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## Reply to Farr et al. Letter (Benyshek et al.)

Reply:

We welcome the opportunity to respond to the comments by Farr and colleagues in a Letter to *Birth*.

Farr and colleagues raise four points: (1) “biased” data set used in our analyses, (2) insufficient acknowledgment of the lack of evidence supporting the efficacy of the most commonly cited reason for engaging in placentophagy—preventing postpartum depression, (3) “distortion” of their recent review of human placentophagy,<sup>1</sup> and the article’s characterization of the evidence basis of their clinical recommendation against it, and (4) “unprofessional” recommendations for maternity care providers based on our study findings.

1. The main objection to our work raised by Farr et al is that we used data from the MANA Stats system. They erroneously claim that MANA Stats data are “self-reported”—on the contrary, they are based on medical records as are the vast majority of birth registries that track outcomes for midwifery care globally. We actually find it quite shocking that the authors would accuse an entire class of professional care providers of deliberately keeping inaccurate medical records. There is no evidence to support this claim.

Farr et al also describe these data as having “well-known, scientific problems due to systematic bias” and that “no analysis based on MANA Stats can ever be evidence-based [because of this bias].” All data—including MANA Stats data—have bias. Good scientists seek to minimize possible sources of bias when collecting data and acknowledge and clearly discuss any remaining sources when reporting results. We openly acknowledge in all of our papers that our sample is not representative of all childbearing women in the United States, though it is representative of women who choose community birth. We openly acknowledge that not all midwives choose to participate, and thus the data set contains a sample of the total population of

women planning community births. Both of these contribute to selection bias potentially affecting external validity. However, most clinical research is based on samples, as enrolling entire populations is rarely feasible. Indeed, in the most recent issues of *JAMA* and the *New England Journal of Medicine*, every research paper used a sample from the target population, ranging in size from  $n = 24$  to  $n = 75\,782$ . One-fourth of the papers were medical records–based cohort studies. Our methods are thus not unusual. Furthermore, to the extent that we explore research questions involving etiology (eg, is placentophagy harmful to neonates?) rather than demographic characteristics (eg, who engages in placentophagy?), external validity becomes less important,<sup>2</sup> as basic human physiology varies little according to demographics. These concepts are so basic to epidemiology that to question them suggests a bias of their own on the part of the authors.

In terms of limiting selection biases, there are extensive protocols in place to ensure that the MANA Stats system collects complete data from all midwives who *do* participate<sup>3</sup>—indeed, it is impossible, given the system’s checks and balances, for a midwife to “report only half of cases” or “not report adverse outcomes,” as Farr and colleagues suggest. To suggest that fellow health care professionals would misrepresent data—in the absence of any evidence—is a serious and deeply concerning allegation.

There *are*, likely, numerous examples of misclassification bias in our data, just as would be found in any medical records–based data set. Some variables are highly accurate (eg, cesarean), and others more prone to inaccuracies (eg, time of labor onset). Again, we openly acknowledge these potential errors in our manuscripts, and when possible, conduct sensitivity analyses to determine the extent to which they might alter our conclusions. Numerous peer-reviewed papers have been published using MANA Stats data, in the last several years,<sup>3-8</sup> and not a single peer reviewer, nor any postpublication letters to the editor (other than the one written by Farr

and his co-signers here), has ever suggested that these data are so biased that they should be entirely discounted. Results have been presented and favorably received at several national and international conferences, and MANA Stats data are included in the Gates Foundation's Healthy Birth, Growth, & Development *knowledge integration* data consortium. Over 30 different midwifery, public health, and physician researchers from several countries are currently working with these data.

2. Farr et al say "At no point did the authors make it clear that there is no indication for placentophagy." We call our colleagues' attention to *four* instances in our report where we do just that (Abstract: Conclusions; Section 1: second paragraph; Section 4: fifth paragraph; Section 4.2: first paragraph). For example, in the abstract we state, "The majority of women consumed their placentas in uncooked/encapsulated form and hoping to avoid postpartum depression, although no evidence currently exists to support this strategy."<sup>9</sup>
3. In their letter, Farr et al also say: "The citation of our paper is a distortion of it and violates the scholarly standard of accurately reporting the content of papers cited," in reference to the evidence-based rationale for their clinical recommendation against placentophagy. Firstly, we would point out that we reference nearly the identical suite of human studies investigating the purported benefits of placentophagy in our manuscript, and that four of the five studies highlighted by Farr et al in their review (Table 1)<sup>1</sup> were conducted by the lead author of this paper. Dr. Benyshek is thus intimately familiar with the findings having conducted the studies in question. We also stand by our characterization of Farr et al's rationale for their recommendation against placentophagy. Beyond published self-reports of minor maternal side effects of the practice by placentophagic mothers<sup>10</sup> (which Farr et al dismiss as weak and unreliable evidence<sup>1</sup>), the only study cited by Farr et al which could be interpreted as direct evidence of harmful effects of placentophagy to neonates is the single Centers for Disease Control and Prevention (CDC) case report of an infant who was readmitted to the hospital with a late-onset group B *Streptococcus agalactiae* (GBS) infection that may have been transmitted via the mother's placenta capsules, which tested positive for GBS (although the authors could not confirm with certainty that the capsules were the source of the neonate's infection).<sup>11</sup> Epidemiology best practices would suggest that a single case study is insufficient evidence from which to extend a clinical recommendation. Clinical guidelines based on such limited evidence would be graded "I" for "insufficient" by the U.S. Preventive Services Task Force. On the contrary, our medical records-based study of more than 7000 placenta consumers, with a control group of over 10 000 non-consumers, found no evidence of harm to

the neonate. We would also like to point Farr and colleagues to a recently published study on the effects of various preparation methods on hormones, metals, and bacteria in placental tissue, which concludes that the maternal and neonatal infection risk from dehydrated encapsulated placenta is very low.<sup>12</sup> These studies, and not a single case study alone, can and should inform shared decision making around maternal placentophagy.

4. Finally, we take issue with the assertion that our team is "unprofessional" for not recommending directive counseling against placentophagy based on our findings. Our assessment of the current literature on maternal placentophagy is that there is no clear evidence of benefit and no evidence of harm. In such instances, recommending directive counseling against the practice would not be supported by evidence.

We want to close by noting that part of why a growing number of families are choosing community birth is that they fear just the sort of directive counseling that Farr and colleagues are advocating. We have all had the opportunity to work closely with numerous obstetricians over the course of our academic and professional lives, and we believe that the viewpoints conveyed in the Farr et al letter to the editor, and the willingness to level blatant *ad hominem* attacks, are not majority held perspectives.

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