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# A Response: In Defense of Truth in the Science of the Billings Ovulation Method

by

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Mr. John Kippley's paper, "Natural Family Planning: The Various Components," appeared in the August, 2001 issue of this journal. I wish to raise concern with regard to Mr. Kippley's reference to the Wade et al.<sup>1,2</sup> study and equating the "ovulation method" used in this study with the Billings Ovulation Method (BOM). The ovulation method used by Wade, et al.<sup>1,2</sup> was not the Billings Ovulation Method. To suggest, as Mr. Kippley does, that this trial "puts to the test" the Billings Ovulation Method compared to the symptothermal method is incorrect. Wade and colleagues defined an ovulation method that reportedly was "based upon the atlas published by the Billings and associates in 1973," but defines the fertile phase as the observation of the cervical mucus pattern as starting "on the first day of mucus secretion and continues until the evening of the fourth day past 'peak' or *maximal mucus secretion*."<sup>1</sup> The *Billings Atlas of the Ovulation Method*<sup>3</sup>, however, defines Peak not as the maximal mucus secretion. "It is not the amount of mucus which is important, it is the slippery, lubricative sensation that it produces at the vulva which is the important observation; the last day on which this kind of mucus is present is called the **Peak** of the mucus."<sup>3</sup> It is important to note that large quantities of slippery, stringy mucus does not necessarily coincide with Peak. Even before the Peak, mucus may dwindle in amount, but the persistence of the

wet, slippery sensation at the vulva tells the woman she has not yet passed Peak. This is a consequence of the presence of the P-mucus with its mucolytic activity<sup>4,5,6</sup>. This sensation of mucus at the vulva is detectable even with quantities of mucus not readily visualized by the eye. Also, the end of the fertile phase in the BOM is marked by the beginning, not the evening, of the fourth day following the Peak of the mucus as was defined in the Wade study.

The comparison of methods such as The Billings Ovulation Method and The Couple to Couple League symptothermal method would only be truly valid in a study if performed by certified instructors in either method. The Wade study stated that "there were no formally established training programs in southern California for teachers of either method when this study began. Teachers were recruited from women who were currently using or had previously used NFP."<sup>2</sup> Had certified teachers been utilized, perhaps a factor as critical as definition of Peak would not have been overlooked.

The importance of this error is most apparent in the results of the number of user-failure pregnancies in the training and formal phases of the Wade study. As Mr. Kippley has pointed out in his article, the pearl indexes were 39.7% for the ovulation method (OM) and 13.7% for the symptothermal method (STM) during the formal phase. Similarly, the pearl indexes were 34.9% for the ovulation method (OM) and 16.6% for the symptothermal method (STM) during the training phase. What Mr. Kippley does not note is that there were no statistical differences of "user-failure pregnancies" among those who failed to follow the rules of the two methods studied (51.5% for OM; 56.9% for STM).<sup>2</sup> There was, however, a profound difference between the OM and STM with regard to "difficulty interpreting Peak symptom." In the OM 35.8% of "user-failure pregnancies" were classified as those having "difficulty interpreting Peak symptom"; 17.6% in the STM group.<sup>2</sup> These are rather high numbers for such an important factor as Peak in either method studied.

I believe it is a very fair conclusion to suggest that the greater difficulty the OM women had identifying Peak was due to how Peak was defined for this group in the study. Identifying "maximal mucus secretion" is a quantitative visual observation. This is very different from a qualitative interpretation of sensation at the vulva as defines Peak in the Billings Ovulation Method. Also, "maximal mucus secretion" is usually not at its maximum on the Peak Day as defined by the Billings method. The quantity and also the characteristic strings of mucus are more commonly greater on the day preceding the Peak.<sup>4</sup> In this case it is very clear that defining Peak as "maximal mucus secretion" and applying the Billings Peak Rule for the postponement of pregnancy will result in defining the onset of the post-ovulatory phase at least one day early. This error in the understanding of

Peak probably played a significant role in the "perfect-use" unplanned pregnancy rate of 5.7% for the OFM method compared to zero for the STM method. As a matter of fact, I am surprised the rate is not higher for the OM method in the Wade study given the degree of difficulty women had identifying Peak.

