

March 25, 2014

Howard Bauchner, MD
Editor-in Chief, JAMA

Re: Association of Testosterone Therapy With Mortality, Myocardial Infarction, and Stroke in Men With Low Testosterone Levels by Vigen et al

Dear Dr. Bauchner,

In the best interests of medical science, we write to recommend retraction of the article by Vigen et al published in JAMA Nov 13, 2013 (1).

As physicians and scientists interested in the testosterone field, we welcome any new addition to the scientific literature that furthers knowledge in this important area. However, there must be a reasonable minimum standard for the quality of publications such that the reported science is credible. The publication of results that are unlikely to be accurate is a disservice to the scientific community and the literature. Due to new revelations, we believe the article by Vigen et al no longer meets the acceptable minimum standard.

The credibility of this article was initially compromised by its original mis-reporting of data, requiring a post-publication revision on January 15, 2014 (2). Now it has been revealed via a new published correction that there were major errors in values presented in the text and figure. The quality and magnitude of these errors indicate gross data mismanagement and contamination, to a degree that the reported results are no longer reliable. Our recommendation for retraction follows guidelines published by The Committee On Publication Ethics (COPE) (3), which has stated that journal editors should consider retracting a publication if “they have clear evidence the results are unreliable, either as a result of misconduct (eg, data fabrication), or honest error (eg, miscalculation or experimental error).”

On March 4, 2014 JAMA published several letters regarding this article (4), the authors’ reply (5), and also a new correction (6). In response to the criticism that the authors had improperly excluded 1132 men from analysis who had received a testosterone prescription after experiencing an event (MI or stroke), the authors indicated they had revisited this value presented in the text and Figure 1, and had made “an incorrect notation” regarding this value. They now assert the numbers of men excluded for this reason was 128, not 1132. This is an 89% error rate, involving >1000 individuals. The number of men now excluded due to missing coronary anatomy increased from 397 to 1301, a 69% error rate, involving 904 individuals. Astonishingly, 100 women were now identified among the original group of 1132 individuals, meaning that one out of eleven “men” in the study were actually women.

It is impossible for the scientific community to have any confidence in the results of a study when there have been unrecognized errors involving more than a thousand individuals, and nearly 10% of a dataset is populated by the wrong gender. The study by Vigen et al is no longer credible. In the interests of science and the medical literature, we urge you to retract this article immediately.

References

1. Vigen R, O'Donnell CI, Baron AE, et al. Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels. *JAMA*. 2013 ;310(17):1829-1836
2. Correction: Incorrect language. *JAMA* 2014;311(3):306
3. Wager E, Barbour V, Yentis S, Kleinert S; COPE Council. Retractions: guidance from the Committee on Publication Ethics (COPE). *Obes Rev*. 2010 Jan;11(1):64-6.
4. Morgentaler A, Traish A, Kacker R. Re: Deaths and Cardiovascular Events in Men Receiving Testosterone. *JAMA* 2014; 311(9): 961-2.
5. Ho PM, Barón AE, Wierman ME. *JAMA* 2014; 311(9): 964-5.
6. Correction: Incorrect Number of Excluded Patients Reported in the Text and Figure. *JAMA* 2014; 311 (9):967.

Signed,

The Androgen Study Group and fellow concerned physicians and scientists, as follows: