Implementing a Contraception Patient Decision Aid on a Rural Native American Reservation

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Abstract (problem, background, methods, interventions, results, conclusion)

Background In the United States, 51% percent of pregnancies are unplanned and contraception misuse is the primary cause. Unplanned pregnancies may lead to poor health and social outcomes for the pregnant person and the fetus. American Indians/Alaska Natives are at risk for negative outcomes due to socioeconomic inequity. To address contraception disuse, providers must deliver education and employ shared decision-making within the context of the patient's experiences. The "MyBirthControl" patient decision aid (pDA) offers educational modules and allows input of patient preferences. ***Methods*** The pDA was utilized over eight weeks within a primary care clinic on a rural reservation. Matched provider surveys and unmatched patient surveys elicited knowledge, attitudes, and perceptions (KAP) of contraception counseling. ***Findings*** Results showed that for patient survey questions regarding their perceptions of knowledge gained after pDA use, comfort with their contraception choice, and perception that providers considered their preferences, 27 out of 27 patients agreed (95% CI, [0.873, 1]). For question four regarding whether they would like to use pDAs for other health decisions, 26 out of 27 patients agreed (95% CI [0.81, 0.1]) The true proportion of respondents who would "agree" with each question is between 81% and 100% [$p<0.001$, 95% CI]. Five providers were surveyed to determine their knowledge, attitudes, and perceptions regarding contraception counseling before and after pDA use and there were small increases in the average effect for all questions except questions six, seven, and eight, there were no statistically significant changes after pDA use. ***Interpretation*** pDA use improved patient KAP of contraception counseling. Providers reported clinically significant improvements in some aspects of contraception counseling, but the results were not statistically significant. PDAs offer a streamlined approach to shared decision-making and help ensure patient autonomy.

Keywords: Patient decision aid, contraception, American Indian, birth control, shared decision-making, quality improvement

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Problem Description

In the United States, 51% of pregnancies are unplanned and 95% of these pregnancies are due to incorrect use or disuse of contraception methods (Guttmacher Institute, n.d.; Office of Disease Prevention and Health Promotion, n.d.). The effects of unplanned pregnancies on the patient and fetus are numerous and the causes for contraception disuse are multifactorial. Patients with an unplanned pregnancy are at increased risk for depression, domestic violence, lower educational attainment and income, and are less likely to have sufficient prenatal care. Infants of unwanted pregnancies have lower rates of breastfeeding and increased risks of teratogenic exposure, congenital disabilities, low birth weight, low educational attainment, and overall poor health later in life (Goossens et al., 2016; Office of Disease Prevention and Health Promotion, n.d.; Tobias & Enriquez, 2018). Factors that impact contraception use include a lack of knowledge about available methods, insufficient access to educational information, contraception misinformation, barriers to care access, insufficient insurance and cost concerns, personal beliefs, partner influence, and fear of provider judgment (Buckingham et al., 2020; Dehlendorf et al., 2019; Dev et al., 2019; Goldhammer et al., 2017; Goossens et al., 2016; Le Guen et al., 2021; Moreira et al., 2019). These barriers impact equitable delivery of reproductive healthcare to women.

Healthy People 2030 aims to increase the number of women who use effective contraception methods from 60.3% (current) to 65.1% (Department of Health and Human Services, n.d.). Measurement of this metric is challenging, and many states have eliminated contraception use measures as they are coercive and target minorities (Fernandez, 2020). The CDC and Office of Population Affairs highlight recommendations including those geared toward facilitating more collaborative discussions with the patient (Centers for Disease Control and Prevention, 2014).

American Indians (AI) and Alaska Natives (AN) are historically marginalized populations that face increased risks for poor health due to systemic racism, historical trauma, and socioeconomic inequity. Among AI/AN pregnancies, 48% are unplanned (Tobias & Enriquez, 2018). Mistrust of the Western medical community has impacts on patient disclosure of medical information, poor adherence to the plan of care, low patient satisfaction, and poor quality of life (Bazargan et al., 2021). To address these issues, the community participating in this Quality Improvement Project (QIP) is prioritizing preventative interventions that improve pregnancy outcomes. Efforts are aimed at improving patient/provider engagement and prioritizing shared decision-making during care encounters.

Available Knowledge

Patient Decision Aids (pDAs) are tools designed to provide information on treatment options, outcomes, risks, and benefits, as well as to clarify patient values and preferences. The goal of a pDA is to balance evidence-based treatments with patient preferences and improve care delivery via shared decision-making and informed consent (Buckingham et al., 2020; Pope, 2022; U.S. Preventive Services Task Force, 2022; Vromans et al., 2019). PDA use is associated with higher healthcare satisfaction, improved knowledge, enhanced adherence to the care plan, better health outcomes, greater patient trust, heightened self-efficacy, decreased hospitalizations and healthcare costs, and less decisional conflict (Perez Jolles et al., 2019; Poprzeczny et al., 2020). A 2022 Cochrane Collaboration studied the effects of pDAs on 31,034 participants and concluded that using a pDA was significantly associated with improved participant knowledge, empowered decision-making, better awareness of risks, and decreased decisional conflict (U.S. Preventive Services Task Force, 2022). PDA implementation is challenging, but both patients and providers may benefit from pDA utilization.

PDAs are underutilized primarily due to a lack of organizational adoption (Elwyn et al., 2016; U.S. Preventive Services Task Force, 2022). Healthcare organizations that recognize the benefits and challenges of pDAs include the Institute of Medicine, the Joint Commission, the National Quality Forum,

and the Agency for Health Care Research and Quality (Pope, 2022). Providers incorporating pDAs into contraception counseling found they improved the visit's focus, efficiency, and structure (Dehlendorf et al., 2019). Providing the patient with the pDA before the visit facilitated more time for discussion by affording the patient time to formulate questions (Buckingham et al., 2020). Based on evaluations, pDA use enhances patient experiences and reduces grievances and legal challenges (Elwyn et al., 2016). Barriers to provider pDA implementation include time constraints and workflow alterations, a lack of training on proper pDA use, mistrust of the content, and low stakeholder buy-in (Glenn & Urquhart, 2019; Scalia et al., 2019). Barriers to patient pDA use include decreased literacy and unfamiliarity with operating smartphones or tablets (Dev et al., 2019).

"My Birth Control" is an internet-based decision support tool created by the University of California, San Francisco's Person-Centered Reproductive Health Program (Dehlendorf et al., n.d.). The tool provides educational modules and method comparison features that allow the patient to input preferences and health history, and to flag questions to review with the provider. Researchers conducting a randomized controlled trial of the "My Birth Control" tool found that it increased patient satisfaction, improved informed contraception choice, and improved knowledge about long-acting reversible contraception (Dehlendorf et al., n.d.). Providers utilizing the tool felt that their patients had greater knowledge about their options and would continue using the pDA in daily practice (Dehlendorf et al., n.d.). PDA use may improve the provision of patient-centered education particularly in vulnerable populations.

Rationale

The historical context of forced sterilization and a traditionally puritanical outlook on pregnancy in Western medicine has led to distrust about contraception among members of the AI/AN community (Knispel, 2019). Additional barriers to care access for the AI/AN population participating in this QIP include inadequate federal funding, scarce staffing, retention issues, and resource limitations within the

rural setting. The tribe's annual health report states that leading causes of death for infants include disorders related to early gestational age, congenital deformities, and fetal malnourishment, which may be related to an unplanned pregnancy. Addressing contraception disuse in AI/ANs requires additional precautions to ensure autonomy and justice. PDA use may improve health equity, give a voice to the disenfranchised, improve patient engagement, and is associated with women's empowerment by enhancing strategic life choices (Perez Jolles et al., 2019; Prata et al., 2017; U.S. Preventive Services Task Force, 2022). Implementation of a standardized pDA, such as "MyBirthControl", may improve patient experiences of contraception counseling, prevent unintended pregnancies, and improve clinician provision of education.

The Institute for Healthcare Improvement (IHI) Model emphasizes innovation and rapid test cycles to understand the causes of improvement (IHI, n.d.). The IHI methodology tests small-scale changes to processes and provides a framework for continuous reassessment to make timely adjustments to the project implementation. Implementing a Plan-Do-Study-Act (PDSA) cycle will guide the implementation of the intervention, assessment for improvement, and evaluation of the approach while monitoring outcomes and unintended consequences (IHI, n.d.).

Specific Aims

To assess if pDA use improves patient knowledge, attitudes, and perceptions (KAP) about contraception, patients will complete a four-question survey after utilizing the "MyBirthControl" pDA. After an eight-week implementation period, at least 50% of patient survey scores will indicate improved KAP (response indicated by "agree"). A sub-aim seeks to discover providers' KAP about contraception counseling after using the pDA and improvements will be demonstrated by an increase of positive responses between pre-and post-intervention surveys.

Methods

Context

The quality improvement project (QIP) setting is a rural primary care clinic on a Native American reservation in the Pacific Northwest. The clinic offers primary and prenatal care during weekday hours. The medical staff includes six providers, five clinical pharmacists, four registered nurses, seven medical/nursing assistants, and four administrative assistants. The clinic serves approximately 6,000 patients and approximately 1,440 are eligible to participate in this project. Most patients are insured by the state Medicaid program and managed through purchased referred care by the tribal managed care entity.

The clinic offers contraceptive options including oral agents, the patch, the vaginal ring, injectable methods, subcutaneous implants, and intrauterine devices; condoms are available throughout the clinic. Patients are referred to an outside facility if they desire surgical sterilization. Abortion medications and procedures are not available.

To be included in the QIP, the patient must have been present for an in-person appointment and have been at least 18 years old with pregnancy potential. Pregnant women in the third trimester were included as family planning for the post-partum period is a part of routine prenatal care. Those excluded from the study were patients under the age of 18, patients who cannot become pregnant due to a lack of functional female reproductive organs (congenital anomalies, post-surgical procedures like tubal ligation or hysterectomy, trans-female patients, or post-menopausal patients), patients who are not sexually active with men, and those who decline to participate.

Intervention

To introduce the QIP, nursing and provider staff received separate educational presentations to learn about the QIP intervention and a second informal "refresher" presentation the day before implementation. The presentation included a handout with a description of the problem, an

introduction to the "My Birth Control" pDA, instructions on how to use the pDA tool, patient eligibility criteria, and the goals of the QIP. Pharmacy staff were sent an email with the same information shared during the presentation but were not in-serviced in person. After the presentation, providers were given a 16-question survey to elicit their KAP about traditional contraception counseling. A staff member distributed and collected the surveys to ensure the QIP lead/author was blind to the respondents. The QIP lead/author did not complete the survey. After the eight-week intervention phase, provider surveys were distributed and collected by the same staff member.

The electronic tablet containing the pDA and patient surveys were placed at the nursing station. Spare surveys and printouts of the pDA website link for later review were placed within the exam rooms. The QIP lead/author reviewed the clinic schedule every morning and notified staff about eligible patients. During the rooming process, participating eligible patients used the pDA and completed a brief survey after the provider visit. The provider addressed options and patient concerns during the visit to facilitate shared decision-making. Completed patient surveys were placed in a file at the nursing station and collected each evening by the QIP lead/author. Responses and medical record numbers (to monitor for duplicate surveys) were stored on an Excel spreadsheet on the clinic's secured computer and the surveys were shredded. After the QIP ended, all data was de-identified.

Study of the Intervention

To study the effects of the QIP on patient KAP, patients were surveyed after pDA use and provider counseling. The one-time survey included four statements to which the patient could either agree or disagree: 1) The tool gave me enough information to make the best birth control decision for me, 2) I am comfortable with the birth control option I made, 3) The provider considered what matters to me about birth control, and 4) I would use tools like this one for other health decisions (Appendix F). The survey measured patients' knowledge of methods, attitudes about contraception, and perception of collaboration after pDA use. Patients who declined to participate were excluded from data analysis.

To study the effects of the QIP on provider KAP, providers were surveyed before and after the implementation phase. The provider surveys included 16 pre- and post-intervention questions (Appendices G & H). The survey assessed for changes in KAP of pDA utility between pre- and post-implementation. Responses were matched to assess for changes over time.

Clinic software was used to collect the number of contraception prescriptions and sterilization referrals for eligible patients ordered each week for eight weeks prior to the intervention and during each week of the implementation phase. De-identified data was stored on Excel spreadsheets. Originally, the implementation phase was planned to last 12 weeks, but this report describes eight weeks due to time constraints.

Measures

The primary outcome measure was patient post-visit survey responses over eight weeks, illustrating the pDA's impact on the patient's KAP about contraception. The KAP framework was utilized to measure and enhance human behavior as improvements in knowledge and health beliefs are associated with healthy behaviors (Fan et al., 2018). Survey questions were developed based on validated, patient-centered surveys endorsed by the National Quality Forum and altered to reflect the goals of the QIP. Survey responses marked "agree" would indicate a positive impact on the patient's KAP during the contraception counseling visit which was the goal of the intervention.

A secondary outcome measure was the demonstration of an improvement in provider KAP about integrating the pDA during office visits over the eight-week period. Survey questions one through four were developed to elicit provider perceptions of patient knowledge about contraception, questions five through 10 elicit provider perceptions of patient attitude toward contraception, and questions 11 through 16 elicit provider perceptions related to contraception counseling. The goal was to discover if pDA use improved provider KAP about contraception counseling.

