The physiology of the Creighton Model Fertility Care System: physiologic knowledge of patients and their appreciation for their chosen fertility management or family planning system

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1Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81
Abstract

Today, fertility management is an issue impacting 99% of the adult population in the USA. Nearly all sexually experienced American women have used some method of contraception to manage their fertility: 99% in 2006–2008. [34] Oral contraceptives are the most popular method but often produce side effects. The Creighton Model Fertility Care System (CrMS) is an alternative with no side effects and is comparatively effective. The CrMS has method and use effectiveness rates comparable to those of oral contraceptives (99.78%-99.66%, 97%-92% respectively for OCs and 99.5%, 96.8% respectively for CrMS). [31,22] It is intriguing that the CrMS has only one fifth to one third the discontinuation rate after one year that oral contraceptives do (11.3%[22] for CrMS compared to 54.1%[31] or 30% [34] for OCs).

The conclusions of this study suggest that patients appreciate learning about their biology and are satisfied and confident using this biology to manage their fertility through FABMs such as the CrMS. This may be a fertility management method with a wider appeal for patients looking with any of the following characteristics which were appreciated by the participants of this study: strengthening of communication and relationship with their partner because of shared fertility management responsibility, the natural basis of the method, the relief of problems experienced with hormonal birth control, the alignment with religious and moral values, the versatility of the method to both achieve and avoid pregnancy, and increased diagnostic power for women’s health and infertility issues, and the method’s low monetary cost, effectiveness, and simplicity. Each of these areas of appreciation may contribute to the lower discontinuation rates of CrMS users compared to hormonal birth control users. The CrMS could be an effective fertility management method for hormonal birth control users who are dissatisfied with their use of hormonal birth control as a fertility management method.
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**Introduction**

Fertility management has been of interest for thousands of years; the first written document on this subject, the Kahun Gynecological Papyrus dates back to 1900 BC. Now more than ever, new technological advances are being made for both the promotion and the prevention of fertility. Many of these advances medically alter the woman’s natural fertility cycle and produce side effects. While the medical community worldwide is continually learning the intricate workings of the human body, large volumes of research are being conducted on reproductive physiology and its use in managing fertility naturally, without side effects. The Creighton Model Fertility Care System (CrMS) is one of the products of this intensive physiologic research.

Today, fertility management is an issue impacting 99% of the adult population in the USA. Nearly all sexually experienced American women have used some method of contraception to manage their fertility: 98% in 1995 and 2002, and 99% in 2006–2008. [34] Oral contraceptives are the most popular method; 82%, or 43.8 million, American women have used the oral contraceptive pill. [34] Although oral contraception is a widespread tool used for fertility management, it does not work perfectly for everyone. According to the U.S. Department of Health and Human Services Center for Disease Control, of the 43.8 million women who used the pill, 30% discontinued because of dissatisfaction. Out of this group, 64% discontinued because of side effects, 13% were worried about side effects, 11% did not like changes in the menstrual cycle caused by hormonal contraception, 10% became pregnant, and 10% said pill was too difficult to use. [34]

The Creighton Model Fertility Care System (CrMS) is an alternative to hormonal contraceptives that has no side effects and is comparatively effective. The CrMS is one type of
the fertility awareness based methods (FABM) of family planning and was founded using physiologic and clinical research. The CrMS has method and use effectiveness rates comparable to those of oral contraceptives (99.78%-99.66%, 97%-92% respectively for OCs and 99.5%, 96.8% respectively for CrMS). [31,22] It is intriguing that the CrMS has only one fifth to one third the discontinuation rate after one year that oral contraceptives do (11.3%[22] for CrMS compared to 54.1%[31] or 30% [34] for OCs). What could account for this large difference in method discontinuation? Does a system in which patients learn about their physiology build a respect for their bodies, self-confidence, or an appreciation for such a system? This research seeks to explore the physiologic basis of the CrMS, the physiology used in its curriculum, and the physiologic knowledge of those who use the CrMS compared to those who use hormonal birth control; and how such knowledge affects patients’ appreciation of the family planning system they choose to use, their appreciation of their physiology, and their overall self-confidence.

***Physiology of the Creighton Model Fertility Care System***

As a natural method of fertility management, the CrMS is based on the observation of biomarkers that communicate to a woman whether or not she is fertile. [26] Menstruation may be one of the most commonly known biomarkers indicative of the fertility cycle [33], but it is the cervical mucus that is secreted between menstruations that holds invaluable answers for women in regards to their fertility, gynecological, and overall health. First included in published articles in the mid nineteenth century, cervical mucus possesses intricate physiologic characteristics that play a strong roll in controlling the regulation of fertility.
For one and a half centuries, properties of cervical mucus have been discovered, and its importance in fertility regulation has been explored. Dr. Sims, developer of the postcoital test, published two patient reports in 1868 indicating the necessity to determine the effects of cervical mucus on spermatozoa. He noted the most successful time for conception was in the presence of clear and translucent cervical mucus. [45,46] Since Sim’s foundational discovery of the role of cervical mucus in conception, extensive exploration has led to the discovery of its physical properties, biological origin, and power to permit or deflect penetration by sperm and other foreign bodies each which are under strict hormonal control. The World Health Organization held an international Colloquium on Cervical Mucus in Human Reproduction in 1972 to discuss findings and publications surrounding this valuable piece of human physiology. [11]

Cervical mucus has physical properties which bear great importance in its function during the menstrual cycle. Foundational to the use CrMS specifically are the properties of color, consistency, and stretch which were characteristics first explored in detail by Cohen in the 1950s. He demonstrated that profuse, clear, thin, acellular cervical mucus with the greatest degree of Spinnbakeit (fibrosity) was secreted during the most fertile times in the menstrual cycle. This was further confirmed when the administration of estrogens caused the production of this type of mucus, and the administration of progesterone caused the diminishment of quantity and thickening of the mucus. [7] Cohen laid a foundation for hormone responsive cervical mucus that changed properties in accordance with the degree of fertility experienced during the menstrual cycle.

Odeblad, a Swedish biophysicist, first characterized cervical mucus properties as a function of menstrual state. When mucus was dried on slides, crystallization of different types occurred during each stage of the menstrual cycle. As first seen by Odeblad, crystallized fertile
mucus displayed “arborization,” or ferning drying into structures similar to a palm branch or fern frond. [40]

Faccioli studied this crystallization phenomenon further by counting the number of channels present in the dried mucus during multiple days of the menstrual cycle. He found two channels during days six and eight, 70 during day 10, 100 during day 12, and 175 during day 14. The luteinizing hormone surge occurred on day 15 of the cycle, and ovulation occurred on day 16. The number of channels dropped drastically after ovulation to 20 on day 17 and five on day 19. The number of channels present was directly related to estrogen levels in the blood providing evidence for the responsiveness of cervical mucus to hormonal stimuli. [14] He later confirmed that the most channels occurred during the periovulatory phase (165-200) as compared to the preovulatory (70-80) and postovulatory (2-80) phases. (Figures 1 and 2)


**Figure 1.** Scanning electronic feature of cervical mucus during the (from left to right) preovulatory, ovulatory and postovulatory phase.
Hormonal response was also confirmed as mucus that formed canals (canalizing) was estrogen dependent, but mucus that did not form canals (non-canalizing) acted independent of estrogen. [13] Faccioli’s work was confirmed by Garcea who also observed an increase in dendritic crystal formation which was driven by the interaction of high molecular weight substances, mucins, and electrolytes, during the periovulatory phase. He also observed the estrogen dependence of canalization when a linear relationship was observed between estradiol levels and the number of channels formed. [19] An increase in channel number in response to estrogen rise provides strong clues for the role of cervical mucus in fertility management.

Odeblad classified cervical mucus based on its hormonal responsiveness, beginning in the 1960s. Estrogenic mucus (E) allowed for sperm penetration and gestagenic mucus (G) did not. The size of penetration spaces in each type of mucus results from the hormone-dependent linkage of the micelle macromolecule network: under the influence of estrogen, the mucus allows penetration, whereas under the influence of progesterone, very little passage space results.
More types of cervical mucus were classified throughout the 20\textsuperscript{th} century, and in 2003, Menrguez, assisted by Odeblad, confirmed that multiple types of cervical mucus could be present together. There were now four main cervical mucus types categorized: loaf (L), string (S), gestagenic (G), and peak (P). S and P mucus have three and four subtypes, respectively, each with their own distinct crystallization structure. Each mucus type plays a specific role in regulating fertility. (Figures 3 and 4)

Figure 3.


