Creighton Model NaProEducation Technology for Avoiding Pregnancy

Use Effectiveness

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OBJECTIVE: To evaluate the use effectiveness of Creighton Model (CrM) NaProEducation Technology for avoiding pregnancy.

STUDY DESIGN: CrM is a medical model of natural procreation education that is a fully standardized modification of the Billings ovulation method. This system has

been used as a means to avoid pregnancy and has been prospectively evaluated in five use effectiveness studies. prospective life-table analysis of the five studies (meta-analysis) was undertaken, yielding both net and gross rates. Discontinuation rates were also calculated. These studies were conducted at CrM centers in Omaha.

St. Louis, Wichita, Houston, and Milwaukee.

RESULTS: A total of 1,876 couples used CrM NET for a total of 17,130.0 couple months of use. The method and use effectiveness rates for avoiding pregnancy were 99.5 and 96.8 at the 12th ordinal month and 99.5 and 96.4 at the 18th ordinal month, respectively. The discontinuation rate was 11.3% at the 12th ordinal month and 12.1% at the 18th ordinal month.

CONCLUSION: CrM is highly effective as a means of avoiding pregnancy in both its method and use effectiveness. The method effectiveness has remained stable over the years of the studies, but the use effectiveness for avoiding pregnancy appears to have improved over the study period. (J Reprod Med 1998;43:495-502)

Keywords: contraception; contraceptive agents, female; pregnancy; Creighton Model NaProEducation Technology.

for avoiding pregnancy reveal stable

Over the last several years, there has been considerable discussion regarding the lack of development of newer, safer methods of contraception. During this same period, a new system, Creighton Model (CrM) NaProEducation Technology, has

been in development. This model is a standardized medical model of natural procreation education (NaProEducation) that uses an advanced educational technology developed at Creighton University School of Medicine and is available as an allied health professional education and service delivery program.

Since its introduction, in 1980, five prospective trials of the model's use effectiveness have been conducted. These trials give significant insight into its effectiveness and use dynamics. The purpose of this report is to provide a meta-analysis of these

Introduction

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prospective trials and to introduce the new concept of NaProEducation technology.

Materials and Methods

Prospective trials to evaluate the method and use effectiveness of the Creighton Model (CrM) for avoiding a pregnancy have been conducted at five

The system is safe, easy to use and ethically acceptable to all people.

institutions. These include Creighton University School of Medicine, Omaha, Nebraska (1980)¹; St. John's Mercy Medical Center, St. Louis, Missouri (1980)¹; St. Francis Regional Medical Center, Wichita, Kansas (1985)²; St. Joseph Hospital, Houston, Texas (1990)³; and the Marquette University School of Nursing, Milwaukee, Wisconsin (1994).⁴

All these studies evaluated CrM NaProEducation Technology, a fully standardized modification of the Billings ovulation method.⁵ This method is based upon a woman's observation and interpretation of several biologic markers (biomarkers) that differentiate the phases of fertility and infertility in the menstrual cycle. These biomarkers include the observation of vaginal bleeding (menstrual and intermenstrual), presence or absence of a cervical mucous discharge, presence of vulvar dryness (absence of discharge), prepeak and postpeak phases of the cycle and the peak day. All these observations are made from external vulvar observations.6 They are made by the woman every time she uses the bathroom as a standard part of wiping the vulva and vestibule. It was shown previously that external observations of the cervical mucus correlate very well with biophysical changes that occur in the endocervical mucus as it approaches ovulation.6 In addition, extensive basic science evaluation of the ovulation method has established its scientific foundations.⁷ A complete description of the system and how it is used to avoid pregnancy can be found elsewhere.8 The educational program for client couples is built upon a program of one-on-one follow-up. The entry point is a one-hour introductory session (a narrated slide presentation) that is most often conducted in a group setting. Individual follow-ups are subsequently conducted at a recommended schedule of 2, 4, 6, 8, 12, 24, 36 and 52 weeks following the introductory session. The main teaching occurs during the first three months of use.