Process measures aimed to identify any increase in the number of contraception prescriptions and sterilization referrals associated with a provider visit. This was assessed by comparing rates eight weeks prior to and during the eight-week implementation phase. Increasing these numbers was not a goal of this project, but served to assess whether pDA use impacted the uptake of contraception.

Balancing measures examine unintended consequences and were monitored during the implementation phase. Anticipated barriers included time constraints and patient aversions around pDA technology use. Balancing measures were monitored through the exploration of staff experience during the implementation phase and patient responses about their reasons for declining to participate.

Analysis

To analyze patient survey data, binomial exact testing and confidence intervals were completed for each survey question, and the data was displayed with bar graphs (Appendices M & N). Similarly, the sub-aim was analyzed using Likert scale scores of staff pre- and post-intervention survey results. Outcomes were analyzed using paired sample *t*-tests for each survey question to determine the probability, confidence intervals, and mean differences between pre-and post-survey responses for all providers and were displayed using a bar chart (Appendix O). Excel spreadsheets were used to analyze both the inventoried unmatched cross-sectional patient survey results and the matched provider results.

Process measures monitored the QIP's progress. Run charts displayed the rates of contraception prescriptions and sterilization referrals. Factors affecting common variation included the number of eligible patients who presented during the implementation phase, staff absences, and clinic closures. Changes made to the project based on balancing measures were noted.

Ethical Considerations

Prioritization of ethical principles ensured patient autonomy and reduced the risk of patient harm. Participation of patients was voluntary and patients who declined to participate were not withheld a provider visit or treatment. Consent was obtained before participation. All health decisions

chosen by the patient were free of coercion, including having chosen not to utilize contraception. All survey data were de-identified and stored on the clinic's encrypted computers. Support letters for the QIP were obtained from the tribal government and the facility (Appendix C). Both Oregon Health & Science University (Appendix E) and Indian Health Service (Appendix D) Institutional Review Boards granted exemptions for this QIP as the project did not impact human safety. The potential for bias is acknowledged as the QIP lead/author participated in the QIP and had a vested interest in the outcomes however they did not complete pre/post surveys.

Results

QIP Evolution

Between February and April, 2023, 27 eligible patients participated in the QIP. During the first two weeks, there were a few patients presenting with a chief complaint regarding contraception and the inclusion criteria were changed to include females aged 18 to 44 who presented for any chief complaint other than acute illness or injury. Additionally, the clinic pharmacists were invited to use the pDA if a patient presented for contraception which resulted in one use during the project. During weeks six to seven, the QIP lead/author was absent for four days and no eligible patients participated in the QIP. Common factors influencing pDA use included the number of patients presenting who met inclusion criteria and the number of providers in the clinic from week to week.

Patient Survey Results

Binomial exact testing determined agreement between the survey and patient responses. For questions one through three, 27 out of 27 patients agreed (95% CI, [0.873, 1]). For question four, 26 out of 27 patients agreed (95% CI [0.81, 0.1]). The proportion of respondents who would “agree” with each question is between 81% and 100% [95% CI] ($p<0.001$) (Appendix K). Patient survey responses indicated that all patients agreed that pDA use improved their knowledge and confidence in contraception use. All but one patient indicated that they would consider using pDAs for other health decisions.

Provider Survey Results

Five providers were surveyed. There were increases in the average effect for all questions except for questions six, seven, and eight. There were no statistically significant changes in provider KAP after pDA use ($P<0.05$) (Appendix L). There was an increase in providers' perception of patient knowledge of contraception options, benefits, and side effects after PDA use. There was a decrease in provider perception of patient ambivalence toward contraception choice after PDA use. PDA use also resulted in a 20% decrease in provider perception of time constraints to provide education. Provider perception of patient positive attitudes toward contraception and the ability to address contraception misconceptions decreased by 40% in the post-survey. Compared to traditional counseling, providers responded that encouragement to ask questions decreased. There was no change in provider perception of patient knowledge of risks, confidence in contraception choice and correct use, perception of contraception safety, and perception that patients were encouraged to share their personal preferences. All providers responded that it would be helpful for the patient to have more information prior to the visit both before and after PDA use.

Contraception Prescription and Sterilization Referral Results

Prior to QIP implementation, 23 contraception prescriptions and zero sterilization referrals were placed from September 2, 2022 through October 27, 2022 (Appendix I). During the QIP, 18 contraception prescriptions and zero sterilization referrals were placed (Appendix J).

Discussion

Summary

Despite being unable to complete the full 12-week QIP, the two specific aims were met. The primary aim sought to improve patient KAP of contraception counseling after the "MyBirthControl" pDA use. Patient responses were overwhelmingly positive after pDA use indicating that pDAs are effective in improving patient KAP of contraception counseling. The sub-aim, to assess provider KAP of

contraception counseling before and after pDA use, did not show statistically significant changes, but did show clinical improvements in several aspects. The intervention did not increase the number of patients choosing to accept contraception prescriptions or referrals for sterilization, although these were not specific goals of the intervention. This could be considered protective as it may indicate that patients did not feel coerced into choosing a method. The desired outcome of the intervention was to improve patient contraception education and shared decision-making which is consistent with the results. Utilizing the IHI Model for Improvement, PDSA cycles allowed for continuous assessment and modification of the intervention. Buy-in was achieved from most of the staff, however, this could have been improved by increasing training during the in-service or providing more frequent training and reminders.

Interpretation

Like other pDA implementation studies, the patient survey results of this QIP suggest that pDA use in contraception counseling significantly improves patient KAP. There are several possible explanations for the positive patient outcomes. One explanation is that the pDA provided contraception education that positively impacted the patient's knowledge of options, safety, common side effects, and appropriate use. During a busy clinic day, the provider may not always be able to provide such comprehensive education. The pDA also aimed to dispel contraception misinformation which potentially improved patient perceptions about safety. The pDA allowed patients to flag questions for the provider which may have guided improved clinician-delivered education. Additionally, the pDA allowed the patient to input preferences and health history which may have improved the collaboration and self-efficacy around treatment options and subsequent method selection. Another explanation is that patients answered favorably despite their true experience. However, patients commented that the pDA provided more contraception information than they had ever been given and that most of the information was new to them.

Provider responses indicated that there were some clinically significant improvements in some aspects of contraception counseling. Improvements could be due to several factors including the decreased time required to deliver education by the provider as well as the pDA prompts to elicit patient preferences which may be overlooked during traditional counseling. The lack of statistical significance is likely due to the small provider sample size. There was an overall decrease in positive responses when providers were asked about their agreement with the statements "most patients perceive contraception to be safe" and "most patients have a positive attitude about contraception." This could be due to changes in their baseline perceptions after pDA use or it could be due to the pDA itself. Overall, some providers commented that they enjoyed using the tool and found it helpful for the patient to have some education prior to the visit. All providers agreed that it would be helpful for the patient to have more information prior to the visit.

