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documented in 46% of cases reported in Green et al.'s study.¹ The results of the WOMAN trial³ will provide evidence for wider use of tranexamic acid specifically in PPH.

Future work on PPH should include consideration of these important factors as well as on development of simple tools which can be easily taught to non-medical personnel in low resource settings, such as the PPH Butterfly device. ⁴

References

- 1 Green L, Knight M, Seeney FM, Hopkinson C, Collins PW, Collis RE, et al. The epidemiology and outcomes of women with postpartum haemorrhage requiring massive transfusion with eight or more units of red cells: a national cross-sectional study. *BJOG* 2016;123:2164–70.
- **2** Mishra N, Chandraharan E. Postpartum haemorrhage. In Warren R, Arulkumaran S, editors. *Best Practice in Labour and Delivery.* Chapter 15, Cambridge: Cambridge University Press; 2009. pp. 160–9.
- 3 Shakur H, Elbourne D, Gülmezoglu M, Alfirevic Z, Ronsmans C, Allen E, et al. The WOMAN Trial (World Maternal Antifibrinolytic Trial): tranexamic acid for the treatment of postpartum haemorrhage: an international randomised, double blind placebo controlled trial. *Trials* 2010;11:40.
- 4 The Postpartum (PPH) Butterfly Device. [https://clinicaltrials.gov/ct2/show/NCT02692287] Accessed 10 March 2016

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Authors' reply

Sir

We thank Dr Killicoat and colleagues for their interest in our paper. We agree that it is important that both trainee and consultant obstetricians and midwives are skilled in recognising and managing obstetric haemorrhage. Haemorrhage remains the second most frequent cause of direct maternal death in the UK; there has been no significant decrease in maternal death rate from haemorrhage since 2009.¹ The most recent UK Confidential Enquiries into Maternal Deaths which reviewed the care of women who died from haemorrhage reported that improvements in care may have made a difference to outcome in all of the women who died. The report highlighted a number of key messages to improve future care of women with haemorrhage.²

Three women who died were anaemic in the antenatal period and only one received oral iron. Haemoglobin levels below the normal range for pregnancy should be investigated and iron supplementation considered if indicated to optimise haemoglobin before delivery.

Inadequate observations were a feature in seven deaths and abnormal observations were not escalated in five women. Physiological observations including the respiratory rate should be used to monitor all antenatal and postnatal admissions. However, it is the response to the abnormal score that will affect outcome, not simply its documentation. Concerns should be escalated to a senior doctor or midwife if a woman deteriorates, and there should be a named senior doctor in charge of ongoing care.

In several deaths an acute point of care of single haemoglobin measurement result falsely reassured staff. Fluid resuscitation and blood transfusion management, which has been described elsewhere,³ are also important, and should not be delayed because of false reassurance from a single haemoglobin result; the whole clinical picture should be considered.

In several instances, women deteriorated despite ongoing resuscitation because the source of bleeding was not stopped. Of particular relevance to the observations of Dr Killicoat and colleagues, eight women had attempted balloon tamponade and the report notes

that there appeared to be a tendency to try an intrauterine balloon even when the situation was extreme. The figures from Dr Killicoat and colleagues noting a higher rate of intrauterine balloon use in women with a haemorrhage of 3000 ml or more perhaps reflects this. The report highlighted once again the importance of early recourse to hysterectomy if simpler medical and surgical interventions prove ineffective, and this applies equally to intrauterine balloon use.

References

- 1 Knight MNM, Tuffnell D, Kenyon S, Shakespeare J, Gray R, Kurinczuk JJ (eds) on behalf of MBRRACE-UK. Saving Lives, Improving Mothers' Care Surveillance of Maternal Deaths in the UK 2011–13 and Lessons Learned to Inform Maternity Care From the UK and Ireland Confidential Enquiries Into Maternal Deaths and Morbidity 2009-13. Oxford: National Perinatal Epidemiology Unit, University of Oxford 2015
- 2 Paterson-Brown S, Bamber J. Prevention and treatment of haemorrhage. In: Knight M, Kenyon S, Brocklehurst P, et al. editors. Saving Lives, Improving Mothers' Care Lessons Learned to Inform Future Maternity Care From the UK and Ireland Confidential Enquiries Into Maternal Deaths and Morbidity 2009–12. Oxford: National Perinatal Epidemiology Unit, University of Oxford; 2014. pp. 45–55.
- **3** Green L, Knight M, Seeney F, Hopkinson C, Collins PW, Collis RE, et al. The haematological features and transfusion management of women who required massive transfusion for major obstetric haemorrhage in the UK: a population based study. *Br J Haematol* 2016;172:616–24.

