

## **Identification of Female Patient Decision-Making Factors when Considering the Use of the Contraceptive Implant**

A survey of female patients, ages 16-45, to analyze decision-making factors present when patients are considering the use of the contraceptive implant as their preferred contraceptive method.

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### **Abstract:**

The 4 week cohort study consisted of an initial participant encounter, a short educational video on the contraceptive implant, provided by Planned Parenthood's website, and a 14 question paper survey. The participants in the study were 97.5% working-poor Hispanic female patients and 1% non-Hispanic, non-Caucasian, non-African American, or non-Asian. The study was conducting by using the patient population from El Centro de Corzaon (El Centro). The participants took a survey that identified a number of factors that could influence decision making for types of the contraceptive implant (Nexplanon/Implanon). Out a list of options, the top three patient concerns were identified: irregular menstrual cycles (22.6%), irregular bleeding (20.8%), and pain associated with placement and retrieval of device (17.0%). 20.8% of participants did not have any concerns about the use of the contraceptive implant as their preferred contraceptive method. A multiplicity of other factors influencing patient decision was identified as well. Overall, participants are split on their final decision in favor of (52.9%) or against the use (47.1%) of the contraceptive implant.

**Keywords:** contraceptive implant, patient decision-making factors, working-poor Hispanic females, ages 16-45, patient survey, Nexplanon/Implanon, El Centro de Corazon

## **Introduction**

Unplanned pregnancies are a major source of financial, mental, and social stress for all persons involved. This problem is not exclusive to the Community Health Center I was assigned to, El Centro. El Centro is a Federally Qualified Health Center (FQHC) that serves the historic and primarily Hispanic 'Eastside' of Houston, Texas. As a FQHC, El Centro cannot turn any person away, no matter what their financial status. Thus, El Centro has the unique opportunity to care for Houston's medically underserved Hispanic population. El Centro has three health care centers with its own primary care specialty field: the Magnolia Site with Women's and Behavioral Health; the Nathaniel Dunn Site with Pediatrics, Behavioral and Dental Health; and the Eastwood Site with Family Medicine and Dental Health.

I came face to face with the national unplanned pregnancy crisis within my first week at El Centro in the pediatrics site. At the Nathaniel Dunn site, I witnessed many cases of the overworked mother. The mothers always smiled with tired eyes and the fathers were either absent from the children's lives or working long hours to ensure there were funds to maintain food and shelter for the family. Not all families were taxed with this lifestyle. Some women came in for a newborn checkup with glowing faces, lots of questions and grand plans for the baby's future. Other women came in with three children who didn't speak out of turn and lined up in anticipation for their routine check-ups. It was evident that women who had overwhelmed themselves with children were suffering mentally, physically and socially while women who had not were enjoying a healthy lifestyle.

So what delineates these women from each other? Although there are many factors, I would like to discuss family planning through non abortive means. Not all women are created the

same; therefore not all women will unanimously agree on one option. Therefore, different options must be present to fit the different lifestyles of women. The same is true for family planning methods that do not harm the fetus. Women across the nation need to be educated on the non-harmful options that are present within contraceptive methods. Once educated, women can make a choice that is unique to their goals and lifestyle. This will lead to a dramatic decrease in the amount of unplanned pregnancies and abortions in the nation.

Upon talking with a public health official and other staff members at El Centro, I learned of a pilot program through Merck & Co that El Centro will have the opportunity to partake in. Merck & Co is a pharmaceutical company that constructs and sells Nexplanon/Implanon, a contraceptive implant. The program will offer the placement procedure and the device free of charge to interested female patients. I conducted a literature review of Nexplanon studies conducted and came across a couple of interesting sources. After the literature review, I decided to conduct my own research on the contraceptive implant that included a question proposed during the primary patient encounter component, an educational component, and an identification of patient decision-making factors component.

## **Background**

There are about 3 million unintended pregnancies each year.<sup>1</sup> The amount of unintended pregnancies presents a multitude of economic, ethical, and social problems. Currently, United States tax payers pay \$11 billion to cover unplanned births. Unplanned pregnancies lead to abortion in 40% of the cases which leads to an annual figure of 1.2 million abortions.<sup>1</sup> The nation faces a preventable crisis. Despite a great deal of research on unintended pregnancies, no clear answer has been discovered. A review of contraceptive methods, an extensive look at the

contraceptive implant, and a review of relevant research in the field could present a research question that could prove valuable to reducing this national crisis.