Like other studies, time and adjustments to the workflow were barriers. Providers noted that the pDA took extra time for patients to complete, but the patient had foundational knowledge prior to the visit which positively impacted the provider's experiences. As expected, it was noted that pDA utilization decreased when there were fewer providers in the clinic. Additionally, pDA utilization decreased when the QIP lead/author was not in the clinic to triage the scheduling software. The pDA altered workflow by requiring the MA to complete additional tasks. Increasing workload may have deterred some staff from offering the pDA at times. Other routine screenings and forms may have been omitted due to the time required to implement the pDA. The clinic context may have influenced patient responses. The clinic does not routinely use pDAs or utilize electronic tablets for patient care and unfamiliarity with these tools may have caused distrust. In the setting of historical trauma, some patients may have felt the pDA helped promote autonomy. Other possible barriers could have been due to differences in literacy and visual capabilities. Access to the singular tablet within the clinic also affected the ability to offer the pDA

to multiple patients at once. Costs related to this QIP are minimal and include the cost of the tablet, paper for the surveys, and staff time.

Limitations

Limitations of this QIP included both the patient and provider population sizes, provider participation, generalizability, and patient/provider bias. The population represented in the QIP was primarily AI/AN living on a rural reservation and the perceptions and experiences of this group are not representative of all populations. Patient responses may have been influenced by social desirability bias wherein respondents answer in a way that will be favorably viewed by providers (Stuart & Grimes, 2009). The sample size of both providers and patients was low and staff buy-in was limited due to heavy workloads in the face of staffing shortages. Patients under the age of 18 were excluded from this QIP which potentially limits useful information for this age group. Some studies noted that pDA counseling plus phone follow-up was more effective than counseling alone but was not feasible for this QIP. Finally, the QIP was completed over eight weeks whereas a 12-week duration would have allowed for a more accurate interpretation of the run charts.

Conclusions

The outcomes of this QIP indicate that pDA use may be useful for other health decisions within this population. The pDA is free for public use and is easily utilized on most devices and continued use of the pDA is feasible. However, PDAs are under-utilized within healthcare. Expansion of pDA use requires development and adoption by healthcare facilities as well as oversight to ensure the pDA is accurate. Further inquiry into the specific reasons for contraception disuse within AI/AN populations is also warranted and could be considered for future qualitative inquiries. Ideally, the development of future contraception pDAs would include specific cultural considerations for individual populations such as AI/ANs. Additionally, arranging for the patient to utilize the pDA at home prior to the visit may allow more time for the patient to explore the tool and formulate questions. Improving the provision of

contraception counseling for AI/ANs in a comprehensive, ethical, and inclusive manner may lead to decreased unplanned pregnancies in those who wish to avoid them and subsequently improve pregnancy outcomes.

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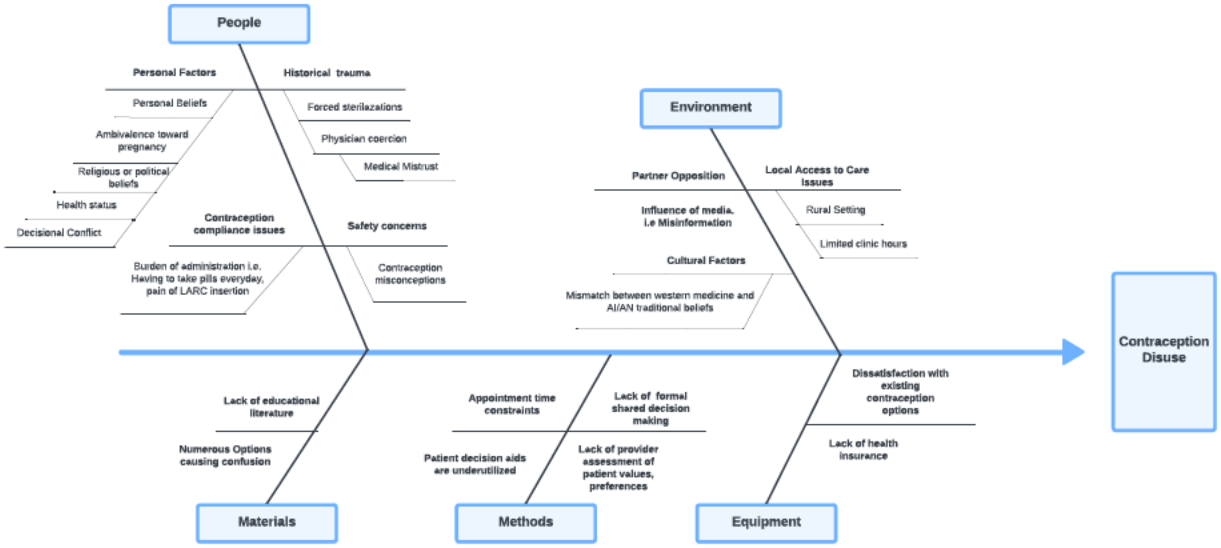
Appendix A

Project Timeline

	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	Jun 23
Finalize project design and approach	X							
Complete IRB determination or approval				X				
PDSA Cycle 1 2/24/23-3/23/23				X				
PDSA Cycle 2 (703B) (3/24/23-4/20/23)					X			
Final data analysis						X		
Write sections 13-17 of final paper							X	
Prepare for project dissemination							X	

