

# Researchers urged to share landmark trial data on safety of starch solutions

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A group of researchers are today being urged to share their data for a landmark trial that raised safety concerns about the use of starch solutions.

In a special report published today, *The BMJ's* Associate Editor Peter Doshi sets out the facts of the case and asks, is it right for academics to withhold data and prevent independent scrutiny of their results?

The CHEST trial raised safety concerns about the use of hydroxyethyl starch (HES) to replace lost blood volume in critically ill patients. It was published in the *New England Journal of Medicine* (NEJM) in 2012 and led European and American regulators to suspend use of HES across much of the world.

Fresenius Kabi - a leading manufacturer of HES products and a major sponsor of the CHEST trial - questions the results and wants to verify the data.

But the trial investigators have refused to share the raw study data because they are concerned that the company would bias the reanalysis.

They have also refused a request to release the data to Yale cardiologist Harlan Krumholz for reanalysis by independent parties under his Yale open data access (YODA) scheme.

Fresenius Kabi agreed to fund Yale's efforts but otherwise not influence

the process.

Principal CHEST trial investigator, John Myburgh said "We have no issue with the concept of data sharing. The concerns we have come down to the people with ulterior motives which contradict or do not adhere to the scientific principles we adhere to. That's the danger."

"This case exemplifies the broader cultural shift in medicine," commented physician author and transparency advocate Ben Goldacre, whom Fresenius Kabi contacted for help. He added: "The researchers should hand these data over, and if they want to be taken seriously, the sponsors [Fresenius Kabi] should set out their protocol for analysing it before they receive the files."

Myburgh is confident about the conclusions that can be drawn from his trial. But another CHEST study investigator who was not a coauthor of the NEJM article told *The BMJ* on condition of anonymity that he was "uncomfortable with the way renal complications were interpreted [in the NEJM paper]."

Fresenius claims to have discovered problems in the CHEST investigators' handling of adverse event data. But when the company put its concerns to NEJM, the journal said there had been no breach of scientific protocol and that no change was needed to its published material.

Doshi points out that when regulators issued public warnings about HES products, they did so without any access to the CHEST trial's underlying data. He says this case "highlights the degree to which current scientific publishing practices and regulatory decisions are based on blind trust and strengthens the call for a shift to open data."

Independent investigators "should not shy away from a secondary

analysis that raises legitimate questions about the original study," writes Professor Michael Murray in an accompanying editorial.

Although he shares concerns about bias when data are released to anyone who may have a hidden agenda, he says "we must remember that not all primary investigators are above reproach and not all drug companies are pariahs."

"My view is that [data](#) sharing is good, whoever makes the request. It's up to us to overcome any bumps in the road that we encounter in our search for answers," he concludes.

**More information:** Data too important to share: do those who control the data control the message? [www.bmj.com/cgi/doi/10.1136/bmj.i1027](http://www.bmj.com/cgi/doi/10.1136/bmj.i1027)

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