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Response to fertility awareness-based methods of family planning: A review of effectiveness for avoiding pregnancy using SORT

To the Editor:

I read with interest the review article in the January-February 2013 issue of *Osteopathic Family Physician* entitled, “Fertility Awareness-Based Methods of Family Planning: A Review of Effectiveness for Avoiding Pregnancy Using SORT” (Manhart M.D., Duane M., Lind A., Sinai I., and Golden-Tevald J).¹ Although it is of significance that your journal would publish a paper dealing with these issues, it contains a significant number of errors and omissions. I would like to outline some of these for you.

This paper defines “typical use” within the context of “intentionality,” but, in actual fact, that is not the definition of the “typical use” pregnancy rate. In addition, the concept of intentionality, though it is a word that is often used, is usually undefined and there is very little research on it to be able to make it objective.

It was reported that the “typical use” for the *Creighton Model FertilityCare System* could not be reported because it was not obtained. The “typical use” pregnancy rate is defined as the effectiveness of a method of contraception during “actual use” (including inconsistent or incorrect use) to avoid pregnancy. The “perfect use” is defined as the effectiveness of a contraceptive method where “perfect use” is defined as following the directions for use to avoid pregnancy.²

In reality, the *Creighton Model System* has published its “typical use” pregnancy rate. Our meta-analysis involving 5 centers and 1876 couples for 17,130 couple months of use revealed a “typical use” rate of 3.2.³ This statistic was expressed as the use effectiveness to avoid pregnancy, which is a terminology not used much anymore because James Trussel wanted a terminology that would be more colloquial and better understood by patients. I have no argument with that, however, the overall concept by definition did not change. Thus, the use effectiveness to avoid pregnancy that we published is, in fact, the “typical use” (to avoid pregnancy) pregnancy rate.

The use of the strength of recommendation taxonomy (SORT) is a worthy attempt; however, noteworthy items were missing from the list of “critical features of a high quality...cohort clinical design.” For example, the means by which pregnancies were evaluated is not included. Although it is noted that pregnancies needed to be detected and

recorded, the need to evaluate them apparently was not considered vital. It is in the pregnancy evaluation that one learns more about the use reality of a natural method of family planning.⁴ As I indicated earlier, pregnancy intention was itself not in the SORT criteria most likely because the actual concept of intention is very subjective (outside of making a declaration in advance of the cycle—described later). The discontinuation rate, which becomes extremely important in the use of any family planning system, was also left out of the SORT criteria.

In addition to these, although the SORT criteria called for standardized counseling, it gave no definition as to what that meant. Follow-up was also not defined except that there be some follow-up over a 1-year period of time, but from an educational point of view, individual follow-up is very important and critical since these are learned methods of family planning. Although a standardized teaching approach was considered to be present and available for nearly all of the methods, in reality, very few of them have truly standardized teaching. The *Creighton Model System* is an exception to this.⁵ Also unique to the *Creighton Model System* is that it is a professional delivery system with a professional infrastructure, concepts that were also left out of the SORT criteria.

It might be helpful to cite some comments from our paper on use effectiveness that was previously published³:

Because the *Creighton Model System* can be used to achieve pregnancy as well as to avoid it, it is not strictly a method of contraception, but rather a true method of family planning. It therefore, gives the couple the freedom to use it as a means to achieve or avoid pregnancy as they so wish, with full knowledge of the likely consequences of either choice. Some couples knowingly choose to use the days of fertility to achieve pregnancy and are successful at doing so.

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

With regard to the use of these methods for “medical diagnosis,” the Billings Method and Marquette Methods are

identified as being for “medical diagnosis.” And yet, there is no research that has been done to support the use of either of these 2 methods as a diagnostic tool. This is not to say that clinical experience might allow 1 or another of these 2 systems to provide some fairly simple diagnostic input, it is important to recognize that the *Creighton Model FertilityCare System* is the foundational system upon which a whole new women's health science has been developed (*NaProTechnology*). This has been published in a 1244-page medical textbook entitled, “*The Medical & Surgical Practice of NaProTECHNOLOGY*.”⁶ In this textbook, large volumes of research data are presented to support the *Creighton Model System* in its use with a whole variety of underlying medical and surgical conditions observed in women of reproductive age.

In the years of conducting use-effectiveness studies in the various natural methods of family planning, there has been very little effort placed into the better understanding of the statistical measures upon which family planning systems are actually studied. There has been an emphasis to try to match up a natural method with a contraceptive method with regard to statistical protocols. And yet, one system, the contraceptive method, can be used in only one way, and therefore, its measurement for use can be accomplished only from that point of view. A natural method can be used to both achieve and avoid pregnancy, and most achievers are successful users, not failures. Thus, they need to be looked at separately and we have published a life table protocol that helps accomplish this.⁷ There are many reasons why they should be evaluated separately, but these are too long to go into at this time. However, if

somebody would like more information on this, I would be happy to provide it to them.

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Response to letter to the editor of osteopathic family physician from Dr Thomas Hilgers

We read with interest Dr Hilgers' comments on our paper. The purpose of the paper was to establish the parameters that would define a robust cohort study. These parameters allowed us to use SORT criteria to review the literature and identify the modern FABMs that had sufficient evidence to support their recommendation to couples who are seeking to avoid pregnancy. Dr Hilgers disagrees with our definition of typical use pregnancies, criticizes the criteria for not further elaborating on the means of pregnancy evaluation and standardized counseling used within the studies, and takes exception to the idea that more than one FABM may be useful in medical diagnosis.

We agree with Dr Hilgers that natural methods are unique as they can be used both to achieve and avoid pregnancy. In contrast, a contraceptive method is only used to avoid pregnancy, so if a pregnancy results, it is reasonable to conclude that it is a failure of the method. As Dr Hilgers, and our review, point out, this is not the case for natural methods; couples have the freedom to use the

method as they choose—either to avoid or to achieve a pregnancy—at any time. This complicates the definition of typical use.

We chose to use the definition of “typical use” to include the analysis of all pregnancies in all cycles of use. This makes the conservative assumption that the pregnancy is unintentional if not declared prospectively as intentional by the couple (one of our critical study parameters). In contrast, the Creighton Model FertilityCare System (CrMS) studies cited a different definition of typical use relying on couples' behavior during the fertile window. Although this approach is logical, all the other literature does not evaluate pregnancies in this way. We pointed this difference out in the review text and factually stated “typical use effectiveness cannot be defined as in other trials” for the CrMS trials.

In developing the SORT criteria, we sought to set a robust standard yet not be so limiting as to exclude all but a few of the well-conducted studies. Although the precise approach to pregnancy evaluation can influence outcomes, we believe the combination of mechanisms to capture all pregnancies in all study participants, limiting intended pregnancies to the definition provided, and application of