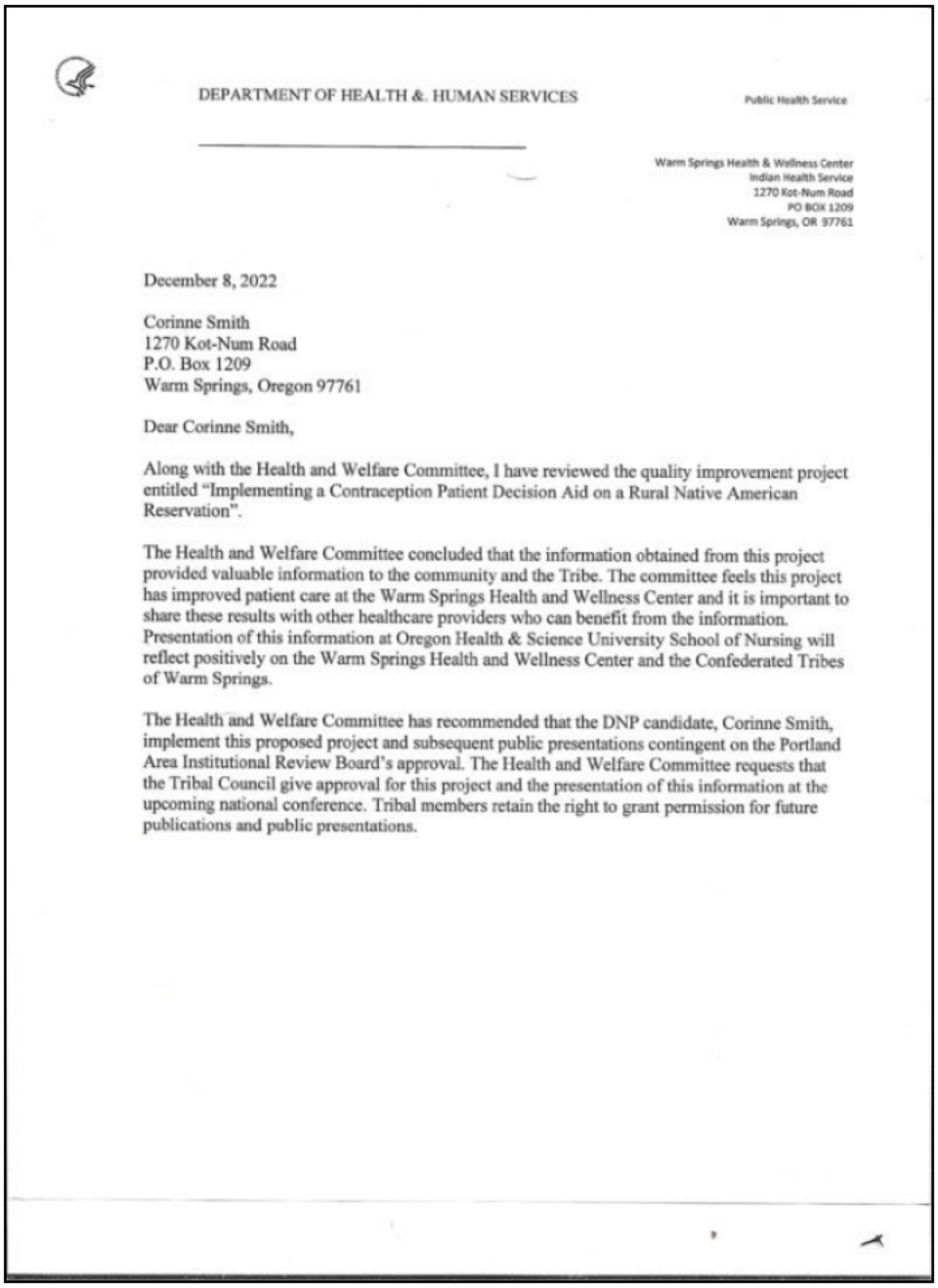
Appendix B

Decision Tree



Appendix C

Clinical Site Support Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Warm Springs Health & Wellness Center
Indian Health Service
1270 Kot-Num Road
PO BOX 1209
Warm Springs, OR 97761

December 8, 2022

Corinne Smith
1270 Kot-Num Road
P.O. Box 1209
Warm Springs, Oregon 97761

Dear Corinne Smith,

Along with the Health and Welfare Committee, I have reviewed the quality improvement project entitled "Implementing a Contraception Patient Decision Aid on a Rural Native American Reservation".

The Health and Welfare Committee concluded that the information obtained from this project provided valuable information to the community and the Tribe. The committee feels this project has improved patient care at the Warm Springs Health and Wellness Center and it is important to share these results with other healthcare providers who can benefit from the information. Presentation of this information at Oregon Health & Science University School of Nursing will reflect positively on the Warm Springs Health and Wellness Center and the Confederated Tribes of Warm Springs.

The Health and Welfare Committee has recommended that the DNP candidate, Corinne Smith, implement this proposed project and subsequent public presentations contingent on the Portland Area Institutional Review Board's approval. The Health and Welfare Committee requests that the Tribal Council give approval for this project and the presentation of this information at the upcoming national conference. Tribal members retain the right to grant permission for future publications and public presentations.

Appendix D

Indian Health Service IRB Exemption

Portland Area Institutional Review Board (PAIRB)

DATE: February 22, 2023

TO: Corinne Smith
FROM: Portland Area Indian Health Service IRB

PROJECT TITLE: [2018255-1] Implementing a Contraception Patient Decision Aid on a Rural Native American Reservation
REFERENCE #:
SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS
DECISION DATE: February 22, 2023

Thank you for your submission of New Project materials for this project. The Portland Area Indian Health Service IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will retain a copy of this correspondence within our records.

We appreciate your interest in providing the benefits of health research to Northwest American Indian and Alaska Native individuals and communities. If there are any questions regarding this letter or your submission, please do not hesitate to contact the PAIRB Coordinator, Ms. Clarice Charging, at 503-416-3256 or by email at PAIRB@ihs.gov. The IRB Co-Chairs can be contacted directly at 503-416-3298 (Dr. Weiser, Co-Chair) or 503-414-4492 (Rena Macy, Co-Chair) or by email at PAIRB@ihs.gov.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Portland Area Indian Health Service IRB's records.

Appendix E

Oregon Health & Science University IRB Exemption Letter

OREGON HEALTH & SCIENCE UNIVERSITY

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

February 27, 2023

Dear Investigator:

On 2/27/2023, the IRB reviewed the following submission:

Title of Study:	Implementing a Contraception Patient Decision Aid on a Rural Native American Reservation
Investigator:	Corinne Smith
IRB ID:	STUDY00025526
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office

Appendix F

Patient Survey

Contraception Patient Decision Aid Survey

MRN _____ Date _____

You are invited to complete a survey as a part of a quality improvement project on contraception (birth control) patient decision aids. The goal of the project is to assess how the patient decision aid affects your knowledge and feelings about birth control. It is your choice if you want to participate in the project or not. If you choose not to participate, there will be no penalty or change to your medical care. Choosing not to participate will not affect your relationship with your provider or the clinic. Your personal information will not be made public at any point, and all your health information will be securely stored.

I consent to allow my survey answers to be a part of this project and understand the statement above

YES

NO

Signature of Patient _____

How do you think the "My Birth Control" tool affected your visit?