The American Congress of Obstetricians and Gynecologists define the following as contraceptive methods: sterilization for Women and Men; Barrier Methods of Birth Control: Diaphragm, Sponge, Cervical Cap, and Condom; Fertility Awareness: Rhythm Method, Basal Body Temperature Method, etc; Sterilization by Laparoscopy; Postpartum Sterilization; Emergency Contraception; Hysteroscopic Sterilization; Long-Acting Reversible Contraception: IUD and Implant; Combined Hormonal Birth Control: Pill, Patch and Ring; Progestin-Only Hormonal Birth Control: Pill and Injection.<sup>2</sup> For the purposes of this study, Long Acting Reversible Contraception (LARC) methods will be defined first and then the contraceptive implant method will be defined and further explored. LARC methods have the highest efficacy in preventing pregnancy than any other contraceptive method.<sup>3</sup> In addition, LARC methods last for 3 (implant) or 5 (IUD) years and remain manageable for patients. These LARC methods are reversible for women considering pregnancy or another contraceptive method.<sup>2</sup>

The contraceptive implant is a small pliable tube that is inserted under the skin by a physician. The implant prevents pregnancy by releasing hormones that prevent ovulation and thickening of the cervical mucous. The contraceptive implant can prevent pregnancy for up to three years.<sup>4</sup> The contraceptive implant, like all contraceptive methods, present with both positive and negative side effects. The most common side effect is unpredictable bleeding. Some women's bleeding patterns gradually improve while other women stop having menstrual bleeding completely. Another common side effect is that women using the contraceptive implant have less menstrual pain. Other common side effects such as mood changes, headaches, acnes,

and depression are also possible. Lastly, the risk associated with the contraceptive implant are less than 2% and associated with insertion and removal of the implant.<sup>2</sup>

Currently, the only product on the market of the contraceptive implant is Nexplanon/Implanon.<sup>5</sup> Nexplanon and Implanon are essentially the same product except that Nexplanon and Implanon NXT are x-ray detectable and contain a pre-loaded applicator for easier insertion.<sup>6</sup> Nexplanon/Implanon is manufactured into a single rod made of ethylene vinylacetate. The Nexplanon/Implanon rod is 4cm long and 2mm in diameter.<sup>7</sup> The synthesized hormone etonogestrel is used to prevent ovulation and thickening of the mucous. The Nexplanon/Implanon rod contains 68mg of etonogestrel, a type of progestin.<sup>8</sup> Etonogestrel is initially released at the peak value of 781-894 pg/mL in the first few weeks of the first year. As the Nexplanon/Implanon rod remains in the arm, the amount released decreases annually: 192-261 pg/mL released after year one, 154-194pg/mL after year two, and 156-177 pg/mL after year three.<sup>9</sup> The insertion process is an uncomplicated, quick procedure carried out by a healthcare provider that places the Nexplanon/Implanon rod under the skin into the subdermal tissue on the inner side of the arm between the biceps and triceps muscles.<sup>8</sup> The Nexplanon/Implanon rod can be removed at any time upon the patient's preferences and is not recommended to be kept longer than 3 years. The removal process is carried out by a healthcare provider. He/she will make a small incision into the skin and the Nexplanon/Implanon rod is removed using forceps.<sup>8</sup> The Nexplanon/Implanon rods have a failure rate of 0.05% in both perfect and typical use.<sup>10</sup> The side effects of Nexplanon/Implanon use are: irregular bleeding and spotting may occur<sup>2</sup>, insertion complications<sup>8</sup>, migration of device<sup>11</sup>, possible weight gain<sup>8</sup>, ovarian cysts<sup>8</sup>, drug interactions<sup>8</sup>, pregnancy<sup>8</sup>, acne<sup>12</sup>, other possible symptoms (headache, emotional lability, abdominal pain, loss

of libido, and vaginal dryness)<sup>8</sup>. Of note, as of January 2012, Implanon is no longer sold in the United States, making Nexplanon the only single-rod implant in the United States.<sup>5</sup>

The current research on LARC method patient compliance is of particular interest for this study. Two research studies helped frame this project: ONE KEY QUESTION and The CHOICE Project. Both studies aimed at reducing the overall number of unplanned pregnancies.