The process through which standardization is accomplished is made up of basically two components. The first revolves around actual delivery of the information in a standardized (uniform) fashion so that "equal access" to that information for new client couples can be ensured. The educational service has been developed to allow an assessment of the user's retainment and application of the knowledge that she or he is learning. This component has been satisfied through the thorough development of educational tools that have been coordinated and integrated into a completely standardized teaching system.^{8,9} These educational tools, when used properly and in an integrated fashion, represent a new, advanced educational technology, the principles of which have not been used previously in health education. This new technology is NaProEducation Technology and involves several components.

First, the Picture Dictionary of the Ovulation Method⁹ is a teaching aid that was developed to assist both the teacher and client couple in understanding the terminology used in describing the mucous observations. The pictures in the dictionary were systematically obtained through careful gynecologic evaluation of users of the ovulation method of natural family planning. This research process involved 157 women from all reproductive categories through 444 actual vulvar and endocervical mucous observations taken at random. In each case the vulvar mucous observation was directly observed and then immediately followed up by gynecologic examination, visualizing the cervix and testing the ferning and channel characteristics of the cervical mucus.6 This project allowed direct visualization and photographing vulvar mucus by women using the method. Through this evaluation, a system of standardized terminology for mucous observations was developed and is utilized by new users and teachers alike. The dictionary visually depicts that system of standardized terminology and teaches the couple the use of a vaginal discharge recording system (VDRS),8,9 which makes the recording of observations easy, accurate and objective.

Second, as couples begin to learn and use CrM, the teacher uses an ovulation method follow-up form,⁸ which serves as a checklist so that no item essential to effective learning is inadvertently left out. The 26-page form (designed to be used during the

first 12 months of teaching and learning) allows the teacher to monitor the client's new learning from one follow-up to the next through the assessment and validation of specific learning objectives. The form serves as a mechanism through which the educational content of the follow-up can be carefully documented. Such documentation is essential to quality assurance monitoring and the objective classification of pregnancies based upon actual use.

Third, a standardized pregnancy evaluation form is used to evaluate all pregnancies. This form investigates the following information: the client's reproductive history, how the pregnancy evaluation was conducted (in person or by telephone or letter), how the pregnancy was confirmed, the onset of early pregnancy symptoms, mucous observations during the course of the conception cycle, a review of the client's charting, a review of any special discharges, such as seminal and arousal fluid, and their impact on the use of the method, evaluation of any genital contact that may have occurred during the conception cycle, an evaluation of spousal support and the couple's satisfaction with and confidence in the method and dating of the estimated time of conception.

The pregnancy evaluation form is designed to be integrated with the client's knowledge and application of the system-related information that is documented in the follow-up form during the course of learning. In this fashion, an objective assessment of the client's use of the method and an objective classification of the pregnancy can be obtained.

Fourth, in addition to the above, a training text for CrM natural family planning teachers⁸ and a specially prepared introductory booklet designed for all new client couples is used. ¹⁰ The introductory session is in a standardized slide presentation format, and the couple use a charting system that is standardized (using the VDRS). Various assessment forms are used at prescribed points in the teaching process and include an observational review, reproductive category–specific cycle reviews and other organizational forms. Sample teaching charts are also available for use.

The second component through which standardization is accomplished is education of the teachers who deliver the natural family planning services. Such education is thorough and is conducted according to an allied health education model with a developed (written) 13-month curriculum.¹¹ This provides the teacher with the adequate theoretical and clinical exposure necessary to develop the basic

and advanced teaching skills essential to the provision of quality educational services. It also gives teachers the opportunity to learn how to use the various educational tools that have been developed for teaching purposes.