Question	Disagree Agree
The tool gave me enough information to make the best birth control decision for me *(Ex: Information about options, risks, benefits, side effects, and how to use it)*	
I am comfortable with the birth control choice I made *(even if I chose not to use birth control)*	
The provider considered what matters to me about birth control *(Ex: My preferences on birth control type, my religious beliefs, my cultural beliefs, my concerns about side effects or safety, etc.)*	
I would use tools like this one for other health decisions if available	

If you have concerns about your rights as a quality improvement project participant, please contact the Portland Area IRB Chair, Thomas Weiser, toll-free: (877) 664-0604

STAFF ONLY: Patient Refused ☐

Appendix G

Staff Pre-Intervention Survey

Staff Pre-intervention Survey

Date _____ # 1

Please answer the following questions based on your current contraception counseling practices:

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
After current contraception counseling, patients have a good knowledgebase of all their contraception *options*					
After current contraception counseling, patients have a good knowledgebase of contraception *risks*					
After current contraception counseling, patients have a good knowledgebase of contraception *benefits*					
After current contraception counseling, patients have a good knowledgebase about contraception *side effects*					
After current contraception counseling, I feel patients are *confident* in their contraception choice					
After current contraception counseling, most patients have a positive attitude about contraception					
After current contraception counseling, most patients perceive contraception to be safe					
Many patients are ambivalent about their contraception choice and rely on the provider to choose for them					
Many patients have difficulty making a contraception decision					
After current contraception counseling, I am confident that patients use their contraception correctly most of the time (Ex: A patient who uses OC takes their pills at the same time each day)					
Current contraception counseling methods address misconceptions about contraception (Ex: "birth control causes cancer", "The pill made me gain a lot of weight") Current contraception counseling methods encourage the patient to ask questions					
Current contraception counseling methods encourage the patient to share their values and preferences (Ex: religious beliefs, cultural beliefs)					
Appointment time constraints limit the ability to provide detailed education to patients					
It would be helpful to have information about contraception options provided to the patient *before* the visit					
I am skeptical about the accuracy of educational handouts					

Appendix H

Staff Post-Intervention Survey

Staff Post-intervention Survey

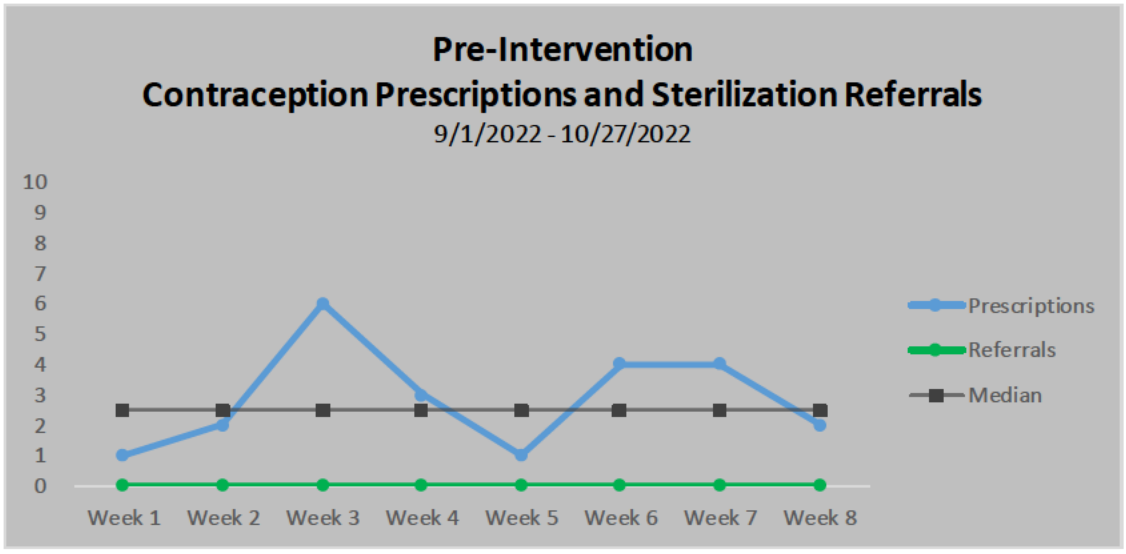
Date _____

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
After using the "MyBirthControl" aid, patients have a good knowledgebase of all their contraception *options*					
After using the "MyBirthControl" aid, patients have a good knowledgebase of contraception *risks* After using the "MyBirthControl" aid, patients have a good knowledgebase of contraception *benefits*					
After using the "MyBirthControl" aid, patients have a good knowledgebase about contraception *side effects*					
After using the "MyBirthControl" aid, I feel patients are *confident* in their contraception choice					
After using the "MyBirthControl" aid, most patients have a positive attitude about contraception					
After using the "MyBirthControl" aid, most patients perceive contraception to be safe					
Many patients are ambivalent about their contraception choice and rely on the provider to choose for them					
Many patients have difficulty making a contraception decision					
After using the "MyBirthControl" aid, I am confident that patients use their contraception correctly most of the time (Ex: A patient who uses OC takes their pills at the same time each day)					
The "MyBirthControl" aid addressed misconceptions about contraception (Ex: "birth control causes cancer", "The pill made me gain a lot of weight")					
The "MyBirthControl" aid encourages the patient to ask questions					
The "MyBirthControl" aid encourages the patient to share their values and preferences (Ex: religious beliefs, cultural beliefs)					
Appointment time constraints limit the ability to utilize the "MyBirthControl" aid					
It is helpful to have information about contraception options provided to the patient *before* the visit					
I am skeptical about the accuracy of "MyBirthControl"					

If you have any other thoughts or comments about the Patient Decision Aid comment below:

