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Letter to the Editors

A PATH to action perhaps?

The article by Geist et al. creatively continues to advance our collective understanding of both pregnancy intendedness and cessation of contraception utilizing PATH questions (*P*regnancy, *A*ttitudes, *T*iming and *H*ow important is pregnancy prevention) [1]. From more abstract perspective, however, this work seems to replace one close ended question "Would you like to become pregnant in the next year?" with four other closed-ended questions. One wonders, why do we not just ask one open ended question: "How do you think you would *feel* if you got pregnant in the coming year?" A happy response should prompt clinicians to direct their counseling toward preconception care. A strong negative response is really its own motivational counseling for LARCs. Ambivalent, indifferent or undecided responses would shine a spotlight on a woman who is likely to be at risk for suboptimal contraceptive use. Either we supplement her with folic acid or we suggest she might want to think about using a convenient easily reversible method (IUD or implant) until she is sure she wants pregnancy.

At a more fundamental level, much of the current work that attempts to define pregnancy intendedness (a concept) may inevitably fall short of a more tangible and productive objective (an action). The case for a woman with diabetes who conceived when her hemoglobin A1C was 12 is not a success by any measure, even if her pregnancy was planned. The woman who was not sure if she wanted pregnancy, but did receive preconceptional evaluation, counseling, immunization updates and folic acid is in a far better position to have a healthier pregnancy. As a society, we need to move the goal post. Part of the issue we now are struggling with may be due to the fact that we are trying to measure something that is too amorphous and may be in frequent flux. Action is always a more secure outcome to monitor.

Just a thought,
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Reference

[1] Geist C, Aiken AR, Sanders JN, Everett BG, Myers K, Cason P, et al. Beyond intent: exploring the association of contraceptive choice with questions about pregnancy attitudes, timing and how important is pregnancy prevention (PATH) questions. Contraception 2019;99(1):22–6.

Response to the letter to the editor

We appreciate Dr. Nelson's thoughtful comments on our article assessing the PATH questions (*P*arenting/*P*regnancy *A*ttitudes, *T*iming and *H*ow important is pregnancy prevention) and contraceptive method selection. We acknowledge that many clinicians and researchers want well-defined risks and benefits to guide precise treatments. However, the everyday reality of patient care is more nuanced, especially concerning the multidimensional issues of reproduction, contraceptive method choice and use.

Dr. Nelson's suggested query about happiness regarding a potential pregnancy is not at odds with our survey, which included the question "How would you feel about getting pregnant in the next month?", with response options ranging from "worst feeling you can imagine" to 100 with the anchor of "happiest you could possibly feel." However, emotional disposition regarding pregnancy is only one important aspect of reproductive goals counseling. Other dimensions including timing, the importance of pregnancy prevention, plans, and intentions also impact behavior and, importantly, are not always aligned with each other.

We believe PATH questions are placed at the intersection of precision and the reality of human behavior. We adapted the three PATH questions into a survey format for our data collection, but in a clinical setting PATH questions facilitate conversation and rely on listening (for further information about PATH, visit: https://www.envisionsrh.com/path-questions). Patient emotions are clearly a part of this exchange. Often, the conversations PATH questions facilitate help providers to offer appropriate resources, such as contraception and pre-pregnancy care. They do not, however, result in provider directives.

The underlying paradigm of reproductive goals counseling is to help patients clarify what *they* want with regard to reproduction. By obtaining salient information from the patient in an efficient, patient-centered way, providers can offer relevant information and services in support of their client's goals. Underlying this premise is the fact that people will make their own choices about whether and when to have children; the best we can do as providers is to contribute essential scientific evidence and offer appropriate services to support this decision-making, without our value judgments. This approach acknowledges that health is but one of many components which influence reproductive choices and places providers in a supportive, rather than directive, role.

We understand Dr. Nelson's desire to bolster the health of her patients through specific, decision-making tools. However, we believe that more nuanced conversations around reproductive goals can achieve both improved health care and result in increased patient trust and satisfaction.

