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An Explosion Of Medical Research Fraud Underlines The Wisdom Of Boosting Public Funding For Research To Reduce Dependence On Drug Company Money

IN THE world of anaesthetics, Joachim Boldt is a household name. By the end of last year, the 57-year-old German anaesthetist had published hundreds of studies in respected medical journals and was regularly speaking at international conferences.

One of his specialties was colloids, fluids given intravenously to millions of patients each year to maintain their blood pressure during surgery. After years of doubt about safety and efficacy, Boldt's research consistently recommended colloids over a vastly cheaper and more effective product known as crystalloids.

However, last October, Boldt's professional credibility took a sudden blow when a reader of his latest research on colloids in the American journal *Anaesthesia and Analgesia* decided the research looked implausibly perfect.

The observation was reported to the journal's editor, who soon discovered the study lacked approval from Germany's Institutional Review Board, a committee that oversees medical research.

The finding marked the beginning of an investigation into what is now suspected to be an extraordinary case of medical research fraud. Two months ago, the editors of 16 medical journals, including the editor of *Anaesthesia and Analgesia*, retracted 89 of 102 of Boldt's studies because they had also not been approved by the review board.

While there appeared to be no immediate safety concerns for the patients involved, the editors said the hospital where Boldt worked was checking his work against patient and laboratory records to see if any "data fabrication, falsification and misrepresentation" had occurred.

Meanwhile, Boldt's employer, Ludwigshafen Hospital in Rhineland, stood him down as chief anaesthetist and the University Hospital of Giessen stripped him of his professorship.

While the investigation continues, shocked doctors around the world are waiting for the next installment. Is Boldt guilty of fudging his data? And if so, why would such a successful doctor do such a thing?

It has become clear that Boldt's research was increasingly pushing colloids over crystalloids, even though previous studies had suggested a link between colloids and kidney failure and blood loss. It is also clear that Boldt had received research funding from several colloid manufacturers including B.Braun, Baxter and Fresenius Kabi.

According to British reports, some of Boldt's work on colloids had been factored into the Consensus Guidelines on Intravenous Fluid Therapy, a respected guide for doctors published by six British medical groups including the Association of Surgeons and the Intensive Care Society. The guidelines, which had the potential to affect the management of millions of patients, were withdrawn for review shortly after the allegations emerged.

Neville Gibbs, an anaesthetics specialist and editor of Australian journal *Anaesthesia and Intensive Care*, says although Boldt's work on colloids did not change any Australian guidelines that doctors follow for their work, it may have quietly altered some doctors' views of colloids, making them feel more comfortable about using them.

"Joachim Boldt was of very high repute with a large number of publications, so he was possibly able to sway people in any country," Gibbs says.

Gibbs says if Boldt's research was indeed fraudulent and continued to go undetected, it could have caused enormous damage.

"Any harm that came from fraud in this area could have very long-lasting effects and very extensive effects. The risk to individual patients would have been low but millions of patients worldwide could have been exposed to inappropriate fluid therapy that was not warranted, and in many cases, not ideal."

However, what has gotten Australian doctors talking is the fact the Boldt case follows a string of high-profile examples of dubious research being published in reputable medical journals without the editors detecting bias or fraud. And for many patients, the consequences have been disastrous.

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