Prospective Trials

In all five prospective trials, life-table techniques were used as the statistical tool through which effectiveness was measured. This yielded net pregnancy and discontinuation rates as originally described by Tietze and Lewit.¹² The life-table technique in this study has been described in detail elsewhere.¹³ All five of the prospective studies met the essential prerequisites of performance of an objective effectiveness study of natural methods of family planning.¹³ These prerequisites are:

- 1. The education program was developed and utilized for maintaining close follow-up (both short and long term) of all clients in the program so that the status of each client couple could be accurately monitored.
- 2. The teaching methodology was thoroughly standardized (including the education materials) using medical concepts of standardization applied to education.
- 3. The education curriculum and qualifications of the natural family planning teachers were met, and the teachers had undergone evaluations ensuring that they were qualified to teach.
- Each client had "equal access" to methodspecific information, and it was thoroughly documented.
- 5. Complete documentation of the client's educational progress from one follow-up to the next was undertaken in detail throughout the course of the study (and as a natural course of standard CrM procedures).
- 6. Objective assessment of each client's learning progress and application of the knowledge of the method was accomplished and documented.
- 7. Pregnancy evaluation interviews were conducted in a prospective fashion using a standardized format so that an objective assessment and classification of the pregnancies could be obtained. Such pregnancy evaluations were generally conducted in person during the first trimester and assessed the couples' use of CrM.
- 8. The studies included clients from all reproductive categories except those with known infertility. This item is important because it allows an overall evaluation of the versatility and general

applicability of the natural family planning method under investigation.

9. The couple's freedom to utilize the method in the way they wish is provided to them and adequately protected. In addition, the teaching attitude to which the clients are exposed is supportive of their freedom to make those reproductive choices, and such support is present prospectively from their entry into the program.

In addition to evaluating the five prospective trials, the raw data for each of the five surveys were obtained from the original investigators. These data were then compiled into a five-study composite, allowing a large series of couples and couple-months of use to be further evaluated. This, too, was conducted according to life-table techniques previously described.¹³

One of the key elements of the classification of pregnancies in the CrM is instruction to couples, which begins at the very first point of entry, the introductory session, that the method is not a method of contraception but rather a true means of family planning. In this context, the clients are informed that the method can be used in two different ways and that the goal of instruction will be to educate them as to whether they are fertile or infertile on any given day. In this fashion, decisions can be made relative to one's fertility on any given day. The couples are taught that, de facto, when they begin using days of fertility, they have abandoned the method as a means of avoiding pregnancy and have adopted it as a means of achieving pregnancy (basically, two methods incorporated into one, unlike contraceptives, which have only the function of avoiding pregnancy). In this fashion, achievers could be prospectively identified and separated out of the pregnancy avoidance phase of this study. This group will be the subject of a subsequent report.

Pregnancy Classification

The following pregnancy classification system was utilized:

- I. Achieving related pregnancy
 From the available information, the method
 was used as a method of achieving pregnancy,
 and the woman became pregnant.
- II. Avoiding related pregnancy
 From the available information, the method
 was used as a method of avoiding pregnancy,
 and the woman became pregnant.
 - A. Method related

From the available information, the method was used correctly as a method of avoiding pregnancy, and the woman became pregnant.

B. Using related

From the available information, the method was used incorrectly (but taught correctly) as a method of avoiding pregnancy, and the woman became pregnant.

C. Teaching related

From the available information, the method was taught incorrectly (but used correctly according to instruction) as a method of avoiding pregnancy, and the woman became pregnant.

D. Using/teaching related
 A combination of using related and using/teaching related.

III. Unresolved pregnancy

From the available information, the circumstances of the pregnancy cannot be placed into any of the above classifications.

Results

A total of 3,056 women prospectively and consecutively entered these studies. The total client base for the Creighton/St. John's Mercy study was 1,0121; St. Francis Hospital, 5862; St. Joseph Hospital, 1,135³; and the Marquette Nursing Center, 323.⁴ For the five-study composite, 375 clients were eliminated because they attended only the introductory session and did not choose to use the method (12.3%). Another 297 couples were excluded because they entered the program with an infertility problem (9.7%). Other couples were eliminated from the evaluation because they were interested only in fertility awareness and were not genitally active (n = 209, 6.8%), the woman was pregnant at the time of the introductory session (n = 49, 1.6%), they used barrier methods at the time of fertility and thus were not using the natural method under study (n = 34, 1.1%), or they were being taught other methods of natural family planning (applies only to the Houston study, n = 216, 7.1%). Thus, 1,876 client couples entered the composite study as couples who initially entered the program to use the method to avoid pregnancy. In this five-study composite, 17,130.0 couple-months of use were generated through 18 ordinal months. The reproductive categories of those entering the composite included the following: regular cycles (n = 809, 43.1%); long cycles (> 38 days in duration) (n = 96, 5.1%); breastfeeding—total (n=135, 7.2%); breast-feeding—weaning (n=224, 11.9%); post-Pill within the past year (n=487, 26.0%); premenopause (\geq 40 years of age) (n=50, 2.7%); postpartum—not breast-feeding (n=58, 3.1%); postabortion (n=13, 0.7%); and reproductive category not known (n=4, 0.2%).