**Figure 4.**

<table>
<thead>
<tr>
<th>Photo Number</th>
<th>Type of Cervical Mucus</th>
<th>Origin</th>
<th>Photo Number</th>
<th>Type of Cervical Mucus</th>
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<td>9</td>
<td>III (mostly S)</td>
<td>Cervical Canal</td>
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<td>10</td>
<td>S</td>
<td>Cervical Crypts</td>
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<td>G</td>
<td>Cervical Canal</td>
<td>11</td>
<td>P</td>
<td>Cervical Crypts</td>
</tr>
<tr>
<td>4</td>
<td>P4</td>
<td>Cervical Canal</td>
<td>12</td>
<td>L</td>
<td>Cervical Crypts</td>
</tr>
<tr>
<td>5</td>
<td>L</td>
<td>Cervical Canal</td>
<td>13</td>
<td>S</td>
<td>Cervical Crypts</td>
</tr>
<tr>
<td>6</td>
<td>S3</td>
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<td>14</td>
<td>L</td>
<td>Cervical Crypts</td>
</tr>
<tr>
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<td>15</td>
<td>S</td>
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<tr>
<td>8</td>
<td>II (mostly L)</td>
<td>Cervical Canal</td>
<td>16</td>
<td>P</td>
<td>Cervical Crypts</td>
</tr>
</tbody>
</table>

**Figure 3 and 4 description of cervical mucus types**
The macroscopic classifications of cervical mucus as a function of stages within the menstrual cycle were developed from the different appearance of mucus as viewed microscopically. Odeblad began this study of microscopic structure by exploring variation of the water content of cervical mucus throughout the menstrual cycle. Cervical mucus contained 2\% dry substance at midcycle and 12\% during the luteal phase. Midcycle mucus is more hydrated and is formed into micelles with larger spaces for spermigration (1 um to 10um in diameter, averaging 3um during midcycle) whereas luteal phase mucus is less hydrated with smaller spaces (0.3um). [39] This classification scale was supported by the work of Takano, using cryoscanning. Takano observed that the spaces in the mesh-like structure of the cervical mucus increased in size toward ovulation, reaching maximum of 10-25um in diameter at ovulation, and rapidly decreased to 1 to 2um two days after ovulation. [48] Odeblad’s later experimental work classified mucus by space size in the mesh network: I compact (0.2-0.4 um), II marine sponge (0.4-1.3 um), III network, parallel (1.5-7um), IV parallel (0.4-2 um). [32] As the diameter of the sperm head averages 3um, these measurements provided the first evidence that cervical mucus acts a biological valve, allowing, and selecting for, vital sperm penetration during fertile times of the cycle.

The microscopic structure of cervical mucus has been described as a mesh network varying in tightness. New insights on microscopic-cervical mucus structure were revealed when the mucus was observed in its three dimensional form under atomic force microscopy in 2007. This new technology showed fixed ovulatory cervical mucus is composed of floating globules of mucin aggregates. These globules transitioned from globular ovulatory mucus to fibrous preovulatory mucus when exposed to a decrease in pH. [6] Viewing mucus in three dimensional
form and without drying sheds a new light on the microscopic structure and of cervical mucus, perhaps, the mechanism of spermigration. (Figure 5)

Figure 5. Cervical mucus under atomic force microscopy. Two spermatozoa are imaged to the same magnification for comparison.

The physical structure of cervical mucus depends highly on its origin of secretion. Cervical crypts line the walls of the cervix and house the epithelial cells that secrete the mucus. When mucus is produced, these crypts gradually fill until extended and then expel the mucus as a result of vascular change in the cervix. This allows the mucus to move from low to high entropy. [38] Rudolfsson originally found two types of cervical mucus in one crypt, but it was later realized that multiple crypts could branch from one canal leading to the lumen of the cervix. [43] String mucus remains as one unit, extending from the crypt to the external os creating channels
for spermigration. Loaf mucus remains close to the crypt to catch malformed sperm. If sperm are caught in the crypts, they have a chance to be expelled once more with the mucus and have their sperm motility reactivated. [38] Hormone regulation of fertility may also occur through hormonal regulation of the cervical crypts.

The hormone induced production of cervical mucus during times of fertility suggests mucus plays a role in conception. Without cervical mucus present, conception is less likely. [28] Not only is cervical mucus important for the protection of sperm, it aids in their motility and penetration of the os. When placed in E mucus, which is present at times of fertility, sperm can move three to five times faster than they can in G mucus, which is present at times of infertility. [38] There is a dose related effect of cervical mucins on sperm motility as well. For sperm exposed to mucins, there is a 27% increase in linearity (straightness of movement) and 16% increase in linear-velocity immediately. After three hours in contact with the mucins, there is a 25% increase in both linearity and velocity. Cervical mucus has a large effect on sperm: it can increase the percentage of motile sperm. [12] Contributing to the motility of the sperm is a key role of cervical mucus in promoting conception.

The mesh network of cervical mucus not only controls and contributes to the penetration of sperm, but of viruses and other foreign bodies as well. Cervical mucus may be a clinically protective mechanism against major sexually transmitted viruses. Most pores in cervical mucus have diameters much larger than human viruses, yet Herpes simplex virus is trapped in cervical mucus. [30] Non-ionic detergent caused average pore size to decrease, suggesting hydrophobic interactions between the micelles regulate pore size. Not only does cervical mucus act as a gatekeeper for the reproductive organs, but also for any other organs that may be damaged by entering pathological organisms.
The discovery of the importance of cervical mucus in conception, findings surrounding its hormone regulated physical properties, and the ability of these properties to regulate penetration all provide a foundation for the study of gynecological health and its role in conception.

**Fertility Awareness Based Method Development**

The properties of cervical mucus allow couples to manage their fertility naturally in a very effective manner. The relationship between cervical mucus and ovulation has been evaluated by studying cervical mucus in correlation with the time of ovulation, which has been tested multiple ways: vascular levels of LH, urinary levels of LH, and ultrasound.

Using vascular levels of LH to measure ovulation day, Billings found that lubricative mucus occurred on ovulation day for five patients, one day before ovulation for nine patients, and two days before ovulation for four patients. [3] Depares found similar results using ultrasound to detect ovulation. He stated, “By identifying the day of most abundant fertile cervical mucus, women can accurately pinpoint the day of ovulation almost as precisely as LH measurements.” [10] Using urinary LH measurements (tested twice daily for accuracy) to detect ovulation, maximal cervical mucus scores consistently coincided with the urinary LH surge and preceded ovulation detected by ultrasound by zero to 24 hours. Mucus scores rapidly declined in the 24 hour period following urinary LH surge. A strong correlation exists between the urinary LH surge and both the serum LH peak and ultrasound evidence of ovulation. [35] Each of these studies demonstrated that most healthy women can assess their cervical mucus symptoms with very high accuracy to give good estimates of ovulation timing.
After describing the biology of cervical mucus in detecting ovulation, and thus regulating fertility, the Billings developed the first international standardized method in which any women could be taught how to observe and assess her cervical mucus symptoms: The Billings Ovulation Method (BOM). During a trial in 1981 that helped to accurately develop the BOM, 24/27 women demonstrated the ability to recognize mucus discharge and peak symptom after the first cycle of teaching, 2/27 after the second cycle, and 1/27 was anovulatory. The time between ovulation (day following LH peak) and peak symptom ranged from -2 to +1 days averaging two days. The time from first recorded symptom to ovulation ranged from three to 10 days averaging six days. Two correlations are evidence that the cervical mucus pattern accurately mirrors the hormonal events stimulating ovulation: the correlation between the onset of mucus symptoms and the level of circulating estradiol-17, and the correlation between the peak symptom and the LH peak. [8] Billings and his wife developed a system used around the world to teach, learn, and practice fertility management. Most libraries have a copy of the instruction book. [4] The Billings laid the foundation for the world population to have a reliable, scientifically founded FABM to use.

To be an internationally used system, the BOM had to be tested throughout the world. Studies reporting the success of the BOM involve participants from multiple classes, literacy ranges, industrialized and unindustrialized countries, and cultural backgrounds. [4] Individual studies were conducted in Tonga, Australia, Korea, India, Ireland, and the United States of America, and a conglomerate study was conducted by the World Health Organization in New Zealand, Ireland, India, the Philippines, and El Salvador. In one of the first published studies, 282 native Tongan women used the method for 2503 months with one case of method failure and two cases of user failure. [50] A FABM had been developed that could be used effectively throughout the world.
Recently, Scarpa assessed the accuracy of the BOM in 2006. The probabilities of pregnancy found were 0.3% on days with no noticeable secretions and 29% on days with the most fertile-type mucus. Probability of the presence of the most fertile type mucus was less than 20% outside of days 10 through 17 and 59% on day 13. Probability of conception using the BOM is essentially zero on days without secretions and dramatically increases to near 30% on days with most fertile-type mucus regardless of the timing (day 1 defined as first day of red fresh bleeding). Probability of conception is 100 times higher with fertile type mucus compared to no mucus. [44] Scarpa’s data demonstrate the importance of cervical mucus in fertility management and the ability to use a FABM to manage fertility accurately and safely.

