

to excellent glycemic control, such as careful monitoring of blood glucose (blood sugar) levels, meticulous attention to insulin administration, vigilant exercise management, etc, which can confuse or confound attribution of the VLCD to glycemic outcomes. Nutrition guidance for patients and families living with type 1 diabetes must be made on the basis of appropriate scientific evidence, not on what more closely resembles testimonials. We agree with the authors that VLCDs may confer benefits for some patients with type 1 diabetes and that rigorous science is needed on this topic. The problem we now face is that it is far too easy for the potential benefits and safety of VLCDs to be publicized broadly on the basis of this report because although findings were definitive, they could be used to potentially mislead the public and add to the substantial confusion that exists around whether VLCDs should be used in type 1 diabetes. Promulgating such methodologically weak although enticing data broadly through the media creates a risk that patients or providers may pursue such plans without adequate insulin adjustment, resulting in serious issues with hypoglycemia as well as risk for nutritional deficiencies without adequate monitoring because of the substantially reduced intake of fruits and vegetables while on the VLCD.<sup>3,4</sup>

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## Authors' Response

Mayer-Davis and colleagues criticize the professional and media attention to our study, but we do not think that the suppression of information about a novel treatment of type 1 diabetes is in the public interest.

For decades, the professional diabetes establishment focused almost exclusively on drug and technology development to the neglect of research into nutritional therapies. Unfortunately, the management of type 1 diabetes remains suboptimal, placing many at increased risk for life-threatening complications.

In our study, we document exceptional glycemic control, low rates of complications, and high patient satisfaction among a community of children and adults following a VLCD. In our study design, we included an extensive review of medical records and a survey of diabetes medical care providers to confirm diagnoses and validate reported data.

The study was observational, and we fully acknowledged the limitations of

this design in our article. But to document a phenomenon that is not thought possible by many diabetes professionals, this design is an appropriate next step. The estimates by Drs Mayer-Davis, Laffel, and Buse regarding potential selection bias may be exaggerated because a significant number of members in the social media community were likely not active or did not have type 1 diabetes themselves.

In any event, those at *Pediatrics* considered the findings of sufficient importance to commission an accompanying commentary.<sup>1</sup>

The American Diabetes Association considered our study of sufficient merit to publish a DiabetesPro SmartBrief.<sup>2</sup>

The *New York Times* coverage was balanced, including opinions from 2 highly regarded diabetes experts with no role in the study.<sup>3</sup> In that article, we urged caution, saying “because our study was observational, the results should not, by themselves, justify a change in diabetes management.”

Of special significance, reader comments on the *New York Times* article included hundreds of testimonials from people with type 1 diabetes who overwhelmingly reported remarkable benefits from a low-carbohydrate diet that were often dismissed by their doctors.

Of course, media hyperbole can be a problem in any research area of interest to the public. Scientists, physicians, and public health experts are certainly within their rights to correct misleading stories. However, we should avoid selective enforcement against research that challenges (versus supports) conventional thinking. On that account, we would note that a relatively high-carbohydrate diet is actively promoted for people with type 1 diabetes despite the lack of any high-quality clinical trials revealing superiority.

One hundred years ago, before the discovery of insulin, a VLCD was considered the most effective treatment of diabetes, including type 1.<sup>4,5</sup> Yet to this day, there have been no major government-funded studies of a VLCD in the management of diabetes. It sometimes takes patient activism to stimulate research into neglected treatments, and a VLCD for diabetes may be 1 such area. If the media attention surrounding our study helps stimulate that research, it will have done a public health service.

Additionally, Dr Bistran in his comment raises 2 valid points regarding our study. Relating to terminology, we agree that our acronym for a VLCD has been previously used for a very low-calorie diet as well, and this may cause confusion. For clarity, we would note that our participants consumed an isocaloric diet with an average of 36 g of carbohydrates per day. Also, per the approach specified by Dr Bernstein, they did not aim for ketosis. Because of the high protein content of this diet, participants may or may not have been in nutritional ketosis, depending on individual differences in metabolism, physical

activity level, and other variables (a conventional ketogenic diet typically limits dietary protein to  $\leq 20\%$  of total energy).

Regarding the second point by Dr Bistran, we agree that a VLCD, by inducing nutritional ketosis (ketoacids  $\leq 5$  mEq/L), could theoretically increase risk for ketoacidosis (ketoacids  $\geq 7$  to 10 mEq/L). However, we did not observe evidence of increased rates of ketoacidosis in the study, nor did our review of the literature substantiate this concern. Conversely, it is also possible that for someone who maintains such low average glucose levels, as is typical with a VLCD, that rises in glucose levels would alert to impending ketoacidosis sooner than might be the case for someone on a convention diet, for whom substantial hyperglycemia may not be unusual. In any event, the issue warrants examination in clinical trials.

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