Demographic characteristics of the client populations were available for three of the study populations²⁻⁴ (and not available for the Creighton and St. John's Mercy studies). The subjects were predominantly Catholic (59.8, 80.2%), were Caucasian (83.2-93.0%), had a high school or better education (97.6-98.0%), were ≤ 29 years of age (55.4-77.0%)and had an annual income of \geq \$20,000 (50.1-80.9%). While we cannot be sure, we think empirically that the demographic characteristics for the Creighton and St. John's Mercy groups were within these ranges. Within this demographic profile, there were a considerable number of people who participated who were not Catholic (19.8-40.2%), were not Caucasian (7.0-16.8%), were older than 29 years (23.0-44.6%) and had an annual income of <\$20,000 per year (19.1–49.9%).

Pregnancy evaluations were conducted in all five studies either in person or by telephone. In some cases the pregnancy evaluation was in an abbreviated (15.4, 31.7%) format. However, in all cases of difficult pregnancies, an in-person, full pregnancy evaluation was conducted. In some studies a small

percentage (<2) of pregnancies were not evaluated for various reasons. These pregnancies were included in the study but categorized as "unresolved."

The cumulative loss to follow-up rate for the five-study composite was well within the acceptable range. At 12 ordinal months it was 6.0% and at 18 ordinal months, 7.2%. The range for the individual studies was 2.4–11.0% (12 ordinal months) and 3.4–16.4% (18 ordinal months).

The method and use effectiveness of CrM as a method of avoiding pregnancy is presented in Table I. The method effectiveness at the 12th ordinal month for the composite was 99.5 per 100 couple-years, and the use effectiveness at the same point was 96.8. At the 18th ordinal month those figures maintained themselves at 99.5 and 96.4. The method effectiveness at the 12th ordinal month ranged from 98.7 to 99.8 over the five studies, while the use effectiveness ranged from 94.6 to 97.9.

Discontinuation categories (unrelated to pregnancy) for the five-study composite are given in Table II. The data are presented by reason for the discontinuation and the ordinal month of use. The total discontinuation rate at the 12th ordinal month was 11.3% and at the 18th ordinal month, 12.1%. A majority, 55.4%, of all discontinuations occurred in the first three months of use, and 77.7 percent of all discontinuations occurred within the first six

Table I The CrM Method and Use Effectiveness for Avoiding Pregnancy, by Centers: Five-Study Composite and Ordinal Month of Use

Parameter	Creighton University	St. John's Mercy Hospital	St. Francis Hospital	St. Joseph Hospital	Marquette Nursing Center	Five-study composite
Year of study	1980	1980	1985	1989	1994	1994
No. of couples	286	273	378	697	242	1,876
No. of couple-months	2,224.0a	1,980.0a	2,471.0a	7,084.5 ^b	1,819.5a	17,130.0b
Method effectiveness						
Ordinal month						
1	100.0	100.0	100.0	100.0	100.0	100.0
6	99.6	99.6	99.4	100.0	99.6	99.8
12	99.6	99.6	99.1	99.8	98.7	99.5°
18	N/A	N/A	N/A	99.8	N/A	99.5°
Use effectiveness						
Ordinal month						
1	100.0	99.6	99.7	100.0	100.0	99.9
6.	95.8	96.4	97.3	98.4	98.7	97.9
12	94.6	95.1	96.2	97.2	97.9	96.8c
18	N/A	N/A	N/A	97.1	N/A	96.4°

^aThrough 12 ordinal months.

bThrough 18 ordinal months.

cGross rates were also calculated for the five-study composite and are as follows: method effectiveness for avoiding pregnancy at month 12, 99.9; at month 18, 99.04. Use effectiveness for avoiding pregnancy at month 12, 95.27, at month 18, 92.70. N/A = not applicable.