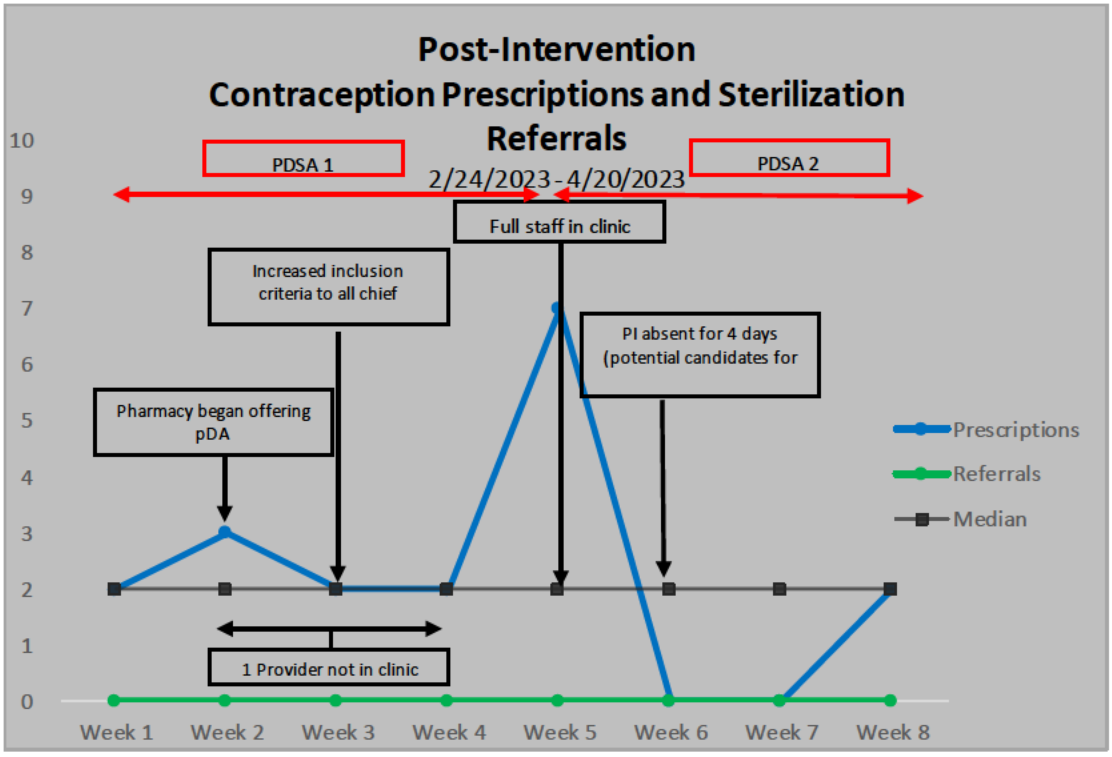
Appendix I

Pre- Intervention Run Chart



Appendix J

Post- Intervention Run Chart



Appendix K

Patient Survey Results

Question	Agree	Disagree	Pval	Lower CI	Upper CI
The tool gave me enough information to make the best birth control decision for me	27	0	1.49012E-08	0.872297	1
I am comfortable with the birth control choice I made	27	0	1.49012E-08	0.872297	1
The provider considered what matters to me about birth control	27	0	1.49012E-08	0.872297	1
I would use tools like this one for other health decisions if available	26	1	4.17233E-07	0.810294	0.999063

Appendix L

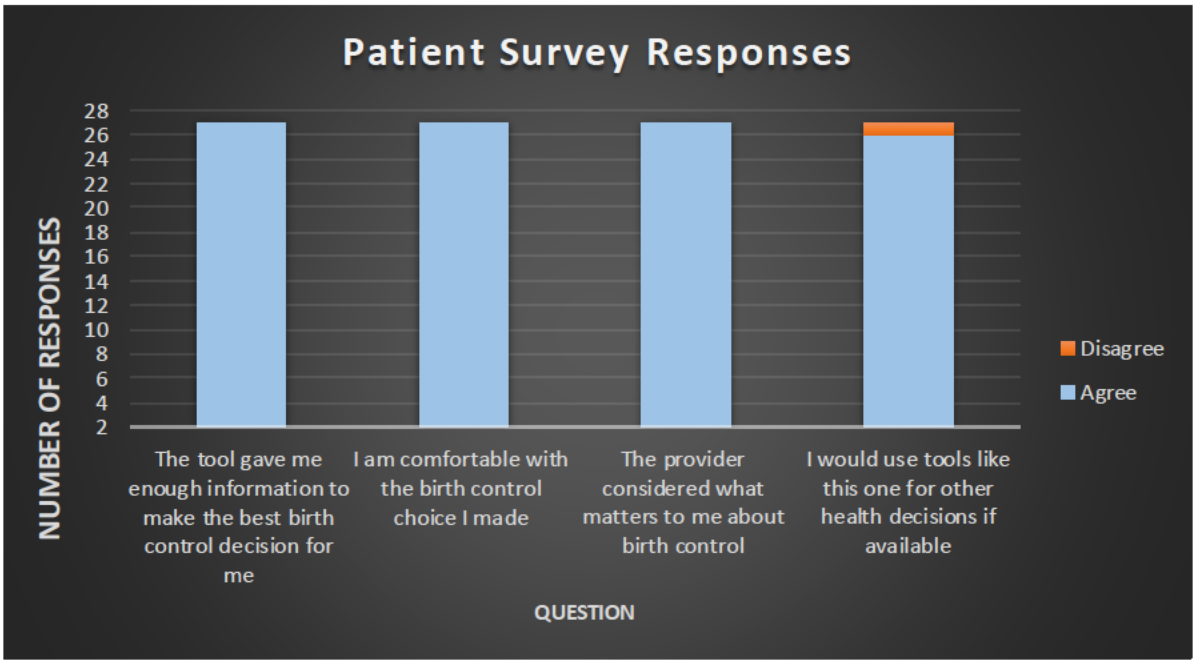
Provider Survey Results

Question 1							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	3	0	0.24198153	-1.9764451	2.41893178	0.8
2	3	3	0				
3	3	4	1				
4	1	4	3				
5	3	3	0				
Question 2							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	3	0	0.42631721	-1.2830767	2.48307669	0.6
2	2	2	0				
3	3	4	1				
4	1	4	3				
5	3	2	-1				
Question 3							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	3	0	0.30455878	-0.8157148	2.05157148	0.6
2	2	3	1				
3	2	4	2				
4	3	4	1				
5	3	2	-1				
Question 4							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	3	0	0.23019964	-0.9632432	2.96324316	1
2	3	2	-1				
3	3	4	1				
4	1	4	3				
5	1	3	2				
Question 5							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	3	0	0.30455878	-0.8157148	2.01571478	0.6
2	2	4	2				
3	3	4	1				
4	2	3	1				
5	4	3	-1				
Question 6							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	4	1	0.54146974	-2.6368347	1.26586706	-0.4
2	4	2	-2				
3	3	4	1				
4	3	2	-1				
5	4	3	-1				
Question 7							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	3	0	0.37390097	-0.755289	0.35528902	-0.2
2	4	3	-1				
3	4	4	0				
4	3	3	0				
5	3	3	0				
Question 8							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	4	2	-2	1	-3.0414432	3.04144323	0
2	0	0	0				
3	0	4	4				
4	1	1	0				
5	3	1	-2				

Question 9							
Provider	Pre--	Post	Difference	Pval	Lower CI	Upper CI	d
1	4	3	-1	0.37390097	-0.710578	1.51057804	0.4
2	2	3	1				
3	3	3	0				
4	2	3	1				
5	2	3	1				
Question 10							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	1	3	2	0.24198153	-0.8189318	2.41893179	0.8
2	3	2	-1				
3	1	3	2				
4	1	2	1				
5	2	2	0				
Question 11							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	4	1	0.10870095	-0.4189318	2.81893179	1.2
2	1	3	2				
3	3	3	0				
4	1	4	3				
5	3	3	0				
Question 12							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	4	1	0.6213083	-0.8388506	1.23885063	0.2
2	3	2	-1				
3	3	3	0				
4	3	4	1				
5	3	3	0				
Question 13							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	1	3	2	0.58704964	-1.4830767	2.28307669	0.4
2	3	1	-2				
3	4	4	0				
4	1	2	1				
5	1	2	1				
Question 14							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	3	2	-1	0.47662067	-1.0157148	1.81571478	0.4
2	3	4	1				
3	4	4	0				
4	4	4	0				
5	1	3	2				
Question 15							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	4	4	0	0.070484	-0.0800874	1.28008738	0.6
2	3	4	1				
3	4	4	0				
4	3	4	1				
5	3	4	1				
Question 16							
Provider	Pre-	Post-	Difference	Pval	Lower CI	Upper CI	d
1	1	1	0	0.37390097	-0.355289	0.75528902	0.2
2	2	2	0				
3	1	1	0				
4	0	0	0				