Outside of the BOM, multiple trials have been run to test the reliability of ovulation based family planning systems. For example, Fehring ran a study to see the effects of including a urinary LH monitor in the fertility management process. Correct use of the system resulted in a pregnancy rate of 2.1%, whereas, imperfect use of the system resulted in a pregnancy rate of 14.2%. Correct use of an electronic hormonal fertility monitor in addition to observations of cervical mucus can be as effective or more effective than other current FABMs. [17]

Bigelow found a trend in the day-specific probabilities of pregnancy with increase in the cervical mucus score. But, adjusting for cervical mucus score, timing of fertile window by BBT had limited variability. Mucus monitoring provides a useful clinical marker of days with high conception probability; cervical mucus symptoms should be held superior to timing of the fertile window of the menstrual cycle found with basal body temperature (BBT). [2]

Flynn assessed patients’ ability to succeed in identifying the fertile phase. Appearance of any mucus averaged 5.2 days before the LH surge. The last day of fertile mucus averaged 0.7
days from the last day of the LH surge. Once again, this demonstrates that patients can be taught to predict the time of ovulation by observing the changes in cervical mucus. \[18\]

Despite the large body of research on cervical mucus and fertility awareness methods like the BOM, there were no clinical practice standards for FABM. While in his fourth year of medical school at the University of Minnesota, Dr. Thomas Hilgers began the research that led to the development of a strictly standardized FABM that had deep roots in scientific foundations. Starting off completing research on certain aspects of the BOM, Dr. Hilgers standardized this method into the Creighton Model Fertility Care System.

Hilgers published four deliberate papers during the founding of the CrMS. First, the accuracy of the Peak symptom of cervical mucus was established when ovulation was estimated to occur (based on progesterone measurements) three days before to three days after Peak symptom with a mean of 0.31 days before. The accuracy of the Peak symptom correlating to time of human ovulation is foundational to the CrMS. \[24\] Second, the definitions of fertility and infertility were developed in regards to cervical mucus observation of ferning and canalization. \[21\] Third, the superiority of the Peak symptom to BBT was developed due to inherent error rate of BBT. \[20\] Fourth, intermenstrual symptoms (intermenstrual pain, breast tenderness, abdominal bloating, low backache, intermenstrual bleeding, vulvar swelling) were found to be impractical measures of fertility; the most promising as a practical symptom was breast tenderness. \[23\]

These foundational studies, in addition to the previously mentioned studies and much other data, led to the development of the Creighton Model Fertility Care System. While analyzing pregnancies occurring during use of the ovulation method, Dr. Hilgers found some resulted because of poor teaching. \[25\] The CrMS was founded with the knowledge that clear
and explicit instruction by well-trained instructors is necessary for proper use of the ovulation method. Instruction for the CrMS takes place through professional teachers extensively trained [27] by Dr. Hilgers in a 13 month program. Successful use of the CrMS requires learning from a qualified CrMS instructor. [29]

FertilityCare Professionals (FCP) teach the course to clients starting with an introductory session in which the method is explained in detail. After this, the couple or individual is given a handbook [26], charts, and stickers to begin charting before meeting with the FCP at two weeks, four weeks, six weeks, eight weeks, 12 weeks, 24 week, nine months, and every six to 12 months after wards. The client observes cervical mucus noting its sensation, color, and stretchability by wiping with layers of flat white toilet tissue before and after urination, bowel movements, and showering or swimming. If a couple is charting together, the man is encouraged to chart the women’s most fertile sign of the day using a number and letter code described on the chart and a sticker indicating menstruation (red sticker), fertility (white sticker with a baby on it), or infertility (green sticker). From when fertile mucus is present until the evening of the fourth day after the Peak symptom (last day of fertile mucus), genital contact is to be avoided if the method is being used to avoid pregnancy; the opposite is true if the method is being used to achieve pregnancy. Couples are encouraged to express their love in other ways during this time which is reported to lead to increased communication. NFP couples had a statistically higher self-esteem and intellectual intimacy than couples using oral contraceptives. [15]

The CrMS system of fertility management does not stop at charting, but is a stepping stone into a quickly expanding area of women’s health and infertility issues. Of all of the FABMs, the CrMS system is unique in that it has an extensive network of other medical professionals (physicians, nurse practitioners, physician assistants) who have undergone training
in Dr. Hilgers’ Medical Consultant program to use the charting system as a springboard for treatment of women’s health and infertility issues. [28] If there are ever medical problems that may be demonstrated through charting, the FCP will refer the client to a Medical Consultant (MD, NP, and PA).

Multiple studies have addressed the efficacy of the CrMS throughout the country. Efficacy is calculated using specific formulas and definitions defined by Tietze’s standardization of the statistical evaluation of contraceptive methods. [42, 49] In early reviews of the evaluation of FABMs, the necessity to distinguish between use effectiveness and method effectiveness and strongly define each of these terms was expressed. [1, 5] Tietze’s work resulted in the standardization of these terms. Theoretic, or method effectiveness is defined as the capacity of a fertility management method to reduce the chance of pregnancy under perfect use conditions whereas use effectiveness is defined as the capacity of a fertility management method to reduce the chance of pregnancy under real life conditions while taking user error into account.

In a large meta-analysis of multiple smaller studies [16], including a total of 1,876 couples and 17,130 couple months, the overall method and use effectiveness for the CrMS in the 12th ordinal month was 99.5% and 96.8% respectively; 18th ordinal month was 99.5% and 96.4% respectively. [22] Because ovum survives 12-24 hours, NFP failure is usually not due to unreliability, but user failure. [10]
Table 11.1
The CrMS Method and Use Effectiveness for Avoiding Pregnancy, by Centers: Five-Study Composite and Ordinal Month of Use

<table>
<thead>
<tr>
<th>Parameter</th>
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<th>St. Francis Hospital</th>
<th>St. Joseph Hospital</th>
<th>Marquette Nursing Center</th>
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<td>697</td>
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<td>18</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>97.1</td>
<td>N/A</td>
<td>96.4</td>
</tr>
</tbody>
</table>


Table 11.2
Achieving related pregnancy rates²
CREIGHTON MODEL FERTILITYCARE™ SYSTEM
by Center, 5 study composite and ordinal month of use
(Per 100 Couples)

<table>
<thead>
<tr>
<th>Ordinal Month</th>
<th>Creighton University Omaha</th>
<th>St. John’s Mercy St. Louis</th>
<th>St. Francis Med. Ctr. Wichita</th>
<th>St. Joseph Hospital Houston</th>
<th>Marquette Nursing Center Milwaukee</th>
<th>5 STUDY COMPOSITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.1</td>
<td>1.8</td>
<td>5.3</td>
<td>0.7</td>
<td>1.2</td>
<td>2.1</td>
</tr>
<tr>
<td>6</td>
<td>10.5</td>
<td>13.6</td>
<td>19.9</td>
<td>7.9</td>
<td>14.0</td>
<td>12.8</td>
</tr>
<tr>
<td>12</td>
<td>19.1*</td>
<td>23.7*</td>
<td>28.6**</td>
<td>14.2</td>
<td>24.8***</td>
<td>21.0</td>
</tr>
<tr>
<td>18</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>17.9**</td>
<td>N/A</td>
<td>25.6***</td>
</tr>
</tbody>
</table>

N/A = Not Applicable ² 2,224.0 couple months of use. ³ 1,080.0 couple months of use. ² 2,471.0 couple months of use. ⁴ 7,084.5 couple months of use. ³ 1,819.5 couple months of use. ⁴ A total of 17,130.0 couple months of use (1,876 couples).

2. In Press.


Figure 6. Efficacy of the CrMS for avoiding and achieving pregnancy
Studies have also been done by outside groups to assess the CrMS. In one hundred couples in one year there were 0.14 method-related pregnancies, 2.72 user/teacher error pregnancies, 12.84 achieving related behavior pregnancies (choice of genital contact during known fertile time), 1.43 unresolved pregnancies, and 17.12 total pregnancies. If one was to use the CrMS perfectly to avoid pregnancy, probability of pregnancy within first year would be less than 1%. Probability of pregnancy within first year for normal users is 3-4%. Genital contact on known fertile days results in a probability of pregnancy within the first cycle greater than 50%. All couples who start using the CrMS, regardless of whether they are using the method to avoid or achieve pregnancy, have a probability of pregnancy within first year of 17%. [29] From both internal and external studies of the CrMS, efficacy rates similar to oral contraceptives have been reported. [29, 22]

Women with regular cycles, with irregular cycles, who are breastfeeding, and who are following the stop of OC can use the CrMS successfully as well because it is dependent on biomarkers consistently produced during ovulation. [29] For those with cycle abnormalities, Daly discovered that follicular growth is heavily correlated with cervical mucus maturation. [9] The ability to consistently manage fertility using the CrMS despite cycle irregularities and other health issues is a powerful tool addressed to the fullest extent in the CrMS method. [28]

The CrMS is also a unique form of family planning in that it can be used to both achieve and avoid pregnancy. Often, couples begin using the system to further assess infertility. For both fertile and infertile couples, the highest probability of pregnancy occurred on the peak day of vulvar mucus observation: 38% for fertile couples and 14% for subfertile couples. [47] Further treatment for infertility using the symptoms charted in the CrMS is available through NaProTechnology.
There is very strong evidence that most normal women can assess their cervical mucus symptoms with very high accuracy which provides a good estimate of ovulation. The research on and development of FABMs has led to a method, the CrMS, with efficacy rates similar to those of hormonal birth control that can also be used effectively for both regular and irregular cycles and to treat women’s health and infertility issues.