Numbers in boldface = indicate composite data and 12th (vertical) ordinal month data (horizontal).

Table II CrM Cumulative Discontinuation Rates,^{1,2} by Reason and Ordinal Month of Use: Five-Study Composite

	Rate of discontinuation (%), by ordinal month					
Reason for discontinuation	1	3	6	12	18	
To use another natural						
method	0.0	0.3	0.3	0.7	0.7	
To use an artificial method	0.2	2.5	3.9	4.5	4.9	
Lack of confidence	0.2	0.6	0.6	0.7	0.8	
Difficulty avoiding genital						
contact	0.2	0.5	0.6	0.7	0.7	
Personal reasons	8.0	2.6	3.8	4.4	4.6	
Medically induced						
infertility	0.0	0.2	0.2	0.3	0.4	
Total	1.4	6.7a	9.4b	11.3	12.1	

^aOf all discontinuations, 55.4% occurred in the first three months. ^bOf all discontinuations, 77.7% occurred in the first six months. The discontinuation rate after the first six months was 2.7.

months. The discontinuation rate after the first six months was 2.7%. Estimated continuation rates for four of the five studies were available. The combined continuation rate for the Creighton University/St. John's Mercy Study was 76.3% (12th ordinal month) and 73.5% (18th ordinal month). For the St. Francis Regional Medical Center Program the rate was 70.0% (12th ordinal month) and for the Marquette University Nursing Center Program, 78.0% (12th ordinal month). The estimated continuation rate includes those individuals who either are using or have intended to use the method following pregnancy. However, it does not include any prorated continuation rate for those who have been lost to follow-up or have moved out of town while using the method under study.

Discussion

CrM is a new model of natural procreation education. It is based upon the delivery of a standardized educational content, objective and measurable standards, an allied health education model for the delivery of service and the education of its teachers and is the only model of natural family planning with specific medical applications. ¹⁴ This system has been extensively evaluated over a period of 14 years, and this meta-analysis allows us to review that evaluation and gain insight into the use effectiveness of this method of family planning.

This analysis reviewed five prospective trials of the method conducted in the United States as a means of avoiding pregnancy. The study involved a composite of 1,876 couples over 17,130.0 couplemonths of use. Of those 3,056 clients (not including the male partner, although most of the time he was in attendance) who attended an introductory session, 87.7% chose to use the method. The point of entry into the program, for the purposes of these studies, was the introductory session. There was no learning phase, as had been incorporated into other studies. 15,16 Learning phases have the distinct possibility of artificially disturbing the use dynamics of a method of natural family planning and do not allow adequate measurement of use effectiveness reality from the true point of entry.

The method effectiveness of CrM for avoiding pregnancy has remained stable throughout the course of its 14-year history of evaluation (98.7-99.8/100 couple-years). It has also remained competitive with reversible methods of contraception.¹⁷ At the same time, the use effectiveness of the method appears to have improved over this same period of time. The earliest use effectiveness for avoiding pregnancy was 94.6%, and this increased to 97.9% in the most current study. We think that this reflects a refinement in the teaching methodology. The original studies done at Creighton University and St. John's Mercy Medical Center utilized a second-generation follow-up form, whereas the latter three studies used a third-generation form, which we consider to be superior. In addition, this improvement in use effectiveness reflects an improvement in the training of teachers, the availability of better teaching aids and overall improvement in the delivery of the educational service.