The ONE KEY QUESTION study deals with addressing the issue of diminishing access to contraceptive services in primary care. The study does this by proposing that primary care providers ask women, ages 16-45: “Would you like to become pregnant in the next year?”. The women who answer “yes” are offered preconception counseling and screenings to ensure that they are in optimal health for a pregnancy. The women who answer “no” are counseled by physicians on the full range of contraceptive options to ensure that their contraceptive method is best suited for their lifestyle. The women who remain ambivalent or unsure about their intentions are offered by physicians a combination of both services. Currently, there are no publishable studies on the ONE KEY QUESTION study to determine its effectiveness. Despite this, the state of Oregon (where the study is being conducted) and all professional organizations within it have shown support and recognition of the study.<sup>13</sup>

ONE KEY QUESTION aided this study’s methodology because it placed a necessary emphasis on the need for physician-patient interaction and patient education on contraceptive methods. With this in mind, this study needed to have a component that proposed a question about contraceptive method interest to the patient and a mode of education for the patient. For these reasons, the first question patients were asked in this study was if they were interested in or are currently using any contraceptive methods. If compliant, then the patient was shown a short

educational video on the Nexplanon/Implanon rod courtesy of Planned Parenthood and then asked to fill out a survey.

The CHOICE project study introduced and promoted the use of Long-Acting Reversible Contraceptive (LARC) methods by removing financial and knowledge barriers. The study is a prospective cohort study of 10,000 women ages 14-45 that do not want to become pregnant and are starting a new form of reversible contraception. Participants that were screened for the study were read a script that served to educate them on LARC use and to raise awareness of their options. Then, the participants chose their contraceptive method which was offered free of charge. The CHOICE projects results showed a 67% enrollment in LARC methods. Within the LARC methods, 56% chose the IUD and 11% chose the subdermal implant. The CHOICE project study concluded that without financial and education barriers present, two-thirds of patients would choose a LARC method.<sup>1</sup>

The CHOICE project study helped the scope and direction of this study. After reviewing the CHOICE project's results and conclusion, it became evident that women ages 16-45 interested in contraceptive methods are a good sampling of the female patient population for a cohort. Secondly, addressing the disparity between the most effective contraceptive method, LARC methods, and patient awareness was of particular interest. Lastly, the CHOICE project's results showed a marked difference in the patients who choose the IUD and patients who choose the contraceptive implant. For these reasons, this study was focused on a cohort of women ages 16-45 interested in or currently using contraceptive methods. The purpose of this study was to identify decision-making factors that influence the participant when considering the use of the contraceptive implant.

## **Methodology**

### *Participant Encounter*

The participant was asked if she was interested in or currently using contraceptive methods. If participant said “yes”, then she would be asked to watch a short video and then fill out a survey.

### *Participant Video*

The participants were shown a two minute video about Nexplanon/Implanon, available in both English and Spanish. The video was made publically available by the Planned Parenthood website. The video gave basic information about the contraceptive implant.

### *Participant Survey*

The survey consisted of 14 questions aimed at identifying various decision-making factors that are considered in the process of deciding in favor or against contraceptive implant use. The first three questions of the survey served as a method of defining the study cohort. The survey was available in both English and Spanish versions.

## **Results**

The study was conducted over a four week period and data from 43 surveys was extracted.

### *Question 1*

Question 1 asked for the participant's age. The data was split into three groups 16-20, 21-30, 31-40, and 41-45. The average age was 28.5 +/- 6.6.

### *Question 2*

Question 2 asked if the participant had medical insurance. 60.5% answered "no" while 39.5% answered "yes".

### *Question 3*

Question 3 asked for the participant's race. 97.6% identified themselves as "Hispanic" while only one person identified themselves as "other".

### *Question 4*

Question 4 asked for how many prior pregnancies the participants have had. The results are as follows: 7.0% with no pregnancies, 23.3% with one pregnancy, 20.9% with two pregnancies, 23.3% with three pregnancies, 18.6% with four pregnancies, 2.3% with five pregnancies and 4.7% with six pregnancies. The average number of pregnancies was 2.49 +/- 1.48.

