Evidence-based research for weight management of the obese woman around the time of conception is not as simple as you think!

More than one-third of women entering pregnancy are classified as obese. Maternal obesity not only makes becoming pregnant more difficult but also increases incidence of gestational diabetes, labor and delivery complications including cesarean sections and preterm birth, maternal and fetal death, hypertension, fetal congenital anomalies, and infants born large for gestational age. To mitigate the negative effects obesity may have on maternal and infant health, in a 2009 report titled "Weight Gain During Pregnancy: Reexamining the Guidelines," the Institute of Medicine (IOM) put forth recommendations for women to enter pregnancy at a healthy weight and for those women affected by obesity to achieve weight loss before conception. Furthermore, in Committee Opinion number 600, The American College of Obstetricians and Gynecologists (ACOG) holds the physician responsible for recognizing the reproductive complications associated with obesity and providing appropriate, unbiased medical care focused on the medical, cultural, and social needs of each patient. If a physician does not have the resources or knowledge to properly care for patients with obesity, consultation with or referral to other healthcare professionals is endorsed by the College. The guidelines for obesity treatment established in 2013 by the American College of Cardiology and American Heart Association and endorsed by many others provide specific recommendations for the delivery of effective lifestyle modification programs, including minimum number for contacts, acceptable rates of weight loss, and delivery approaches to achieve a weight loss efficacy replicated in clinical trials. Although such interventions have been tested in the general population, evidence-based research is needed in specific populations, such as women and couples affected by obesity and trying to conceive.

The study conducted by Rothberg et al. (1) in this issue of *Fertility and Sterility* was specifically designed to address this shortcoming in evidence and aimed to deliver an intensive weight loss intervention in line with the obesity treatment guidelines and the recommendations of the IOM and ACOG to women before conception. The intensive weight loss intervention was tailored for delivery in a clinical setting and importantly included many evidence-based characteristics of a successful weight loss intervention, such as an average of 1.7 in-person weight management counseling sessions per week with a dietitian, physician, or other trained professional, a calorie restricted dietary prescription, the use of portion-controlled foods or meal replacement shakes, and a weight loss target of 15% over a 16-week period. Although the intensive weight loss intervention did result in greater weight loss (-14.3 ± 6.1 kg vs. -4.6 ± 4.6 kg) and more successful pregnancies than in the standard-of-care nutrition counseling group (3 [50%] vs. 0 [0%]), only 11 subjects completed the study. The findings unfortunately are limited by the ability to recruit the target sample size of 32 subjects.

This research group is not alone in their struggle to recruit women for weight management interventions during the perinatal period. There are several studies with similar weight loss or weight management objectives that were inadequately powered (2, 3). Moreover, studies that have enrolled women with overweight or obesity alongside those of normal weight have reported a doubling in the length of time needed to recruit (4). A large National Institutes of Health consortium testing lifestyle interventions for promotion of healthy weight management during pregnancy originally targeting 2,032 women with overweight and obesity (5) will now only study 1,150 women, with clinicaltrials.gov noting the early end to recruitment with reduced numbers of subjects from that originally planned at three clinical centers. These observations regarding recruitment are as equally important as the reporting of the clinical outcomes. Although it is perplexing given the obvious need and also benefit for women before and during pregnancy, collectively these studies highlight a critical gap in knowledge and/or acceptance from patients regarding the seriousness of obesity on conception and pregnancy-related outcomes in both the short and long term.

Perhaps if patients seeking pregnancy had a better understanding of the well-known risks of obesity on poorer rates of pregnancy success and maternal and infant outcomes, engaging patients in studies or treatment programs such as this, which have the potential to improve maternal and infant health, might be more successful? For ACOG, IOM, and other organizations to implement evidenced-based guidelines for weight management of the obese woman before pregnancy, studies are clearly needed to understand how to effectively communicate the issues related to obesity with patients. With the growing focus on patient-centered outcomes in research, one strategy is for clinical weight management programs to foster the involvement of key stake holders, including patients and various healthcare providers, in the development of programs that are grounded in effective weight management strategies, while at the same time being sensitive to the needs and attitudes of patients with obesity. Finally, there is a growing responsibility for national organizations such as ACOG to launch public awareness campaigns to highlight the well-known health concerns for the pregnant patient with obesity and to simultaneously promote the importance of optimal health for all women (and couples) around the time of conception. With the growing prevalence of obesity among reproductive-aged women there is no argument that weight loss is needed, the most opportune time is before conception, and that evidenced-based guidelines for delivery and implementation are lacking. Therefore participation of patients in clinical research with support of the primary care physician

is crucial to understanding the optimal treatment for medical conditions in specific patient populations and improving the health of all.

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