

The NICE-SUGAR and RENAL statistical analysis plans

Manoj K Saxena

TO THE EDITOR: I wish to thank Finfer and colleagues for placing in the public domain not only the statistical analysis plans for the NICE-SUGAR (Normoglycaemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation)¹ and RENAL (Randomised Evaluation of Normal vs. Augmented Level of Replacement Therapy)² studies, but also the protocol for the NICE-SUGAR Study.³ The free availability of these documents, along with the NICE-SUGAR clinical trial results,⁴ is important for the reasons elegantly expressed by Finfer and Bellomo in the accompanying editorial on transparency.⁵ However, there is a further benefit that deserves emphasis.

As an early-stage researcher, I find these documents extremely valuable for understanding the design, conduct and governance of clinical research. To illustrate, our research interest is the effect of targeting normothermia after traumatic brain injury. The NICE-SUGAR statistical analysis plan¹ has helped in this research both generally — in understanding the process and structure of data analysis — and specifically — because of the similarity in analysis between serial glucose measurements and our serial temperature measurements. In addition, the NICE-SUGAR protocol³ aided our understanding of process, structure and governance, and facilitated the development of our protocol for a Phase 2b clinical trial.

The free availability of these resources is both a generous and valuable investment in improving the quality, conduct and interpretation of future research. In the future, we intend to follow this altruistic example and urge others to do so as well.

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- 5 Finfer S, Bellomo R. Why publish statistical analysis plans? *Crit Care Resusc* 2009; 11: 5-6. □

Information for authors

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