Response to commentary by D Roth

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To the Editor:
We read with interest Dr Roth's commentary[1] published in response to our lactation/vitamin D trial published in *Pediatrics*.[2] Dr Roth raises points that question the validity and applicability of our study to clinical practice.

First, when designing this study, it is known that infant formula supplies adequate vitamin D at 400 IU/quart. The unknown question is, can human breast milk supply the same amount as infant formula or direct infant supplementation? If combined feeding with infant formula corrupted the study, the answer to the human milk question would never be determined. In our study, we did have many women who violated the combined feeding restriction and had to be eliminated from the study's final analysis. In fact, that was the major reason the number of mothers dropped so dramatically as the study went to completion. Infants that were combination fed essentially achieved the same circulating 25(OH)D levels as those ingesting breast milk from mothers receiving 6400 IU/day vitamin D_3. Common sense would suggest this would be so since both fluids would contain approximately 400 IU vitamin D/quart.[3] Thus, whether infants are breastfed from mothers consuming 6400 IU/day vitamin D_3, receiving combined breast-milk/formula feeding, or breastfed and receiving 400 IU/day direct vitamin D supplementation, the circulating level of 25(OH)D in those infants is equivalent and that would be the goal based on American Academy of Pediatrics' recommendations.[4]

Dr Roth also raises questions with respect to the safety of our study because our vitamin D dose exceeded the Institute of Medicine (IOM's) tolerable upper intake level (UL) of 4000 IU/day. We would remind Dr Roth that this is the same IOM that set that UL at 2000 IU/day in 1997 on essentially no data, just as with the current 4000 IU/day UL. When actual science is applied to this determination, 10 000 IU/day is established as the UL, as was recently reported by The Endocrine Society Guidelines. Our studies never revealed a single adverse event due to vitamin D supplementation. Also, with respect to the circulating maternal 25(OH)D levels, none were outside the normal range of circulating 25(OH)D as defined by The American Society for Bone and Mineral Research for decades and are similar to women from indigenous areas living in sun-rich environments.[5] Why these levels would be labelled, as 'above the tolerable upper intake level,' is a mystery to us and based on no data we are aware of.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval MUSC Institutional Review Board.

Provenance and peer review Not commissioned; internally peer reviewed.

Data sharing statement The data generated from our RCT are available for anyone who desires to reanalyse the data.

References

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