**Hypothesis**

An analysis of the literature on FABMs inspires the following questions. What could account for the large difference in method discontinuation (11.3% [22] for CrMS compared to 54.1% [31] or 30% [34] for OCs)? Does a system in which patients learn about their physiology build a respect for their bodies, self-confidence, or an appreciation for such a system? How does the physiologic knowledge of those who use the CrMS compare to those who use hormonal birth control; and how does such knowledge affects patients’ appreciation of the family planning system they choose to use, their appreciation of their physiology, and their overall self-confidence? Therefore, the purpose of the following study was to survey women who use either hormonal birth control or the CrMS and ask these women about their knowledge of reproductive physiology and their satisfaction with their current form of fertility management.

**Methods**

This research was conducted by completing extensive literature reviews on the physiologic basis and efficacy of the CrMS; participating in the CrMS class and follow-up appointments and noting the physiology that is presented; conducting patient surveys containing a reproductive physiology knowledge test and questions on method appreciation, physiologic
appreciation and self-confidence; and analyzing survey responses for correlation between method used (either CrMS or hormonal birth control), physiologic knowledge, method appreciation, knowledge appreciation, and self-confidence.

Attending the CrMS class gave the primary investigator insight as to why the CrMS is successful. The teachers are very specific and repetitive making sure the clients know the answers to all of the review questions. During each meeting, an amount of new information is added, and the old information is reviewed to make sure the knowledge has been retained. The teacher uses a book in which every review question must be checked off; thus, allowing for consistency between teachers. Because the teaching system was standardized, learning was efficient and accurate.

The research process for this project has been approved through the University of Minnesota’s Internal Review Board under Exempt Category Two project number 1012E94315 and through the Park Nicollet Institute’s Internal Review Board under Exempt Category Two project number 04090-11-A. Approval letters can be found in the appendix. Females of childbearing age who were using either the Creighton Model Fertility Care System or hormonal birth control were recruited in primary care clinics with fliers handed to the patients by the nursing or receptionist staff. The fliers briefly explained the study, assured the anonymity of the subjects and confidentiality of the surveys, described the incentive for participation (a five dollar donation to charity and assistance to a student), provided the web address for the survey, and provided contact information for patient questions. A flyer can be found in the appendix. Interested subjects accessed and complete the on-line REDCap survey according to the instructions provided before each set of questions. The survey can be accessed at https://redcap.ahc.umn.edu/surveys/?s=gy9sIW and a copy of the survey questions can be found
in the appendix. The first section of the survey was designed to determine which fertility management category subjects were analyzed in; certain questions in this section only pertained to subjects if they provided a particular answer for a previous question. This “branching logic” can be experienced while taking the online survey.

The survey was piloted with an anonymous group of students from an undergraduate physiology class instructed by the principal investigator’s faculty advisor. Forty-three women completed the survey and nine provided incomplete responses. This data aided greatly in developing questions with streamlined answers. After receiving multiple answers in the section of the survey that defines current method use which were not completely clear, this section of the survey was redefined. “Branching logic” was used to provide multiple layers of definition when patients answered which type of fertility management or family planning method they were currently using.

All precautions were taken to protect the anonymity and well-being of the subjects and the confidentiality of the surveys throughout the entire research process. REDCap is a HIPAA compliant survey tool; the subjects participated anonymously, and personal information or identifying information was not collected by the researchers at any time. Password protected data was accessed only by the PI and her advising professor, and any data that was printed was stored in a locked cabinet in the advising professor's locked office. Data will be stored one year after the study closure date and then be destroyed. Subjects were informed through written communication on the flyer and the survey that they remained anonymous, their answers to the survey were used as data in a University of Minnesota honors thesis, and in filling out the survey, they were giving consent to participate in the research study. They were also assured that their choice to participate in the study would not negatively impact the healthcare they receive in
any way. An incentive for completing the study was provided in the form of a donation to charity or student scholarship. Designating a recipient of the donation ensured that the participants remained anonymous.

The survey was completed in its entirety by 48 FABM users (one BOM user, six Couple to Couple League users, and 41 CrMS users) and one hormonal birth control. Nine FABM users partially completed the survey. The clinics recruiting the FABM users put the flyer in an online newsletter which may have resulted in a larger response compared to the paper flyers handed out in the clinic recruiting hormonal birth control subjects. Before statistical analysis, extreme outliers, calculated by SPSS, were removed, the hormonal birth control response was removed as there was not enough for proper statistical analysis, and the FABM users were grouped together, as their knowledge scores did not differ significantly.

Descriptive statistics were used to evaluate the knowledge and satisfaction scores. The knowledge score was recorded as number correct out of 10, and each question of the satisfaction score (level of agreement/disagreement indicated by number between zero (strongly disagree) and 100 (strongly agree) on a sliding bar scale). All data was tested for normalcy in SPSS and found to be non-parametric.

Inferential statistics were used to evaluate the strength of correlation between the overall knowledge score and each of the sliding bar scaled questions to search for a relationship between reproductive physiologic knowledge and method appreciation, knowledge appreciation, and self-confidence in each of the methods of family planning being evaluated. Spearman’s correlation coefficient, for non-parametric data sets, was calculated using SPSS.

Qualitative answers to the questions on the first page of the survey were coded, grouped and presented as a percentage of responses under each coded category.
**Results**

**Quantitative Data**

Analysis of the survey data provided insight into the answers of the research questions:

What could account for the large difference in method discontinuation (11.3% [22] for CrMS compared to 54.1% [31] or 30% [34] for OCs)? Does a system in which patients learn about their physiology build a respect for their bodies, self-confidence, or an appreciation for such a system? How does the physiologic knowledge of those who use the CrMS compare to those who use hormonal birth control; and how does such knowledge affects patients’ appreciation of the family planning system they choose to use, their appreciation of their physiology, and their overall self-confidence?

**Table 1. Reproductive Knowledge Survey and Scores**

<table>
<thead>
<tr>
<th>Question</th>
<th>Correct Answer</th>
<th>Percent Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>How long is the average menstrual cycle?</td>
<td>28 days</td>
<td>90.74</td>
</tr>
<tr>
<td>How many times per menstrual cycle does ovulation typically occur?</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>During how many days in the average cycle is a woman fertile?</td>
<td>6 days</td>
<td>57.41</td>
</tr>
<tr>
<td>How often is a man fertile?</td>
<td>continuously</td>
<td>98.15</td>
</tr>
<tr>
<td>Once a mature egg is released (ovulated), how long can it survive in the women's body?</td>
<td>24 hours</td>
<td>64.81</td>
</tr>
<tr>
<td>What protective agent for sperm is produced in the women's body?</td>
<td>cervical mucus</td>
<td>100</td>
</tr>
<tr>
<td>Once in contact with a protective agent in the women's body, how long can sperm survive?</td>
<td>3-5 days</td>
<td>92.59</td>
</tr>
<tr>
<td>Pregnancy can occur due to genital contact without intercourse. (True or False)</td>
<td>TRUE</td>
<td>94.44</td>
</tr>
<tr>
<td>Which of the following hormones is produced by the pituitary gland in the brain for the purpose of regulating the menstrual cycle?</td>
<td>Follicle stimulating hormone</td>
<td>29.63</td>
</tr>
<tr>
<td>Which of the following is produced in the ovary to regulate the menstrual cycle?</td>
<td>Estrogen</td>
<td>66.67</td>
</tr>
</tbody>
</table>

Average number correct out of 10: 7.94

The overall knowledge of women using FABMs was strong, as the average score on the knowledge test was 7.94 out of 10 (Table 1). Further work needs to be done to compare this score to the average knowledge score of women in the same population who are not using
FABM. The answer to the rating question “I understand the biology of how my current family planning or fertility management method works” agreed with the knowledge scores with an average rating of 90.7 out of 100. The relationship between the rating of this statement and the knowledge scores did not achieve (but approaches) statistical significance given that Spearman’s correlation coefficient is 0.355. With this sample, there is no evidence for a correlation between reproductive knowledge score and visual analog scores of satisfaction with fertility management method.