Marian Knight, Frances M. Seeney, Cathy Hopkinson, Peter W. Collins, Rachel E. Collis, Nigel A. B. Simpson, Andrew Weeks, Simon S. Stanworth & Laura Green

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Re: Parental physical and lifestyle factors and their association with newborn body composition

Sir,

I was interested to read the paper by McCarthy et al.¹ The authors aimed to evaluate the impact of parental physical characteristics and lifestyle on newborn body composition. They found that adjusted mean difference in neonatal body fat percentage (BF%) between maternal smokers and non-smokers was -0.55 (95% CI -1.07 to -0.03).¹

Although the analyses are correct and the data are interesting, the readers must distinguish difference between statistical significance and clinical importance. As a rule of thumb, clinical importance is more important than statistical significance because statistical significance does not provide information about the effect size or the clinical relevance.² Here, clinically, differences of -0.55 and -0.03 in BF% are nothing and may even be negligible although they were statistically significant.

Large sample size, large mean difference and lower standard deviation of the variable in the study population would easily change *P*-value from non-significant to significant.² As the authors point out in their conclusion, there is an association between maternal smoking and altered BF %. It is important to consider the clinical judgement in this conclusion. ■

References

1 McCarthy F, Khashan A, Murray D, Kiely M, Hourihane JO, Pasupathy D, et al. Parental

- physical and lifestyle factors and their association with newborn body composition. *BJOG* 2016;123:1824–9.
- 2 Fletcher RH, Fletcher SW, Fletcher GS. Clinical Epidemiology: The Essentials. New York, NY: Lippincott Williams & Wilkins, 2012.

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Authors' reply

Sir,

We thank Mr Ayubi for his comments. We agree, the differentiation between statistical and clinical significance is critical to the interpretation of any new research and we would encourage readers to do this.

Can we with certainty say that statistically significant differences of small magnitude amount to nothing and may be even negligible as Mr Ayubi suggests? Similarly, although large effects are more likely to be clinically significant than small ones, even large effects can be clinically insignificant. On the other hand, if the difference between treatment groups is statistically non-significant, it may still be clinically important. These questions are interesting but are well beyond the scope of this paper, although they are discussed elsewhere. ^{1–3}

We agree the magnitude of some of these statistically significant effects that we report is small, but others, such as maternal waist:height ratio, are of greater magnitude (adjusted mean difference 6.59; 95% CI 0.27–12.92) and likely to be clinically significant.⁴ Although many of the changes that we report are of small magnitude, we believe the combination of all these measurements supports a trend that differences in maternal anthropometry

influences neonatal body fat percentage. How this may translate into clinically relevant and translational findings is an ongoing body of work but presenting these findings in an open and transparent manner as we have done we feel allows the reader reach their own conclusion.

References

- 1 Jacobson NS, Roberts LJ, Berns SB, McGlinchey JB. Methods for defining and determining the clinical significance of treatment effects: description, application, and alternatives. *J Consult Clin Psychol* 1999;67:300–7.
- 2 Chavalarias D, Wallach JD, Li AH, Ioannidis JP. Evolution of reporting P values in the biomedical literature, 1990–2015. *JAMA* 2016;315:1141–8.
- 3 Altman DG, Bland JM. Absence of evidence is not evidence of absence. BMJ 1995;311: 485
- **4** McCarthy FP, Khashan AS, Murray D, Kiely M, Hourihane JO, Pasupathy D, et al. Parental physical and lifestyle factors and their association with newborn body composition. *BJOG* 2016;PMID: 27102226. doi: 10.1111/1471-0528.14042. [Epub ahead of print].

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Re: Time to optimise and enforce training in interpretation of intrapartum cardiotocograph

Time is not ripe for imposing pass/fail licensing examination in cardiotocography interpretation in UK

Sir,

The commentary by Ugwumadu et al.¹ begins with a demand for