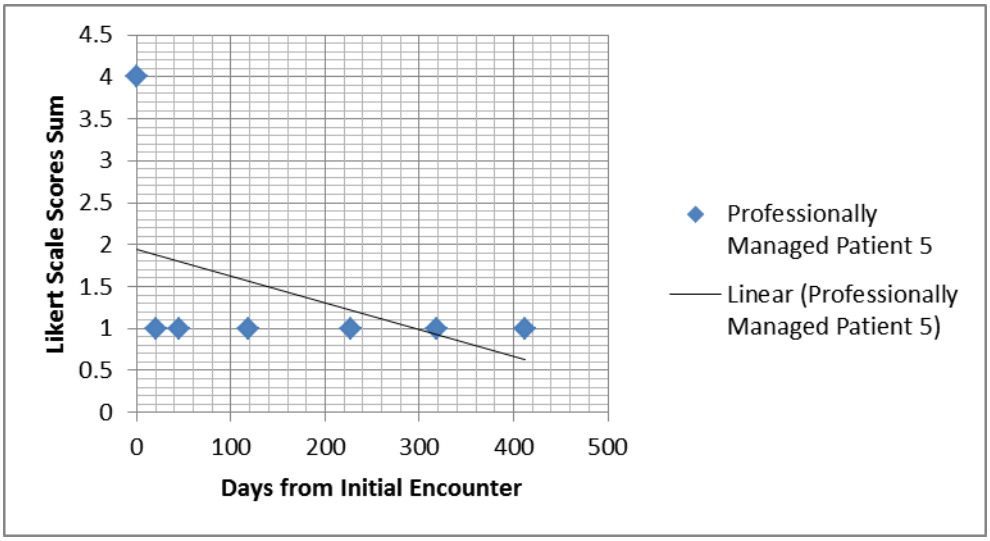

FIGURE D5. *Graph of Professionally Managed Patient 5 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D6. *Professionally Managed Patient 6 Score Scales (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	3	1	1	0	1
2	3	1	0	0	0	1
3	7	2	0	0	0	2
4	14	1	0	0	0	1
5	42	1	0	0	0	1
6	91	1	0	0	0	1
7	133	1	0	0	0	1
8	196	1	0	0	0	1
9	287	2	1	0	0	1
10	336	2	0	0	0	2
11	378	1	0	0	0	1
12	483	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

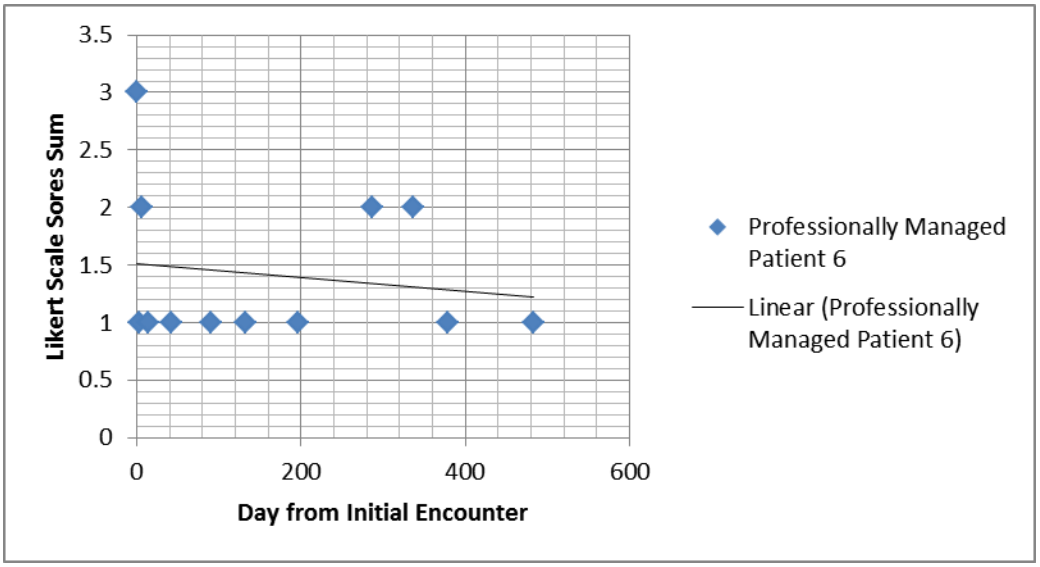

FIGURE D6. *Graph of Professionally Managed Patient 6 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D7. *Professionally Managed Patient 7 Score Scales (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	3	0	1	1	1
2	13	3	0	0	0	3
3	49	1	0	0	0	1
4	140	1	0	0	0	1
5	231	1	0	0	0	1
6	322	1	0	0	0	1
7	427	1	0	0	0	1
8	510	1	0	0	0	1
9	601	1	0	0	0	1
10	692	1	0	0	0	1
11	783	1	0	0	0	1
12	874	1	0	0	0	1
13	965	1	0	0	0	1
14	1056	1	0	0	0	1
15	1147	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