**Table 2. Knowledge Score vs. Satisfaction**

<table>
<thead>
<tr>
<th>Question</th>
<th>Average Rating (out of 100)</th>
<th>Spearman’s Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>I understand the biology of how my current family planning or fertility management method works.</td>
<td>90.79</td>
<td>0.355</td>
</tr>
<tr>
<td>Understanding the biology of my current family planning or fertility management method increases my appreciation of my method.</td>
<td>96.22</td>
<td>0.208</td>
</tr>
<tr>
<td>Understanding the biology of my current family planning or fertility management method increases my satisfaction in my method.</td>
<td>91.83</td>
<td>0.198</td>
</tr>
<tr>
<td>Understanding the biology of my current family planning or fertility management method increased my confidence in my method.</td>
<td>93.94</td>
<td>0.080</td>
</tr>
<tr>
<td>Understanding how my current family planning or fertility management method works increases my appreciation of how my body works.</td>
<td>97.78</td>
<td>0.200</td>
</tr>
<tr>
<td>The more I use my current family planning or fertility management method, the more confidence I feel in my method.</td>
<td>94.29</td>
<td>0.102</td>
</tr>
<tr>
<td>The more I use my current family planning or fertility management method, the more confidence I feel in myself.</td>
<td>84.13</td>
<td>0.113</td>
</tr>
<tr>
<td>The more I understand the biology of my current family planning or fertility management method, the less comfortable I am using it.</td>
<td>0.78</td>
<td>0</td>
</tr>
<tr>
<td>The more I understand about how my current family planning or fertility management method works in my body, the less confident I fell about using my method.</td>
<td>1.98</td>
<td>-0.010</td>
</tr>
</tbody>
</table>

Participants in this sample expressed a high average appreciation and satisfaction for their family planning method because of their understanding of how it biologically works and also more greatly appreciated how their body works because of their understanding of how their current fertility management method works (Table 2). Appreciation and satisfaction scores averaged 96 and 92 out of 100, respectively, for all participants indicating a widespread
importance across the sample. An appreciation of the body resulting from an appreciation of the method was reported as the strongest rating score of all the questions with an average of 98. This is understandable for FABM users, for they must have an understanding of their body to use the system effectively. On average, participants reported an appreciation and satisfaction for their method because of an understanding of its biology and also showed an appreciation for their bodies because of an understanding of their method.

A contrary question demonstrated the importance of participants’ understanding of biology, as they disagreed strongly with the idea that a greater understanding of biology makes them less comfortable using their method with an average score of 0.8 out of 100.

Along with appreciation and satisfaction, biological understanding also affected participants’ confidence in their method. Although no correlation was drawn, on average, participants agreed that biological understanding does increase their confidence in their method with an average score of 94 out of 100. A contrary question also demonstrated this point when participants strongly disagreed that a greater understanding of their biology decreased their confidence in using the method, rating 2 out of 100 on average. In addition to confidence due to biological understanding, participants also expressed confidence due to length of use. Participants on average agreed that the more they used their method, the more confidence they felt in it with an average score of 94 out of 100. Confidence in oneself was also found to be a result of using FABM. On average, participants agreed that a greater use of their family planning method resulted in a greater confidence in themselves with an average rating of 84 out of 100.

Overall, the quantitative portion of the survey demonstrated the importance of understanding the biology of a participant’s current family planning method to their appreciation and confidence in and satisfaction of the method. Agreement was high for all of these areas: a
greater understanding of biology and its impact on appreciation, satisfaction, and confidence in one’s method and oneself, although, none were significantly correlated with a higher knowledge score. One of the hypotheses of this study was that if patients have a greater understanding of reproductive biology, it may lead to an increase in appreciation, satisfaction, and confidence in the patient’s family planning method, however, in this sample, the data do not support this hypothesis. There was also no significant correlation between age and knowledge score.

**Qualitative Data**

Statements declared in the qualitative portion of the survey support the conclusions gathered by the quantitative section of the survey. In regards to the importance of knowledge, 37% of participants chose to use FABM to learn more about the body, and 68.5% stated this knowledge as a reason for appreciating their method (Tables 3 and 4). There were multiple statements describing the confidence participants felt because of their increased knowledge as well. Some examples include: “I feel more in control over our family decisions than I did using any other method.”; “I feel empowered by my knowledge and am better able to make informed decisions about my health.”; “I am in 100% control.”; “I feel more in control and better understand my fertility.”; “I wanted to understand NFP as a way to take control of my fertility.” For both biology knowledge and confidence, qualitative data supported the conclusions drawn by the quantitative data.
<table>
<thead>
<tr>
<th>Why did you choose the family planning or fertility management method you are currently using?</th>
<th>Examples</th>
<th>Percentage</th>
</tr>
</thead>
</table>
| Strengthening of communication and relationship with partner because of shared fertility management responsibility.       | “I feel more fulfilled and happy in my marriage than I ever could have expected.”
“System that BOTH my husband and myself participate in.”
“It helps my wife understand one another and build our relationship.”
“Method encouraged communication, partnership.”
“Allows for the couple to work together to track.”
“We wanted as method that would strengthen our relationship with each other.”                                                                                     | 16.67      |
| Natural                                                                                                                   | “We wanted a method that did not rely on artificial devices or medication.”
“Wanted to practice a more natural, holistic way to family planning.”
“It is natural, it works with the human body.”
“Why take medications when a natural alternative respects and nurtures the gift of fertility?”                                                                    | 35.19      |
| Increased knowledge of body                                                                                              | “I wanted to learn about my cycle and know my body prior to having children.”
“I am fascinated by fertility and love being aware of my body.”
“I was interested in learning more about my body and cycle.”                                                                                                              | 37.04      |
| Problems with hormonal birth control                                                                                     | “Birth control was responsible for liver damage that I was thankfully able to recover from upon stopping hormonal BC.”
“Heath aversions to hormonal birth control.”
“I did not like how hormonal birth control made me feel.”                                                                                                                | 29.63      |
| Religious or moral reasons                                                                                               | “It upholds the values I believe in.”
“It is in line with our religious and moral beliefs.”
“It is in line with the teachings of the Catholic Church.”
“Ethical”                                                                                                                 | 55.56      |
| Versatility of method: useful for both avoiding and achieving pregnancy                                                 | “We also wanted a method […] which could be used to either achieve or avoid a pregnancy.”
“It is versatile in its ability to manage health along with plan families.”
“I can choose to avoid or achieve pregnancy if desired.”                                                                                                                   | 29.63      |
| Increased knowledge and diagnostic power of women’s health issues and/or infertility                                       | “Further pin point issues stemming from my endometriosis.”
“To provide insight into reasons for infertility.”
“History of success for infertility.”
“First learned it as a single woman to identify underlying women’s health issues (which it did very effectively!).”
“Solution to untreated endometriosis.”
“Can help with gynecological problems, such as infertility, PMS, low progesterone, etc through NaProTechnology.” | 33.33      |
| Inexpensive                                                                                                               | “We chose this method for […] financial benefits.”
“an essentially free system”
“cheap”                                                                                                                   | 5.56       |
| Efficacy of method                                                                                                        | “Reliability”
“Good results”
“This is an effective way for us.”
“Accurate and complete”
“Most effective”
“It is quite obviously the best option out there.”                                                                          | 14.81      |
| Simplicity of method                                                                                                      | “We chose this method for simplicity of use.”                                                                                                                                                    | 3.70       |
### Table 4. Appreciated traits of method

<table>
<thead>
<tr>
<th>What do you appreciate about the family planning or fertility management method you are currently using?</th>
<th>Examples</th>
<th>Percentage</th>
</tr>
</thead>
</table>
| Strengthening of communication and relationship with partner because of shared fertility management responsibility. | “My husband’s respect for me and the natural way my body was created.”
“It takes both the man and woman’s participation to make it work. Through charting my cycle we are both aware of times of fertility and infertility and it relieves the woman of being the ‘gatekeeper’.”
“Facilitates communication.”
“I appreciate my fiancé and I are both fully involved in the system. We communicate and are clear about our family planning intentions once we are married.”
“Creates a sense of shared responsibility for family planning between my husband and I. He has a new appreciation for the beautiful gift of our fertility that I don’t believe he would have if I were on hormonal birth control.”
“I appreciate the communication that the method promotes and the emphasis on love and affection that is broader than intercourse.”
“It decreases our chances of divorce and leads to a better sex life.”
“Communication with spouse, respect from spouse regarding fertility, enhanced relationship due to increase in communication.”
“It has brought my husband and I closer as a couple and most importantly spiritually.”
“Though we are not married yet (and this not sexually active), this method has already improved our communication and encouraged us to broach intimate subjects in a healthy, prudent and responsible way.”
“I enjoy working to plan my family with my husband and sharing a closeness only NFP offers.”
“That my husband and I make the decisions together, we know that if we have intercourse during certain times, we could get pregnant. It also makes the times that we do more special because we are aware of my cycle and what the act may or may not bring.” | 44.44 |
| Natural                                                                                         | “It is natural”
“It looks at the whole person/couple. It isn’t just about sex or even fertility, but about being healthy. After dealing with so many drugs and treatments for endometriosis I was excited to find a method that didn’t require me to take any drugs.”
“It looks beyond overriding the body’s system to try to fix what’s not working in the body.”
“Doesn’t involve medication or manipulation of cycle.”
“This system allows the body to be natural.”
“Not a patch or band aid to serious medical condition.”
“I am not putting hormones into my body and my body is allowed to act as it normally would.”
“I like how it makes me more aware of my body and what it is doing, and learning how to make personal and responsible decisions regarding my body.” | 44.44 |
| Increased knowledge of body                                                                      | “Respect for my own body”
“Since I am single, I use the information for awareness only. I love being able to know exactly where I am in my cycle, which helps me plan and schedule my life knowing how I will feel on any given day or week.”
“I feel empowered by my knowledge and am better able to make informed decisions about my own health.”
“I have never been able to predict my menstrual period’s arrival and now I can within a day or two.”
“I appreciate that I have the tools to totally respect myself and my complete reproductive system. I am also totally aware of cyclic changes and abnormalities within my reproductive | 68.52 |
system.”
“I am learning things about my cycle that may affect my chances of getting pregnant. I would not have known these things if I was on birth control.”
“I am learning about my body and have a really good understanding of the way my reproductive cycle works. I am much more in tune with my body.”
“I enjoy knowing my body better and understanding my, would the word be, physiology?”
“It has taught me so much about my own body and has helped me to appreciate my fertility as a gift not a burden.”