### *Question 5*

Question 5 asked if the participant had used a contraceptive method before. 83.7% answered "yes" while 16.3% answered "no".

### *Question 6*

Question 6 served as a follow up question to Question 5. If the participant answered “yes” to Question 5, then they were asked what contraceptive method was used. The results are as follows: 6.6% never use contraceptives, 6.6% use another method not listed, 11.5% use “the morning after” pill, 16.4% use the IUD, 26.2% use contraceptive pills, and 32.8% used the contraceptive injection.

### *Question 7*

Question 7 asked about the number of women the participant knew that use the contraceptive implant. The results are as follows: 5.4% know less than 20, 8.1% know more than 20, and 86.5% know less than 5 or none.

### *Question 8*

Question 8 asked if the video presented adequate information for the participant to be able to make a reliable decision on using the contraceptive implant. 30.6% answered “no” while 69.4% answered “yes”.

### *Question 9*

Question 9 asked if the participant would be interested in using the contraceptive implant. 48.6% said “no” while 51.4% said “yes”.

### *Question 10*

Question 10 asked what apprehensions may the patient have about using the contraceptive implant. The results are as follows: 3.6% are worried about the device preventing

pregnancy, 3.6% are worried about the placement location of the device, 5.5% think it is ineffective, 5.5% think it is dangerous, 16.4% are worried about pain associated with placement and removal of the device, 20.0% are worried about the device causing irregular bleeding, 21.8% are worried about irregular menstrual cycles, and 23.6% don't have any apprehensions toward the use of the device.

#### *Question 11*

Question 11 asked if the participant was currently interested in some form of contraceptive method. The results are as follows: 4.8% answered "do not use", 40.5% answered "no", and 54.8% answered "yes".

#### *Question 12*

Question 12 asked if the participant is currently interested in using some form of contraceptive method. The results are as follows: 4.8% don't use any, 40.5% answered "no", 54.8% answered "yes".

#### *Question 13*

Question 13 asked if why the participant was satisfied with their current contraceptive choice. The results are as follows: 2.4% use it because it isn't controversial, 11.9% use it because it doesn't require a placement or removal procedure, 14.3% use it because it is safe, 21.4% use it because they are accustomed to it, 21.4% use it because it is easy to manage, 28.6% use it because they are satisfied and do not prefer any others.

### *Question 14*

Question 14 asked the participant what factors would increase their interest in the contraceptive implant. The results are as follows: 13.7% would like to know more women who use it, 25.5% would like to receive the contraceptive implant free of charge, 29.4% remains unaffected all things considered, 31.4% would like to receive more information on the contraceptive implant.

### **Discussion**

The first three questions served as data that could be used to accurately define the cohort. The data indicates that the cohort studied is majority Hispanic with 60.5% uninsured and an average age of 28.5 +/- 6.6.

Question 4 reveals the degree of need for a contraceptive implant. The average is 2.49 +/- 1.48 pregnancies per participant. This value isn't terribly concerning, but should be monitored in the El Centro patient population.

Question 5 and 6 indicate how many participants are using contraceptive methods and what types are being used. The most popular contraceptive methods are the oral contraceptive pills and the injection. The oral pills have always been a popular option with women in America, but they present a problem with women in the El Centro population because these women are not as successful with a regimented schedule. The injection is a popular option because it is quick, easy, and lasts for up to a year. The problem with the injection is that it is not reliable as reliable as the LARC methods (3.0% failure rate)<sup>14</sup> and it could cause bone loss<sup>15</sup>.

Question 7 indicates an alarmingly high number of participants who know less than five women that use the contraceptive implant. In the working-poor Hispanic population at El Centro, it is critical that modern medicine have a presence in each household. If there is a medicine prescribed to a patient that a family member, neighbor, or local friend hasn't heard of, then the patient is likely to distrust the medicine's efficacy and safety. These assumptions are usually not based on fact, but on popular opinion. Therefore, if the contraceptive implant is going to be offered to patients of El Centro, then it needs to be popularized in the community.