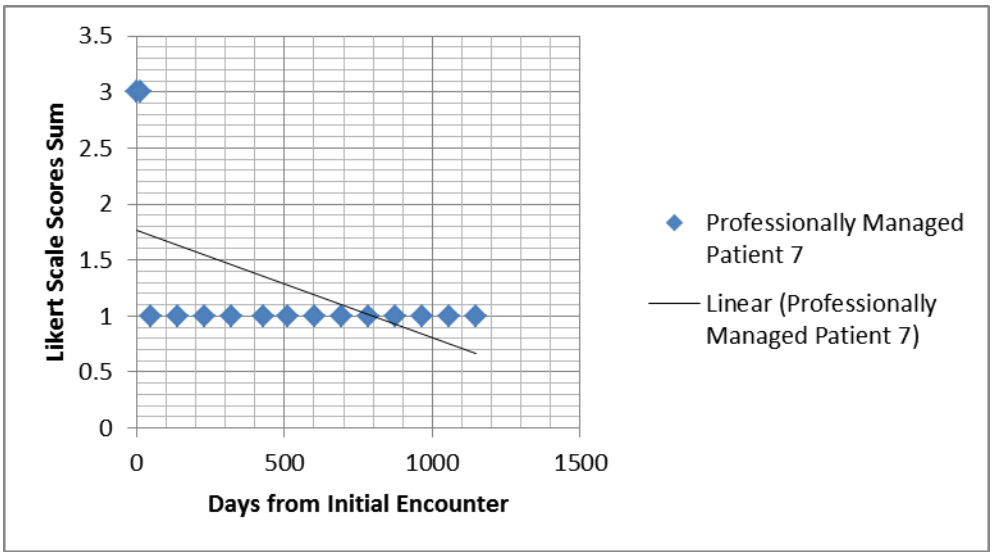

FIGURE D7. *Graph of Professionally Managed Patient 7 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D8. *Patient Managed 1 Score Scales (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	3	1	1	0	1
2	18	1	0	0	0	1
3	109	1	0	0	0	1
4	305	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

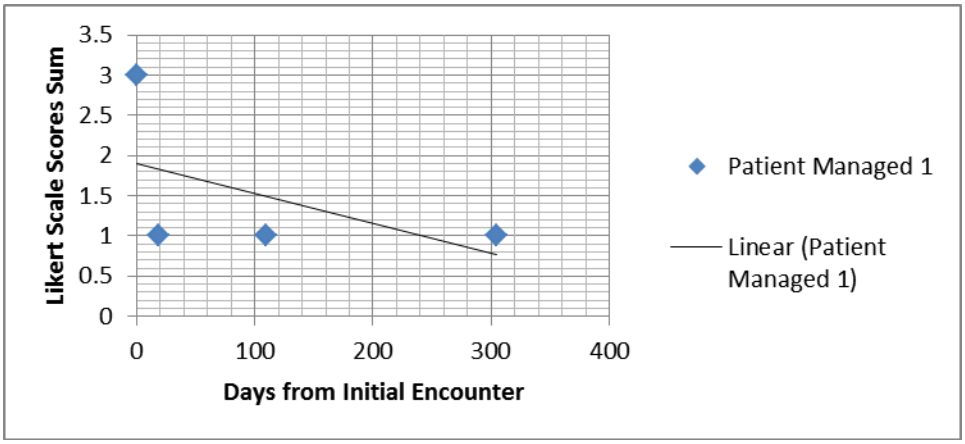

FIGURE D8. *Graph of Patient Managed 1 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D9. *Patient Managed 2 Scale Scores (Decision Rule 2)*