<table>
<thead>
<tr>
<th>Eliminated problems once experienced with hormonal birth control</th>
<th>“No side effects.”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“I would not have known these things [knowledge of cycle] if I was on birth control.”</td>
</tr>
<tr>
<td></td>
<td>3.70</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agrees with religious or moral values</th>
<th>“In accordance with our religious and moral beliefs.”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“We love its foundation in science, nature, and God’s plan for the marriage and the family.”</td>
</tr>
<tr>
<td></td>
<td>“In line with my faith.”</td>
</tr>
<tr>
<td></td>
<td>“Approved by the Catholic Church.”</td>
</tr>
<tr>
<td></td>
<td>“Moral.”</td>
</tr>
<tr>
<td></td>
<td>20.37</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Versatility of method: useful for both avoiding and achieving pregnancy</th>
<th>“Assists in avoiding and achieving pregnancy.”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“It gives us the ability month to month to choose our fertility status.”</td>
</tr>
<tr>
<td></td>
<td>“I always know exactly where in my cycle I am and can avoid sex if avoiding pregnancy, time it right if trying to conceive.”</td>
</tr>
<tr>
<td></td>
<td>“Having the option of planning my pregnancies based on my personal health, financial and living situation.”</td>
</tr>
<tr>
<td></td>
<td>“I truly believe that it helped us achieve pregnancy in a very natural way and that has meant the world to us.”</td>
</tr>
<tr>
<td></td>
<td>“I can easily know when to time intercourse in order to conceive.”</td>
</tr>
<tr>
<td></td>
<td>“I love the ease and flexibility of family planning, as well as fertility management.”</td>
</tr>
<tr>
<td></td>
<td>48.15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Increased knowledge and diagnostic power of women’s health issues and/or infertility</th>
<th>“The medical aspect! I have hormonal issues no other doctor would even know about or know how to address if they didn’t know Dr. Hilger’s Methods.”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Because of all the research Dr. Hilgers has done to help with infertility we now have two amazing boys which we probably wouldn’t have achieved without the CrMS.”</td>
</tr>
<tr>
<td></td>
<td>“The possibility of finding/discovering other underlying conditions that may contribute to infertility.”</td>
</tr>
<tr>
<td></td>
<td>“I am totally aware of cyclic changes and abnormalities within my reproductive system.”</td>
</tr>
<tr>
<td></td>
<td>31.48</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inexpensive</th>
<th>“Inexpensive”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“We appreciate the fact that it is relatively inexpensive.”</td>
</tr>
<tr>
<td></td>
<td>“Cheap”</td>
</tr>
<tr>
<td></td>
<td>9.26</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy of method</th>
<th>“Reliable”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“We appreciate that it is […] as effective —when used properly— as birth control or some other hormonal therapy.”</td>
</tr>
<tr>
<td></td>
<td>“We appreciate the fact that it is […] reliable.”</td>
</tr>
<tr>
<td></td>
<td>9.26</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Simplicity of method</th>
<th>“Easy to track.”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Clearly defined method that is so easy to do.”</td>
</tr>
<tr>
<td></td>
<td>“Once you get used to your cycles it is fairly simple.”</td>
</tr>
<tr>
<td></td>
<td>“It is easy to use.”</td>
</tr>
<tr>
<td></td>
<td>“We appreciate that it is so simple to do.”</td>
</tr>
<tr>
<td></td>
<td>“No temp taking, easy to use.”</td>
</tr>
<tr>
<td></td>
<td>“It’s so easy! I love the ease and flexibility of family planning.”</td>
</tr>
<tr>
<td></td>
<td>“It’s so easy! I like that I don’t have to check my temp every day or check my cervix.”</td>
</tr>
<tr>
<td></td>
<td>20.37</td>
</tr>
</tbody>
</table>
Qualitative data presented multiple further conclusions. In both the areas of deciding why to use the method and acknowledging what was appreciated about the method participants used, very similar themes arose (Tables 3 and 4). Within these themes, participants reported many qualitative statements that further define their reasons for choosing and appreciating their current method. The data was saturated with some repetitive qualitative statements, and all unique statements were presented in the tables. Overall, a greater amount of unique data was reported when the participants were asked about what they appreciated about their method compared to why they chose their method. In the context of choosing their method, participants reported the greatest amount of unique data for strengthening of communication and relationships and increased diagnostic power of women’s health and infertility issues. In regards to appreciation of the current method, participants reported the greatest amount of unique data by far for strengthening of communication and relationships. A large amount was also reported for the natural aspects of the method, increased knowledge of the body, versatility of the method for both achieving and avoiding pregnancy, and increased diagnostic power. The qualitative statements reported by the participants demonstrate a rich variety of appeal for the CrMS.

Comparing the answers to the two qualitative questions answered by every patient provides insight into interesting shifts. (Table 5)
Table 5. Qualitative answer comparisons

<table>
<thead>
<tr>
<th>Answer Theme</th>
<th>Percentage answered to: “Why did you choose the family planning or fertility management method you are currently using?”</th>
<th>Percentage answered to: “What do you appreciate about the family planning or fertility management method you are currently using?”</th>
<th>Shift in percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengthening of communication and relationship with partner because of shared fertility management responsibility.</td>
<td>16.67</td>
<td>44.44</td>
<td>27.77</td>
</tr>
<tr>
<td>Natural</td>
<td>35.19</td>
<td>44.44</td>
<td>9.25</td>
</tr>
<tr>
<td>Increased knowledge of body</td>
<td>37.04</td>
<td>68.52</td>
<td>31.48</td>
</tr>
<tr>
<td>Eliminating problems once experienced with hormonal birth control</td>
<td>29.63</td>
<td>3.70</td>
<td>-25.93</td>
</tr>
<tr>
<td>Agrees with religious or moral values</td>
<td>55.56</td>
<td>20.37</td>
<td>-35.19</td>
</tr>
<tr>
<td>Versatility of method: useful for both avoiding and achieving pregnancy</td>
<td>29.63</td>
<td>48.15</td>
<td>18.52</td>
</tr>
<tr>
<td>Increased knowledge and diagnostic power of women’s health issues and/or infertility</td>
<td>33.33</td>
<td>31.48</td>
<td>-1.85</td>
</tr>
<tr>
<td>Inexpensive</td>
<td>5.56</td>
<td>9.26</td>
<td>3.7</td>
</tr>
<tr>
<td>Efficacy of method</td>
<td>14.81</td>
<td>9.26</td>
<td>-5.55</td>
</tr>
<tr>
<td>Simplicity of method</td>
<td>3.70</td>
<td>20.37</td>
<td>16.67</td>
</tr>
</tbody>
</table>

Although the themes mentioned for each question were similar, the percentage of patients who answered to a particular theme shifted significantly for some categories. The majority of participants reported they started using FABM for religious or moral reasons, and for about a third of the patients each (many patients expressed more than one theme in their answers) the themes of the method’s natural use, increased knowledge of the body, desire to eliminate problems with hormonal birth control, ability to use method for both achieving and avoiding pregnancy, and increased diagnostic power were important in their decision making process.
Alternatively, the great majority of patients answered that they appreciated their method due to an increased knowledge of the body, and nearly half appreciated it for the way it strengthened their relationship, its natural use, and its versatility. About a third appreciated its diagnostic power and a fifth, its agreement with moral and religious values.

