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Measure do not guess: a call to action to end assumed and estimated menstrual cycle phases in research

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INTRODUCTION

Several studies have been published in the last year using assumed or estimated menstrual cycle phases. These phases are 'generated' solely on regular menstruation. As more of these studies are published, founded on data that was not actually measured, it becomes imperative to grasp the difference between what is measured versus what is assumed or estimated. We need to measure, not guess, to draw valid and meaningful conclusions in a research topic that is riddled with considerable debate over contradicting outcomes. Hence, this editorial is a call to action directed at editors and reviewers. It is intended to raise the quality, practical implications, application and integrity of future studies investigating the effect of menstrual cycle phases on a given outcome. We do not intend to focus on individual papers but want to ensure that female populations can use their reproductive data accurately and effectively.

THE PROBLEM

Sometimes, a parameter of interest (eg, ovulation) can be measured in various ways (eg, urinary luteinising hormone kits or transvaginal ultrasound), which are open to debate, but nevertheless, these are still measurements; nothing is guessed. When you assume something, you accept it is true or certain to happen without proof. When you estimate something, you take a guess (ie, a rough calculation based on something else). In both cases, you have not used a technique that allows you actually to measure the parameter of interest. You exploit the relationship between a somewhat associated variable (ie, regular menstruation) and a parameter (ie, the remaining phases of the menstrual cycle). As such, it is assumed that an event has occurred (eg, ovulation), and then the timing of that event is estimated (eg, it occurs at the halfway point of the cycle). Assumptions and estimations are made regardless of what is happening (eg, assuming ovulation has definitely occurred when, in reality, it may not have). These assumptions and estimates are not always harmless; many ovarian hormone profiles exist, and regular menstruation does not preclude menstrual dysfunctions, which go undetected with assumed and estimated phases. When adopting an assumed or estimated approach transparent reporting, including the quantification of confidence in these assumptions and estimations, is of utmost importance. While some limitations are often described, and rarely—if ever—are all of the implications of these assumptions and estimations clearly explained to the reader or user. Studies using an assumed and estimated menstrual cycle phase approach frequently do us a disservice; for example, they use the same terminology when assuming or estimating as other authors use when measuring (eg, using specific phase names associated with measurements—such as 'early luteal'—when they have not measured but assumed that phase and should in fact use the broader term 'non-bleeding day'). When the prevailing narrative is that female populations have been underserved by research, accepting assumptions and estimates is not the progress it is purported to be.

THE SOLUTION

The way to establish menstrual cycle phases in research (ie, laboratory and field-based studies) is clear: in addition to noting regular bleeding, investigators need to measure ovulation and progesterone, noting that the ideal frequency and modality of these measurements are still to be determined. Studies using this approach date back to the early 2000s[1] and guidance on this approach has been produced several times within the last 5 years.[2 3] Although this approach may

be challenging in field-based studies, it is certainly not impossible.

CALL TO ACTION

Given the problem and solution provided here, we strongly urge reviewers and editors to insist on measurements rather than guesses. If measurements were not made, it is imperative that authors provide (1) the rationale why measurements were not made; (2) a completely transparent description of the limitations associated with their study design and (3) a full disclosure of the implications of their assumptions and estimations on research quality, confidence in the findings, ability—or rather inability—to make scientific inferences, and the specific clinical dangers associated with assumptions and estimations.

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