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Response to "study of contraceptive mobile app fails to provide convincing findings"

Before we respond to the comments from the letter by Freundl et al., we would like to clarify a few points. It is in large parts a repetition from a previous letter published by that group, relating to our first contraceptive effectiveness study in the *European Journal of Contraception*, to which we responded [1]. Since the authors do not refer to our response [1] in this letter, our response here will by necessity be repetitive. All of their comments can be addressed and stem primarily from misunderstandings of our manuscript. It is worth mentioning that we have repeatedly tried to engage with this group of researchers as early as 2014, initially to collaborate, later to help them address their misunderstandings that they have built up over the years. They have to date refused to answer our correspondence. More specifically regarding the letter, we do not share their conclusion that the study fails to demonstrate convincing findings.

The study in question is a large prospective observational study published in *Contraception*, which analysed real-world data from 22,785 users of the Natural Cycles application [2]. Such study designs are beneficial as they provide unique insights into the real-life usage of the application and are unbiased by interaction with clinical professionals. However, we acknowledge that there are limitations to such studies, as previously discussed in the literature [2,3].

Firstly, we wish to highlight that the methods section of the publication explicitly describes the inclusion criteria for all participants, how pregnancy was detected, and how unintended pregnancy rates were calculated [2]. One issue raised by Freundl et al. is the calculation of unintended pregnancy rate during perfect use. In this study, we use a method similar to the one previously used by Frank-Herrmann et al. [4] to estimate the efficacy of the symptothermal method. As described in the publication, a perfect-use cycle was defined as a cycle where intercourse was logged and where there was no unprotected intercourse logged on a red (fertile) day. All pregnancies occurring during perfect use were associated with all perfect-use cycles. The decision to include this particular calculation was to align our definition of perfect use with that of Trussell and Grummer-Strawn [5]. This issue was highlighted to us in the previous correspondence from this group [6]; therefore it is strange to us that they would criticise this adaptation. The term "Method Failure" on the other hand is used to describe the rate at which the application is responsible for pregnancy occurring, by falsely returning a green (non-fertile) status rather than a red (fertile) status to the user. The issues with using such a method as a proxy for the perfect-use failure rate have been well described elsewhere [7–10]. However, we believe that the distinction between perfect-use and method failure rates is important for users and for those developing such apps to understand the error attributed to the algorithm itself, with the aim of improvement.

More importantly, Freundl et al. appear to have misunderstood the sample size used to calculate the perfect-use failure rate as they state "The perfect use rate was calculated only for a small subsample (N=17), and therefore, somewhat useless". The number of included perfect-use cycles was actually 21,597, with 17 pregnancies detected, which in our opinion is a substantial number of cycles when compared to similar studies in the field.

Secondly, the assumption of an unintended pregnancy was based on two key factors; (1) all participants had signed-up to use the app as a method of preventing a pregnancy so this was their primary goal, (2) 25 women who had a pregnancy stated during follow-up that they had intended to get pregnant and were therefore removed from the analysis (along with their exposure time) as this outcome was desired. The term "unplanned" is not defined in the publication because we never refer to a pregnancy in this manner, as Freundl et al. seem to suggest in their letter. Freundl et al. make a valid point that cycles were not categorised into those in which abstinence or another contraceptive method (protected intercourse) was practised on a red (fertile) day. An independent clinical study is currently being planned which will address these issues as recording such information will be mandatory. The fact that 47% of participants with a positive pregnancy status did not log sexual intercourse is a caveat of such a real-world study; however, these are typical users and eliminating these participants would bias the estimate of the real-life effectiveness of this method.

Thirdly, the authors of the letter state that many of the conclusions are based on the assumption that the application can predict ovulation correctly, as previously published [11]. This exact argument was presented by the same group in the previous correspondence [6], and rather than repeating ourselves we would refer the reader to our response [1]. However, in this context we would like to highlight that the contraceptive effectiveness shown during typical and perfect-use are the best measures to demonstrate how well the method works.

Finally, Freundl et al. state that the number of participants in the study dropped from 22,785 to 6944. This is not the case, as 6944 is the number of women who had contributed more than 12 months of data. As described in the methods section, the follow up period after final sign-up was from August 2016 to March 2017 so there were some women whose data were included but who had contributed less than 12 months. We calculated the discontinuation rate as 54% at 12 months, resulting in approximately 11,000 women from this cohort who would drop out after 1 year of usage.

To summarise, we believe that the contraceptive effectiveness evidence presented is robust. In the future we hope that discussions on how to best assess contraceptive effectiveness of fertility awareness-based methods could be achieved through constructive dialogue between all interested researchers, rather than through back-and-forth misunderstandings published in scientific journals.

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