Once again, the importance of knowledge was demonstrated. There was a 31.5% positive shift in the number of patients who mentioned the importance of knowledge as a reason for appreciating their method compared to a reason they chose their method; although about one third of the patients chose to start using FABM due to a desire for increased knowledge, over two thirds appreciated this piece of the method. This may indicate that learning leads to further appreciation.
## Table 6. Reasons for switching from OC to FABM

<table>
<thead>
<tr>
<th>Reason</th>
<th>Example</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problems with side effects of hormonal birth control</td>
<td>“I was educated about the side effects of using birth control, and I wanted to get my body back into its natural sync.” “I was suffering many side effects from artificial hormones.” “Birth control pills made me feel different.” “I was concerned about the long term use of the pill and wondered what effect the pill was having on my body.” “I wanted to understand NFP as a way to take control of my fertility and avoid taking unnecessary hormones.” “I was using hormonal birth control for acne. Never made it better and only made me feel more hormonal.” “I was having trouble regulating my diabetes [while using OC].” “I didn’t like the side effects from the hormonal birth control pill and didn’t like taking medicine. I worried about the increased risk of breast cancer with the pill and of decreased fertility.” “Research the dangerous side effects of hormonal birth control.” “I did not want to continue to put additional hormones into my body.” “Bad reaction to hormones.” “After hormonal birth control messed with my body for a year and a half, my husband and I know there had to be a better choice for family planning.” “My arm went numb on oral hormones.”</td>
<td>77.78</td>
</tr>
<tr>
<td>Religious or moral reasons</td>
<td>“Because the Catholic Church does approve of NFP.” “They [OC] could cause a fertilized egg to not be able to attach to the uterine wall.” “Religious reasons.” “We learned how hormonal birth control worked with regards to implantation.”</td>
<td>37.04</td>
</tr>
<tr>
<td>FABM costs less than OC</td>
<td>“The expense of the pill adds up over the years.”</td>
<td>3.70</td>
</tr>
<tr>
<td>Desire to become pregnant</td>
<td>“Trying to conceive our first child.” “I can use it both to achieve and avoid pregnancy.”</td>
<td>18.52</td>
</tr>
<tr>
<td>Desire to diagnose and treat women’s health and/or infertility issues</td>
<td>“Hormonal birth control did not allow me to get pregnant - and now that I am having fertility problems, the Creighton Model is helping figure out why and increase chances of successfully conceiving after fertility treatments haven’t worked.” “I used hormonal birth control originally to help with my cycles and other women’s health issues. Which all that did was mask the problem.” “Contraceptives can also mask serious issues that should be addressed.” “I have endometriosis, so before I was married I used OC. They did not work. So when I was married, I switched to the CrMS.”</td>
<td>11.11</td>
</tr>
</tbody>
</table>
Qualitative data also provided insight into why participants switched from using hormonal birth control to using the CrMS. (Table 6) Of the 55 participants completed this question, 27, or 49.1%, had previously used hormonal contraception. More than three fourths of the participants who switched to using the CrMS did so because of problems they had experienced while using hormonal birth control. Thirty-seven percent of the participants who switched did so because of moral or religious reasons. A few in this category reported concern with the fact that a fertilized egg may not be able to implant in the uterus while hormonal birth control was being used. About a fifth of the participants who switched did so in order to achieve a pregnancy, and others reported the desire to diagnose and treat women’s health and infertility issues. It was also reported that the CrMS is less expensive than hormonal birth control. Qualitative data reported multiple reasons for discontinuation of hormonal birth control in order to use the CrMS.

The qualitative portion of the survey provided rich insight into why FABM and CrMS users choose to use their method, why they appreciate their method, and why some CrMS users discontinue their use of hormonal birth control to use the CrMS. Themes that arose in all three of these areas included the strengthening of communication and relationship with one’s partner because of a shared fertility management responsibility, the natural use of the method, an increased knowledge of the body, problems with the side effects of hormonal birth control, religious or moral reasons, the versatility of the method as it can be used for both achieving and avoiding pregnancy, the increased diagnostic power for women’s health and infertility issues, and the inexpensive cost, efficacy, and simplicity of the method. Example statements in each of these areas provide in depth insight into research questions.
Discussion

In this study, participants were knowledgeable about reproduction and were highly satisfied with their current method of fertility management. This was expressed through both quantitative and qualitative data. A more diverse set of data could draw further conclusions. A set of high knowledge scores for all participants may have occurred because FABM users need to know about their physiology in order to use their method. Recruiting a broader spectrum of participants may allow for further assessment and answers regarding the correlative data between knowledge and appreciation, satisfaction, and confidence. Using online recruiting for both participant pools could aid in data collection thus providing further insight on the research questions.

Some of the greatest insight into the research questions that can be drawn from the current data results from comparing the percentage shift among the themes from why the method was chosen to why it is appreciated. The majority of patients chose their current method due to religious or moral reasons. When comparing this to why patients appreciate their method, there is a large increase in the importance of strengthening relationships along with increased knowledge of the body discussed previously. Although the majority of patients began using the method for moral or religious reason, an even greater majority appreciate the method because of their increased knowledge of the body. This may suggest that a greater population of patients would appreciate this method once they begin using it and discover their appreciation for learning about their biology. Further study could be done in this area by studying patients’ appreciation of these answer themes in a longitudinal trial while they are enrolled in the CrMS class.

Multiple studies have shown the possibility for a broader interest base for FABMs. When FABMs were being developed, Odeblad and Billings independently reached similar conclusions
across the world in regards to method development, but reached different patient bases. Many of the studies conducted on the BOM and CrMS in the United States have a primarily Catholic patient base, yet most people who use and teach the ovulation method in Sweden, including Odeblad, are non-Catholic. [37] Odeblad assessed the affect FABM use had on abortion, as this trend was of concern for possible users. In 1992, he reported that seven out of 1000 women in Sweden use the method, and among these women, there was a 0.5/1000 abortion rate. Using the method did not make the number of abortions increase as previously thought. [36] After exploring the subject base in studies from multiple methods, it is possible that FABMs would be of interest to a greater patient base than it is currently reaching.

Population based studies in both the United States and Germany suggest that up to 25% of women with reproductive potential may be interested in using modern FABMs to avoid pregnancy and up to 33% may be interested in using them to achieve pregnancy. [29] In a 2009 assessment of FABMs, Pallone found that 20% of women express interest in using FABMs, yet only 1% to 3% actually use them. [41] This statement provides question for further research. Why are only 5% to 10% of women who express interest in using FABMs using them? It is possible that patients do not have access to the necessary knowledge or courses for learning about FABMs. Studies suggest the modern US physician’s knowledge of FABMs is incomplete. [41] Because patients find out a great deal of knowledge from their physicians, it is possible that a patients’ knowledge is incomplete because the knowledge of their physician is incomplete. Including up to date and accurate information on FABMs in the curriculum of medical schools may solve this problem.

The conclusions of this study suggest that patients appreciate learning about their biology and are satisfied and confident using this biology to manage their fertility through FABMs such
as the CrMS. This may be a fertility management method with a wider appeal for patients looking for any of the following characteristics which were appreciated by the participants of this study: strengthening of communication and relationship with their partner because of shared fertility management responsibility, the natural basis of the method, the relief of problems experienced with hormonal birth control, the alignment with religious and moral values, the versatility of the method to both achieve and avoid pregnancy, and increased diagnostic power for women’s health and infertility issues, and the method’s low monetary cost, effectiveness, and simplicity. Each of these areas of appreciation may contribute to the lower discontinuation rates of CrMS users compared to hormonal birth control users. The CrMS could be an effective fertility management method for hormonal birth control users who are dissatisfied with their use of hormonal birth control as a fertility management method.

This project initiated the study of the effects of patient physiologic knowledge on the continuation of the use of a medical treatment or management system, the confidence in and appreciation for this system, and the overall confidence of the patient as a result of using this system. This is not only valuable in fertility management, but also in many other areas of communication between patients and medical personnel. This research may open the door to an important component of patient care and communication that could enhance patient treatment plans and improve overall patient outcomes especially in the area of fertility management, which is applicable to 99% of the American population. [34]
Appendices

1) University of Minnesota Internal Review Board Letter of Approval
2) Park Nicollet Institute Internal Review Board Letter of Approval
3) Recruitment Flyer
4) Participant Survey
The IRB: Human Subjects Committee determined that the referenced study is exempt from review under federal guidelines 45 CFR Part 46.101(b) category #2 SURVEYS/INTERVIEWS; STANDARDIZED EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR.

Study Number: 1012E94315

Principal Investigator: Elizabeth Gorecki

Title(s):
The physiology of the Creighton Model Fertility Care System of Natural Family Planning: physiologic knowledge of patients and their appreciation for their chosen family planning system

This e-mail confirmation is your official University of Minnesota RSPP notification of exemption from full committee review. You will not receive a hard copy or letter.

This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

The study number above is assigned to your research. That number and the title of your study must be used in all communication with the IRB office.

Research that involves observation can be approved under this category without obtaining consent.

SURVEY OR INTERVIEW RESEARCH APPROVED AS EXEMPT UNDER THIS CATEGORY IS LIMITED TO ADULT SUBJECTS.