Question 8 and 9 indicate some interesting data. Question 8 reveals that the majority of the cohort feels educated enough to make a decision on contraceptive implant use. It would seem that the choice is still difficult to make despite education on the subject because Question 9 shows a split cohort on choosing and declining the use of the contraceptive implant. These questions are pointing to some interesting questions: What more does the population need in order to make a more consistent decision on contraceptive use? What component of contraceptive use education is missing?

Question 10 indicates some very important data. The top three answers were: causes irregular bleeding, causes irregular menstrual cycles, and no worries present about the contraceptive implant. It is interesting that the most common side effect of the contraceptive implant (irregular bleeding or spotting) deals with two of the top three concerns of participants. For this reason, providers should ensure that the patient is educated on the side effects of the product. Secondly, the most popular choice from Question 10 was that the participants had no worries about the contraceptive implant. This reveals the potential for this method to be used regularly in the El Centro patient population.

Questions 11, 12, and 13 reveal the cohort's interest in the use of contraceptive methods, their satisfaction with their current choice, and their reason for maintaining their choice. A slight majority elicited interest in use of some form of contraceptive method and a slight minority did not. More participants answered that they did not prefer their current choice than those who did. Of note, the majority of participants that answered this question indicated that they do not use any kind of contraceptive method. This value data is very puzzling. Lastly, the top reasons why patients maintained their choice of contraceptive method were: accustomed to contraceptive use, easily manageable, completely satisfied and don't prefer another option. These results indicate the high degree of normalization of contraceptive methods that aren't the contraceptive implant.

Question 14 identifies some major components that can aid the cohort in choosing the contraceptive implant. It would seem that offering more information and offering the device free of charge are the top two answers. This is very important data because the Nexplanon/Implanon pilot program is seeking to interest more female patients in their product by offering education on the product and by offering the product free of charge. Interestingly, it would seem that only a minority of the cohort was affected by the number of other women that used the contraceptive implant.

### **Recommendations**

I have three recommendations for El Centro in regards to the Nexplanon/Implanon pilot program and product in general: implementation of contraceptive education, popularize the product in the clinic and community, and offer the device free of charge.

Implementation of contraceptive education is very important to the success of the all contraceptive methods, especially the Nexplanon product. The women in the community need educational resources offered to them on the product. I think the best way to educate these women on the product is to

create a classroom setting. At present, El Centro hosts a weekly class on Diabetes Management at its Magnolia Site which is where the women's health services are offered. I recommend that the same classroom be used on a different day of the week than the Diabetes Management class and it focus on contraceptive methods. In this way, the women of the community that are interested in family planning and contraceptive methods can have access to a safe, group environment with a well-educated instructor present. The time and space will allow for question and answering and exposure to the many different options offered to women.

Secondly, the Nexplanon product needs to be popularized in the clinic as well as in the community. The Nexplanon product can be popularized in the clinic with the use of information pamphlets handed out at the end of family planning visits. Also, hanging up educational posters and visual aids of the Nexplanon product in the patient rooms can further popularize the product in the clinic. The Nexplanon product can be popularized in the community by setting up an informational booth about it during the multiple community health fairs that El Centro holds. I think it will really get women accustomed to seeing the option and make them more likely to consider using it seriously.

Lastly, the Nexplanon product should be offered to eligible women free of charge. El Centro has worked to cover the costs for the purchase of about 80 Nexplanon products to offer to eligible women free of charge, but that number should not be capped off. The capping off of the number of products means that some women interested in the product run the risk of asking too late and being left with no free of charge option. I think a grant under the Women's Health Initiative or the National Institute of Health should cover the costs of the Nexplanon product at FQHCs like El Centro.

## **Conclusion**

The major factors that influence patient decision on use of the contraceptive implant are as follows: side effects, popularity of other less effective options, education and price. These factors must be addressed by El Centro in order for the Nexplanon product to stand a chance

against its contraceptive competitors. Moreover, these issues must be addressed in order to serve the needs of women looking for family planning options.

El Centro will be making multiple efforts in order to address the results of my study as well as implement my recommendations. The efforts include offering eligible women a limited amount of the Nexplanon product free of charge and launching an education campaign on the Nexplanon product which includes a publicity and small group classroom component.

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