



Prof. Diana R. Elbourne: CONSORT for Cluster Randomized Trials and CONSORT for Noninferiority and Equivalence Trials

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Editor's note

In March 2021, AME Publishing Company initiated the translation of the book “Guidelines for Reporting Health Research: A User’s Manual” into Chinese and complete the work in June 2021. While the Chinese edition is now under the process of official publication, the AME editorial office launches an interview with the book editors and authors, hoping to highlight some update on the status and trends of the reporting guidelines in the Chinese edition.

Here, we take the pleasure to interview Dr. Diana R. Elbourne to share her insights based on the book. Dr. Diana R. Elbourne is two chapters author of the book and her chapter title is “CONSORT for Cluster Randomized Trials, 122/ CONSORT for Noninferiority and Equivalence Trials, 135”.

Chapter 13

AME: [Evidence of the effectiveness of the guidelines] mentioned that the fourth evaluation showed that the quality of the cluster trial report from 2007 to 2010 decreased. What do you think caused this phenomenon?

Prof. Diana R. Elbourne: ‘Suggested’ not necessarily definite. Only 50 trials. Don’t make too much of this.

AME: [Recognition and compliance] Does the implementation of the guideline encounter any challenges?

Prof. Diana R. Elbourne: I think those of us like me involved with DEVELOPING the guidelines do not necessarily have anything to say about how they are IMPLEMENTED.

AME: [Error and misunderstandings] pointed out and explained several common errors and misunderstandings (for example, ICC does not need to adjust the group when it is very small: error; this guideline covers non-design cluster research: incorrect). How can we better avoid these errors and misunderstandings from a wider range?

Prof. Diana R. Elbourne: Hope that statements like CONSORT will help to avoid these errors and misunderstandings in the future.

AME: At the end of the article, it mentioned that the guidelines will be updated if there are important new research findings. It has been 9 years since the release of this guideline. Are there currently any plans for an update?

Prof. Diana R. Elbourne: The authors did not have funding. Doug Altman has since died; Marion Campbell has changed jobs; Gilda Piaggio has retired. So there were no plans for updates from this team. However, the SPIRIT/ CONSORT groups are looking to update more generally, and if so, the cluster extension will be updated.

Chapter 14

AME: It took 3 years to formulate the guidelines for non-inferiority and equivalence randomized trial reports. What is the largest obstacle (for example, there may be controversies over a certain item) and how do you solve it?

Prof. Diana R. Elbourne: No funding so no protected time.



Figure 1 Photo of Prof. Diana R. Elbourne.

AME: It is mentioned in the article that we don't know whether the use of the expanded non-inferiority and equivalence list of CONSORT is related to the improvement of the quality of non-inferiority and equivalence test reports. Does the latest literature and data show the effectiveness of the reporting checklist?

Prof. Diana R. Elbourne: I'm sorry but I don't know. Needs a piece of research to find out.

AME: As far as you know, how about the compliance of the medical journals on implementing the guidelines and stating them in their Author Instruction?

Prof. Diana R. Elbourne: I think those of us like me involved with DEVELOPING the guidelines do not necessarily have anything to say about how they are IMPLEMENTED.

AME: 9 years have passed since the publication of this guideline. Are there any plans for an update?

Prof. Diana R. Elbourne: The authors did not have funding. Doug Altman has since died; Marion Campbell has changed jobs; Gilda Piaggio has retired. So there were no plans for updates from this team. However, the SPIRIT/CONSORT groups are looking to update more generally, and if so, the cluster extension will be updated.

Expert introduction

Prof. Diana R. Elbourne (*Figure 1*) obtained her first degree was in Social Administration from London School of Economics (LSE), after which she gained an MSc (Stats) at Brunel University. Her PhD at LSE was based on a randomised controlled trial (RCT) of women having access to their maternity care records. From 1981–1996, Prof. Diana R. Elbourne was at the National Perinatal Epidemiology Unit in Oxford, holding the roles of social statistician, trials statistician, Deputy Director and later Director of the Perinatal Trials Service. During this period she was involved in a large number of RCTs and systematic reviews. she continued this applied research after moving to the Medical Statistics Department (MSD) at the London School of Hygiene and Tropical Medicine (LSHTM) in 1997, broadening from the perinatal field to also include trials in liver transplantation, intensive care, heart disease, children with diabetes, adolescents, and educational and nutritional interventions. Between 2000 and 2005 she also worked half-time as professor of Evidence-informed policy and practice in the Evidence for Policy and Practice Information and Coordination Centre in the Institute of Education.

Prof. Diana R. Elbourne's main interest as a statistician is in RCTs. As a triallist she works with a highly experienced team in the MSD and the LSHTM Clinical Trials Unit to design, co-ordinate, analyse and report a number of RCTs. Currently these trials include perinatal and child health trials in the Gambia, Uganda and India, cardiac care in the UK, and school-based trials in the UK, Gambia and India.

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Footnote

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