This exemption is valid for five years from the date of this correspondence and will be filed inactive at that time. You will receive a notification prior to inactivation. If this research will extend beyond five years, you must submit a new application to the IRB before the study's expiration date.

Upon receipt of this email, you may begin your research. If you have questions, please call the IRB office at (612) 626-5654.

You may go to the View Completed section of eResearch Central at http://eresearch.umn.edu/ to view further details on your study.

The IRB wishes you success with this research.
April 25, 2011

Elizabeth Gorecki
6-125 Jackson Hall
321 Church Street SE
Minneapolis, MN 55123--

Re: 04090-11-A
The physiology of the Creighton Model Fertility Care System of Natural Family Planning: physiologic knowledge of patients and their appreciation for their chosen family planning system

Dear Ms. Gorecki,

Thank you for sending the Institutional Review Board (IRB) for Park Nicollet Institute the above referenced study. The following were reviewed on April 24, 2011:

~ Study proposal - including budget (version received 4/5/11)
~ Analysis plan supplement for PNI IRB (version received 4/5/11)
~ Family Planning and Fertility Management Survey via REDCap Survey Tool (version received 4/11/11)
~ Recruitment flyer (version received 4/12/11)
~ UMN IRB exemption notification (undated)
~ UMN Research exempt from IRB committee review application - category 2 (12/9/10)
~ Appendix J - Student as principal investigator worksheet (12/16/10).

Park Nicollet Institute IRB Administration has determined that this study meets the exemption criteria under federal guidelines 45 CFR 46.101(b)(category 2), as this study consists of survey procedures which do not collect identifying information nor any other identifying measure linking the human subject to the survey. Research that involves observation can be approved under this category without obtaining consent. Survey or interview research approved as exempt under this category is limited to adult subjects. As such, this study is exempt from the need for IRB review and approval. Should the scope or procedures associated with this study change such that the exempt criteria may no longer apply, you must contact this office. In addition, since only de-identified data is being used in this study, compliance with HIPAA requirements is not applicable.

The study number assigned to this protocol is 04090-11-A. Please refer to this study number and title in all future correspondence pertaining to this study with the IRB office. Please feel free to call me at 952.993.3015 should you have any questions or concerns.

You may now proceed with the research. We wish you success with this research endeavor.

Sincerely,

Tiffany Walker, CIP
IRB Administrator

This isn't just about health care. This is about you.
Would you like to participate in a research study?

Do you use one of the following methods of family planning?
1) Creighton Model Fertility Care System
2) Hormonal Birth Control

You are invited to assist an honors student at the University of Minnesota and fill out an anonymous, short survey.

A $5 donation to charity will be made for your participation.

Interested? Complete the survey at: https://redcap.ahc.umn.edu/surveys/?s=gy9sIW

Please contact Lisa Carney Anderson, PhD at 612-625-5644 with questions. This research project is a senior thesis by a student at the University of Minnesota. All surveys are anonymous and confidential.
Family Planning and Fertility Management

Your participation in this survey positively impacts the research of an honors student at the University of Minnesota. A donation will be made to the charity you choose at the completion of the survey. Thank you for your contribution!

It is important to determine your current knowledge. Therefore, we ask you to simply answer all questions to the best of your ability. This survey should take less than 15 minutes to complete.

This study has been approved by the University of Minnesota IRB as project 1012E94315.

In filling out this survey, you are consenting to anonymously participate in an honors thesis research project in the Department of Integrative Biology and Physiology at the University of Minnesota. Please be assured that your participation will not affect the health care you receive in any way, and all answers will be kept anonymous and confidential.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is your current method of family planning or fertility management?</td>
<td>Fertility Awareness Based Method (applied science that educates women or couples on the physical signs and symptoms experienced by the woman throughout the menstrual cycle, thus allowing for the identification of periods of fertility and infertility characteristic of the hormonal changes during the reproductive cycle)</td>
</tr>
<tr>
<td>Which Fertility Awareness Based Method do you currently use?</td>
<td>Creighton Model Fertility Care System Billings Ovulation Method Couple to Couple League Sympto-Thermal Method Other</td>
</tr>
<tr>
<td>Which Fertility Awareness Based Method do you currently use?</td>
<td>Couplet to Couple League Sympto-Thermal Method Other</td>
</tr>
<tr>
<td>Where did you learn the Fertility Awareness Based Method chosen above?</td>
<td></td>
</tr>
<tr>
<td>What category of hormonal birth control do you currently use?</td>
<td>Pill Patch Injection Other</td>
</tr>
<tr>
<td>What type or brand of hormonal birth control do you use? (what kind of pill, patch, injection, or what kind if other)</td>
<td></td>
</tr>
<tr>
<td>What is your current method of family planning or fertility management?</td>
<td></td>
</tr>
<tr>
<td>How long have you been using your current method of family planning or fertility management?</td>
<td>1-3 months 3-6 months 6-9 months 9-12 months 1-2 years 3 or more years</td>
</tr>
</tbody>
</table>
Why did you choose the family planning or fertility management method you are currently using?

______________________________________________________________________________

What do you appreciate about the family planning or fertility management method you are currently using?

______________________________________________________________________________

Have you used both the Creighton Model Fertility Care System and Hormonal Birth Control?

☐ Yes
☐ No
☐ No, but I have used both a Fertility Awareness Based Method (other than the Creighton Model) and hormonal birth control

______________________________________________________________________________

Why did you switch family planning or fertility management methods?

______________________________________________________________________________

What is your age?

______________________________________________________________________________

What is your ethnicity?

☐ Asian
☐ Hispanic or Latino
☐ Black or African American
☐ American Indian or Alaskan Native
☐ Pacific Islander
☐ Caucasian or White
☐ Other
Reproductive Biology Questions  
The following multiple choice questions are a survey of reproductive biology. It is important to determine your current understanding of reproductive biology and therefore we ask you to simply answer to the best of your ability. There are ten questions and it should take you less than 5 minutes to answer these questions.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>How long is the average menstrual cycle?</td>
<td>14 days, 21 days, 28 days, 35 days</td>
</tr>
<tr>
<td>How many times per menstrual cycle does ovulation typically occur?</td>
<td>1, 3, 5, 7</td>
</tr>
<tr>
<td>During how many days in the average cycle is a woman fertile?</td>
<td>1, 6, 12, 24</td>
</tr>
<tr>
<td>How often is a man fertile?</td>
<td>Once a month, 3-5 times a week, 3 out of 4 weeks, Continuously</td>
</tr>
<tr>
<td>Once a mature egg is released (ovulated), how long can it survive in the women's body?</td>
<td>1 hour, 24 hours, 72 hours, Indefinitely</td>
</tr>
<tr>
<td>What protective agent for sperm is produced in the women's body?</td>
<td>Cervical mucus, Menstrual fluid, Sex hormones, Vaginal secretions</td>
</tr>
<tr>
<td>Once in contact with a protective agent in the women's body, how long can sperm survive?</td>
<td>1-2 hours, 3-5 days, 7-9 days, Indefinitely</td>
</tr>
<tr>
<td>Pregnancy can occur due to genital contact without intercourse.</td>
<td>True, False</td>
</tr>
<tr>
<td>Which of the following hormones is produced by the pituitary gland in the brain for the purpose of regulating the menstrual cycle?</td>
<td>Estrogen, Human chorionic gonadotropin, Follicle stimulating hormone, Progesterone</td>
</tr>
<tr>
<td>Which of the following is produced in the ovary to regulate the menstrual cycle?</td>
<td>Estrogen, Human chorionic gonadotropin, Follicle stimulating hormone, Luteinizing hormone</td>
</tr>
</tbody>
</table>
Appreciation and Confidence Questions    The following questions are for you to indicate your appreciation and satisfaction of certain aspects of your current fertility management or family planning system. Please rate your agreement and/or disagreement with the following statements by sliding the blue box to your agreement or disagreement feeling on the scale.

I understand the biology of how my current family planning or fertility management method works.

Understanding the biology of my current family planning or fertility management method increases my appreciation of my method.

Understanding the biology of my current family planning or fertility management method increases my satisfaction in my method.

Understanding the biology of my current family planning or fertility management method increases my confidence in my method.

Understanding how my current family planning or fertility management method works increases my appreciation of how my body works.

The more I use my current family planning or fertility management method, the more confidence I feel in my method.

The more I use my current family planning or fertility management method, the more confidence I feel in myself.

The more I understand the biology of my current family planning or fertility management method, the less comfortable I am using it.

The more I understand about how my current family planning or fertility management method works in my body, the less confident I feel about using my method.
Your completion of this survey is greatly appreciated!

Thank you for your contribution! Please choose the charity to which you would like a donation to be made for your participation.

- Scholarships for honors students at the University of Minnesota
- Habitat for Humanity
- WomenSource Pregnancy Center
Works Cited


