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LETTERS

DATA TOO IMPORTANT TO SHARE

Update: *New England Journal of Medicine* publishes correction to 2012 CHEST trial of hydroxyethyl starch versus colloids

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After publication of my article,[1] the *New England Journal of Medicine* (*NEJM*) published a correction to the 2012 CHEST trial of hydroxyethyl starch versus colloids.[2 3] A new P value of 0.006 was provided for the comparison of treatment related adverse events between hydroxyethyl starch (HES) and saline groups (180/3871 (4.6%) *v* 95/2870 (3.3%)). Before the correction, this was reported as 180/3416 (5.3%) versus 95/3358 (2.8%); P<0.001.

In additional changes after the correction, the word "efficacy" was added to the Methods section to read "we conducted all efficacy analyses on an intention-to-treat basis." A new supplemental file was added that contains an explanation of why the authors did not analyse adverse events on an intention-to-treat basis, with 1001 more patients in the HES group than the saline group.

The edits to the trial publication come more than two years after the *NEJM* was first questioned about this result. In 2013, the *NEJM* said no changes were necessary as the results were "accurately reported."[1] After renewed questions last year, the *NEJM* sought comment from CHEST trial principal investigator John Myburgh, who described incorrectly reported denominators as being "due to a typographical transcription error."

The new supplemental file explains that adverse events were analysed on the "safety" set rather than the "intention-to-treat" set. But it does not explain when this methodological approach was decided. Neither the approach nor definition of the "safety" population was described in the study's published protocol or statistical analysis plan.[4 5]

Competing interests: I have read and understood BMJ policy on declaration of interests and declare YODA paid all expenses for me to join a June 2012 planning meeting to discuss YODA's forthcoming data sharing policy. This payment was later reimbursed by *The BMJ*. I consider the YODA team to be colleagues. Also, I am an unpaid member of the IMEDS steering committee at the Reagan-Udall Foundation for the FDA, which focuses on drug safety research.

1 Doshi P. Data too important to share: do those who control the data control the message?*BMJ* 2016;352:i1027.
2 Correction. Hydroxyethyl starch or saline for fluid resuscitation in intensive care. *N Engl J Med* 2016 Mar 8 http://www.nejm.org/doi/10.1056/NEJMx160007.
3 Myburgh JA, Finfer S, Bellomo R, et al. CHEST Investigators Australian and New Zealand Intensive Care Society Clinical Trials Group. Hydroxyethyl starch or saline for fluid resuscitation in intensive care. *N Engl J Med* 2012;367:1901-11. http://www.nejm.org/doi/full/10.1056/NEJMoa1209759
4 Crystalloid versus Hydroxyethyl Starch Trial (CHEST) Management Committee. The Crystalloid versus Hydroxyethyl Starch Trial: protocol for a multi-centre randomised controlled trial of fluid resuscitation with 6% hydroxyethyl starch (130/0.4) compared to 0.9% sodium chloride (saline) in intensive care patients on mortality. *Intensive Care Med* 2011;37:816-23.
5 Myburgh J, Li Q, Heritier S, Dan A, Glass P. Crystalloid Versus Hydroxyethyl Starch Trial (CHEST) Management Committee. Statistical analysis plan for the Crystalloid Versus Hydroxyethyl Starch Trial (CHEST). *Crit Care Resusc* 2012;14:44-52.

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