### An Easier Method

The difficulty interpreting the peak symptom found in the Wade study is in stark contrast to the five-nation trial of the Billings Ovulation Method conducted by the World Health Organization (WHO). These trials were undertaken during the same period as the Wade study and published in 1981. The WHO studies demonstrated that 90% of women were able to recognize cervical mucus changes during the menstrual cycle after one teaching session and 94% by the third teaching session. Only 1.3% of women failed to learn how to interpret changes in mucus characteristics during the training phase of the studies.<sup>7</sup> The WHO trial reported a probability of pregnancy outside the designated fertile period as identified by mucus sensation of 0.4%.<sup>7</sup> There are numerous other international trials of the BOM that also contradict the poor results found in the Wade study OM method. I have reviewed twelve trials between 1972 and 2000<sup>8 through 19</sup> with a cumulative method related pregnancy of 1% (range of 0 to 2.9%).

The most recent trial, conducted in China, was just recently published and found a pregnancy rate of 0.5% (all use-related) with a zero method-related pregnancy rate. There were 992 women in the trial with 9870 months of use and one year continuation rate of 96.4%.<sup>19</sup> The strength of this last study results from its design as a prospectively randomized trial (randomized with an IUD contraceptive) and a very high one year continuation rate.

The other unique aspect of this trial is that it is part of the BOM experience in China with more than 156,400 fertile couples using the BOM for avoiding pregnancy and 3,268 infertile couples for achieving pregnancy. Qian and colleagues<sup>19</sup> reported that, "due to its high efficacy, low expenditure and extreme safety incomparable to any other contraceptive methods, BOM is well accepted by the Chinese couple of different cultural and economic background." They go on to note that, "most failure cases had a relatively high cultural level... On the contrary, the illiterate women were generally very attentive to BOM teaching and rigidly stuck to the rules and failures were very rare." From this they drew the following conclusions: "1) the BOM is simple and easy to comprehend; almost all the women, including the illiterate, can successfully learn the method and identify their own mucus symptoms, 2) During the training special attention should be paid to the *intellectuals* and *professionals* (my emphasis added).

The method seems to be too 'simple' to them and they could not get hold of it without strict supervision."

Mr. Kippley points out that the drop out rate for the OM group in the Wade study was twice as high as in the STM group. A detailed look at the study shows that in the 3 to 5 month training phase the voluntary withdrawal rates for the two methods were actually similar, 43.8% for OM and 43.6% for STM; in the 12 month formal phase 36.4% for OM and 26.9% for STM.<sup>2</sup> The difference that Mr. Kippley notes, although not twice as high, regarding total drop-out rates between OM (73.7%) and STM (48.3%) users is due primarily to the differences in the pregnancy rates (26.7% for OM; 10.9% for STM) between the two methods plus the 10% difference in voluntary withdrawal during the formal phase.<sup>2</sup> It is also of interest to note that the dropout rates for the first six months of the formal phase were not statistically different (17.1% for OM; 15.2% for STM). In August 1978, six months prior to the end of the study the couples that were enrolled in the study were informed that a statistically significant trend in the pregnancy rates between the OM and the STM groups had been found.<sup>2</sup> It raises the possibility that the 10% difference (36.4% for OM; 26.9% for STM) for voluntary withdrawal during the formal phase may also be a consequence of introduced bias as a result of informing couples that the OM method used in the study was less effective.

I find it disconcerting that Mr. Kippley states that "the time required to teach the OM was 50% greater than for the STM" when I can find no such reference to this in the publications by Wade and colleagues.

I would also like to comment on Mr. Kippley's discussion regarding the weaknesses of the ovulation method in the Wade study and equating this with the BOM. He raises three main concerns. First, he states that the OM "may not give adequate indication of the start of Phase II," especially with "a combination of a short mucus patch and a long sperm survival." The second weakness he claims is the situation where there is "more than one mucus patch in a given ovulation." Finally, he is concerned that the mucus only sign is "more subjective" and "requires continued personal instruction" because "some women experience confusion about their mucus sign." These concerns may have some merit in the Wade study, but they are fully accounted for in the Billings Ovulation Method.

As the Billings Ovulation Method relies on sensation at the vulva, each of these concerns are fully addressed by an understanding of the Basic Infertile Pattern (BIP) and the application of the Early Day Rules and Peak Rule for pregnancy avoidance. The rules are as follows and are applied following assessment by the woman of the most fertile sign during her normal activities throughout the entire day and are then recorded at the end of the day:

## The Early Day Rules

**Rule 1:** Avoid intercourse on days of heavy bleeding during menstruation.

**Rule 2:** Alternate evenings are available for coitus when these days have been recognized as infertile.

**Rule 3:** Avoid coitus on any day of mucus or bleeding which interrupts the Basic Infertile Pattern. Allow 3 days of Basic Infertile Pattern afterwards before coitus is resumed.

## The Peak Rule

There must be avoidance of all genital contact until the beginning of the fourth day following the Peak of the mucus. From this time until the end of the cycle coitus is available every day at any time.<sup>20</sup>

These rules are formulated to give the earliest possible prediction of ovulation and to allow for the longest possible sperm survivals. It must be understood that the BIP may be either dry days, an unchanging continuous mucus pattern or a combined pattern. During the early infertile days G mucus and minimal quantities of F mucus (both infertile type cervical mucus) and vaginal fluid are produced. Not only the cells of the cervix, but also the cells of the vagina produce mucus made up of membranous glycoproteins that are able to contribute to the presence of mucus on infertile days.<sup>4</sup> Cells lining the vaginal wall are shed, disintegrate and cause a discharge as well.<sup>21</sup> These types of mucus are viscous and do not flow rapidly in the vagina.

Further, the mucus is reabsorbed in the pockets of Shaw. The pockets of Shaw are situated in the inferior part of the vagina and the contribution of vaginal mucus is from the superior part. When ovarian activity is absent and no estrogen is being produced there often can be no mucus noted at the vulva and the feeling is one of dryness. A woman may also experience a slight unchanging mucus; this BIP is due to mucus being shed from the cervical mucus plug (G and F mucus).<sup>4</sup> When a small amount of ovarian activity is present, but not progressive, low level estrogen causes a mucus discharge that comes mainly from the vagina also causing a BIP of discharge. A reason for the appearance of a flow of mucus outside the vagina during the early infertile days may also be due to a reduction of capacity of reabsorption by the pockets of Shaw. An abundance of F mucus may also contribute. This is sometimes common in young women whose reabsorption processes have not yet fully developed.<sup>4</sup> The combined BIP is seen with a prolonged cycle such as during breast feeding, in the pre-

menopausal period or post-pill where intermittent low and intermediate level fluctuations in estrogen are occurring.<sup>21</sup>

Increasing estrogen levels associated with the onset of the fertile phase not only elicits its effect on the cervix with the production of L, S and P fertile mucus, but also upon the vagina where normal reabsorption of mucus by the pockets of Shaw is reduced because of the thickening of the pre-ovulatory vaginal epithelium.<sup>4</sup> This results in a change from the BIP followed by a developing pattern of mucus as sensed at the level of the vulva. An increased sensitivity and swelling of the vulva during the fertile phase may also heighten the woman's awareness of the presence of mucus at the vulva.

The relationship between the physiology of the cervix and vagina is equally important in determining the end of the fertile phase. The LH surge that initiates ovulation also causes progesterone to be produced by the follicle. The progesterone strongly reverses the effect of estrogen on the cervix and the vaginal epithelium in addition to the effects of a fall in estrogen that occurs at this time. The cervical mucus begins to lose its fertile characteristics and the pockets of Shaw once again become active and begin to reabsorb the fertile mucus that is present. This is a definitive change when evaluated at the vulva as in the BOM, although fertile cervical mucus is still being produced. These changes due to progesterone, indicated as the "progesterone change", or PC, are very important because it is this progesterone change that definitely indicates that ovulation is occurring and is closely related in time to ovulation.<sup>22</sup> PC times ovulation to within  $\pm 24$  hours.<sup>22</sup>

Given this understanding of the physiology of the cervix and the vagina and how integral a part they both play in the detection of fertile mucus at the vulva, to suggest, as Mr. Kippley does in the discussion of his article that it is somehow unethical "to withhold from her (a woman) the information that she can obtain her mucus sample from the cervical os...." is completely contradictory to that understanding. Internal mucus investigation at the cervical os as an indicator of fertility is incompatible with the BOM. The BOM relies on an integrated understanding of the natural physiology of the entire organ system, including the cervix, vagina, pockets of Shaw, and vulva, that most accurately reflect the initial rise in estrogen and its fall and the rise in progesterone. It is in these changes of hormones as observed in the mucus symptom that most accurately define the fertile phase and ovulation. Because sensation at the vulva so accurately reflects the initial rise in estrogen and the progesterone change, internal investigation at the cervical os would simply confuse what it is you are trying to identify because the mucus present may or may not be fertile.