			Patient Complaints			
Enc No.	Days from Initial Enc	Scale Scores Sum	Leaking	Pain	IBE	PVR Bladder Scan
1	0	5	1	1	1	2
2	4	2	1	0	0	1
3	17	2	1	0	0	1
4	53	1	0	0	0	1
5	200	1	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

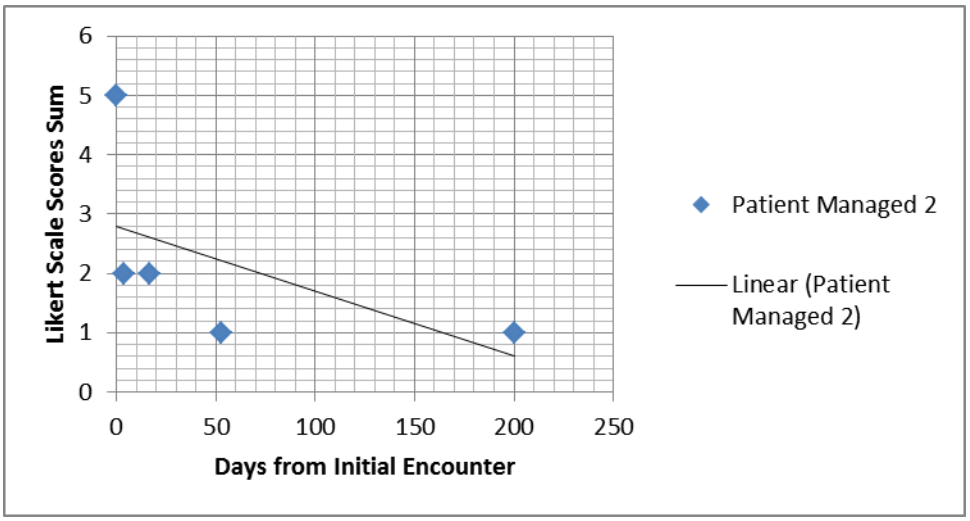

FIGURE D9. *Graph of Patient Managed 2 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

TABLE D10. *Patient Managed 3 Scale Scores (Decision Rule 2)*

			Patient Complaints				
Enc No.	Days from Initial Enc	Scale Scores Sum	Spotting	Leaking	Pain	IBE	PVR Bladder Scan
1	0	4	0	1	1	1	1
2	19	1	0	0	0	0	1
3	145	1	0	0	0	0	1
4	392	2	0	0	1	0	1
5	480	1	0	0	0	0	1
6	676	1	0	0	0	0	1
7	830	1	0	0	0	0	1

Note: Enc = Encounter; IBE = Incomplete Bladder Emptying; No. = Number; PVR = Post Void Residual.

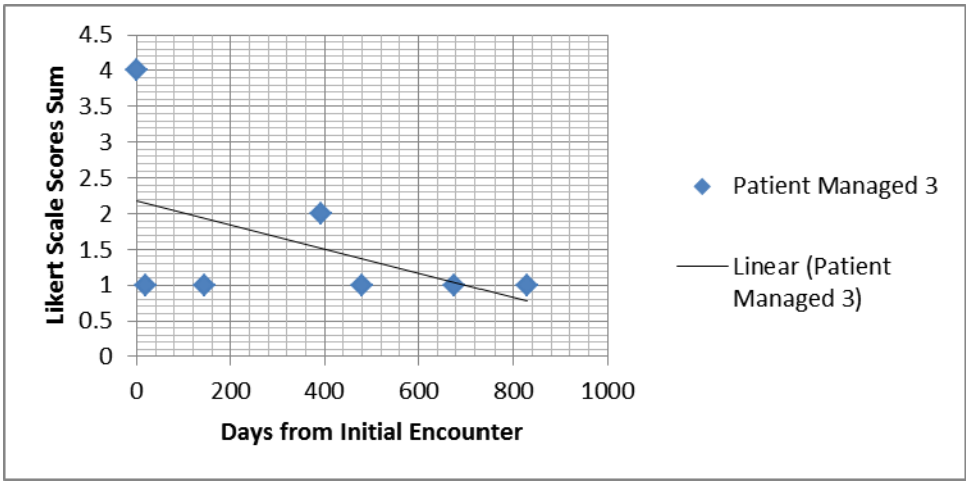

FIGURE D10. *Graph of Patient Managed 3 Scale Scores Sum vs. Days from Initial Encounter (Decision Rule 2)*

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