Appendix M

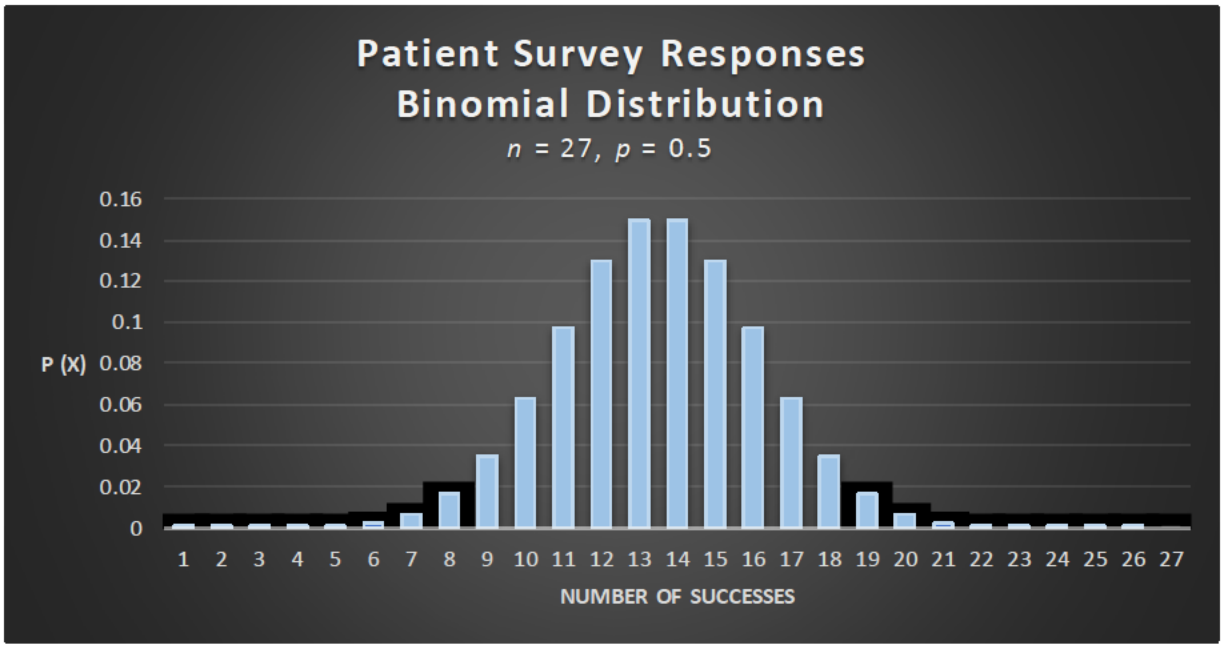
Patient Survey Bar Chart



Appendix M. Bar chart depicting the number of "agree" and "disagree" responses for patient survey Questions.

Appendix N

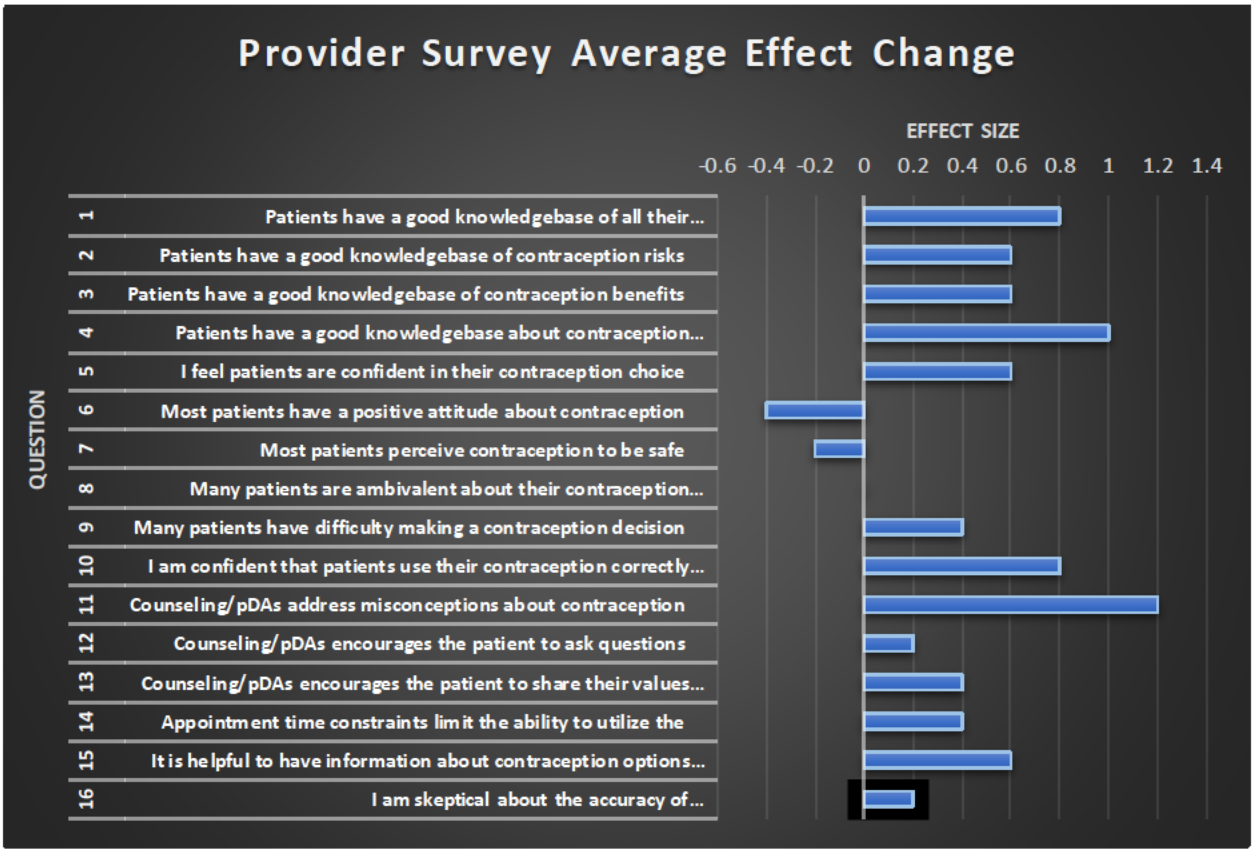
Patient Survey Binomial Distribution Chart



Appendix N. Binomial distribution chart depicting the probability of "agree" responses out of the total number of trials.

Appendix O

Provider Survey Bar Chart



Appendix O. Bar graph depicting the average effect change after pDA use based on the mean differences between pre-and post-intervention surveys.