Fertile mucus when produced at the cervix at the start of the fertile phase, because of its unique fluid makeup, rapidly flows through the vagina

and is sensed at the vulva. The presence of fertile mucus at the vulva is enhanced because the pockets of Shaw are no longer absorbing mucus secondary to the influence of estrogen and can be detected by a woman as she is up and going about her normal activities during the day. This awareness is further enhanced by a heightened sensitivity of the vulva during this time. Similarly, at the end of the fertile phase it is the progesterone change with its accurate timing of ovulation, as discussed above, and reflected in the change from slippery to dry or sticky at the vulva that is most important, not the presence of mucus at the cervical os. Indeed, fertile mucus will still be present at the cervical os following the progesterone change. This mucus is not, however, sensed at the vulva because of the return of activity at the pockets of Shaw. The Peak rule fully accounts for this time when fertile mucus is still present and the 24 hour life span of the ovum. This is ultimately the knowledge that women are interested in for achieving or postponing pregnancy.

### **Double Mucus Patch**

Finally, I would like to address the concern of a "double mucus patch" which Mr. Kippley has raised. An understanding of the physiology of what is properly termed a leuteinized unruptured follicle (LUF) will help give an understanding as to why the Early Day Rules of the BOM work so well in this situation. In the continuum of ovarian activity and fertility the situation arises where FSH levels rise to exceed threshold, a follicle develops, but does not progress to ovulation. The estrogen produced by the developing follicle results in a corresponding change in vaginal discharge as detected at the vulva. The FHS then returns to below threshold, the follicle atreses and the estrogen level drops to baseline values and there is a return to the BIP. Another follicle begins to develop again with rising FSH that may have the same fate as the first, but eventually a follicle develops and proceeds to a full ovulatory response.

In this situation a woman experiences patches of mucus production when each follicle is partly developed and the estrogen level is correspondingly elevated with an intervening return to the BIP when the follicle atreses and estrogen returns to baseline.<sup>22</sup> When the follicle which proceeds to a full ovulatory response develops, however, a cervical mucus response occurs with a progressive developing pattern toward slippery as sensed at the vulva. This is concluded with a progressive change (PC), Peak Day is recognized and consequently a woman can conclude that she has indeed ovulated and entered into the post-ovulatory infertile phase. If the Early Day rules governing the BIP are used correctly, and postponing pregnancy is desired, a woman can confidently manage these variations of normal cycles to avoid pregnancy using the BOM. The BOM rules clearly



account for the 24 hour maximum in the lifespan of the ovum and the duration of sperm survival in fertile mucus, given that sperm survival in the absence of fertile mucus is only minutes to an hour or so.

In conclusion, I wish to comment that the intent of my commentary and presentation is two-fold. First, to present an accurate overview of the science supporting the BOM. I also, however, wish to underscore the importance of presenting information, especially research articles, accurately and with a clear understanding of their content and the scientific method used. In this regard, I wish to emphasize one more point in how we present information about NFP. The different methods of NFP are just that, they are different methods. They provide rules and techniques for managing indicators of fertility. It is critical to understand that an indicator of fertility does not constitute a method, nor is a specific indicator within a method used in the same way between methods. Knowledge of an indicator, therefore, does not constitute knowledge of a method. Unfortunately, among those of us who practice and teach NFP, we have all experienced criticism by teachers of other methods. In my experience these criticisms have largely come out of a lack of knowledge and understanding of indicators of fertility and how they are properly used within a method. I am not referring here to constructive inquiry and challenging questions which are necessary and good. I strongly urge all of us to be vigilant in how we present our criticisms and the presentation of literature on the subject of NFP methods; our comments on other methods must only come from an intimate knowledge of the method. In essence, that means we have been formally trained in the method, can use the method (if applicable) and teach the method correctly.

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