The composite use effectiveness for avoiding pregnancy was 96.8 at 12 ordinal months of use, and this compares favorably with the reported use effectiveness of reversible methods of contraception: 99.7 for injectable hormonal contraception, 98.0 for the intrauterine device, 97.0 for oral contraceptives, 88.0 for condoms and 79.0 for spermicides. 17 However, caution should be exercised in such comparisons because the subjects of this study are not likely to be directly comparable with users of the other methods (and vice versa), upon which these statistics are based. In order to study the applicability of CrM to women across the entire spectrum of reproductive status, this study included some women who were breast-feeding, whom most contraceptive studies exclude. Further, the demographic characteristics of contraceptive users (including age, education and socioeconomic status) have all been shown to have an effect on pregnancy rates.18

In this regard, the subjects of this study of CrM might be expected to have had a relatively higher use effectiveness because of their relatively high educational and socioeconomic status (in aggregate).¹⁹

Because CrM can be used to achieve pregnancy as well as to avoid it, it is not strictly a method of contraception but rather a true method of family planning. It therefore gives the couple the freedom to use it as a means to achieve or avoid pregnancy as they so wish, with full knowledge of the likely consequences of either choice. Some couples knowingly choose to use the days of fertility to achieve pregnancy and are successful in doing so. The pregnancies that have occurred in these women, and the dynamics of their use will be analyzed in detail in a subsequent report.

The CrM documentation system was designed, in part, to objectively assess the method's actual use as a means of achieving and avoiding pregnancy and to do this in such a way as to be able to objectively assess the couple's knowledge and application of the method. While previous studies have enforced the announcement to achieve pregnancy at the beginning of each cycle²⁰ or dropped couples from their studies who announced a "desire for pregnancy,"15,16 CrM prospectively teaches the couple how to use the method to achieve, as well as avoid, pregnancy. Use of standardized documentation tools, like the follow-up form, allows this to be prospectively monitored. When an achievingrelated pregnancy does occur, it becomes a relatively simple technique to identify those who have successfully used the method in this fashion. The pregnancy evaluation form is integrated with the information from the follow-up form and allows identification and separation of those pregnancies that might occur as the result of the method's not working.

In our experience, asking couples to announce that they are going to achieve pregnancy at the beginning of the cycle is an artificial intrusion into the freedom to use the method as they wish. Thus, in order to protect the couples' freedom and autonomy to use the method as they wish and to allow us to measure use effectiveness reality, this prospectively standardized system is used. (After all, couples in real life do not announce their intentions to outside observers in advance.) In fact, it allows objective evaluation and classification of all pregnancies in a format in which the couple's freedom to use the method as they wish is preserved while also

allowing us a better view of the real use dynamics of the method.

One potential criticism of this CrM meta-analysis concerns the contribution to the denominator of the rates of avoiding pregnancy in those couples who have changed their use of the method to knowingly use days of fertility and thus achieve pregnancy. If some of these couples chose to begin trying to achieve pregnancy prior to the month in which they conceived, they might artifically inflate the denominator of those couples who were trying to avoid pregnancy. From other CrM data, we know that those who achieve pregnancy do so on average within 1.58 cycles of beginning to use the fertile period.²¹

To estimate a maximal effect that this might create, we calculated rates under the alternate assumption that all of those who knowingly achieved pregnancy were discontinued from the study two ordinal months prior to their actual pregnancy and that there were couples in the last two months of the study who were starting to try to achieve pregnancy (but had not yet done so by the end of the study); the latter group of couples is assumed to be the same in number per month as in the preceding five months. A model based on these assumptions yields both net and gross rates, which are virtually identical to those shown in Table I (data not shown).

The discontinuation rate for the method was low and it is especially relevant that the discontinuation rate was the highest at the third and the sixth ordinal months, a period during which many previous studies have used as a "learning phase." ^{15,16} Actually, the discontinuation rate following the sixth ordinal month was only 2.7%.

Only 0.7%, at the 12th and 18th ordinal months, discontinued the method for the stated reason "difficulty with avoiding genital contact." While there would be some individuals with that complaint among those who discontinued to "use an artificial method" or for "personal reasons," it does not support the contention that avoiding genital contact makes "a considerable contribution to the failure rates of periodic abstinence methods. . . ."²² Also, lack of confidence was an infrequent reason for discontinuation, as was the discontinuation rate for using another natural method.

This meta-analysis provides a use-effectiveness evaluation of CrM NaProEducation Technology. The method and use effectiveness for avoiding pregnancy reveal stable and very effective method effectiveness ratings and very effective and improving use effectiveness ratings. The system is safe, easy to use and ethically acceptable to all people. The system merits continued study and development.

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