MJ - Decision on Manuscript ID BMJ.2016.034794

Body: 29-Oct-2016

Dear Dr. Nelson

BMJ.2016.034794 entitled "Electronic fetal monitoring, cerebral palsy, and our epidemic of cesarean births"

Thank you for sending us your article, which we read with interest.

We sent it out for external peer review and discussed it at our Analysis editorial meeting (present: Theo Bloom, Sophie Cook, Navjoyt Ladher)

We do not consider it suitable for publication in its present form but if you are able to amend it in the light of our and/or reviewers' comments, we would be happy to consider it again.

The reviewers' comments are at the end of this letter.

The editors' comments are listed below:

1) Editors thought this was an interesting and important topic, and likely to be of interest to our readership. The comments here are intended to strengthen the argument and make the paper more accessible to a general medical readership

2) Editors felt that the detail could be unpicked further. . E.g. to what extent do we think monitoring drives C-sections versus other reasons.The reviewer's point about the need to clarify how many c sections are for foetal distress vs other reasons (ie repeat c section which they say is the majority) is important. Likewise the need to be clear that 16% of CP is thought to be due to birth asphyxia.

3) Could you more clearly explain what you think is the best solution? Editors thought that the paper falls short a little in terms of movement forward.

4) We thought there were issues with tone. The 'epidemic' in the title seems over-stating something that you don't really focus on - not to mention, who are the "we" in "our" epidemic. At times the paper reads as polemic rather than evidence-based, a point the reviewers pick up

5) For a non-specialist readership it may be helpful to explain what is meant by electronic fetal monitoring, e.g. just CTG or other things too? And what are the alternatives?

6) We thought it would be good to press the point about being more honest with patients about the limitations of the tests

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I hope you will find the comments useful. Please don't hesitate to contact me if you wish to discuss this further.

Yours sincerely

Navjoyt Ladher
nladher@bmj.com

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Reviewer(s)' Comments to Author:

Reviewer: 1

Recommendation:

Comments:
Whilst I agree with the main thrust of this article, ie that we are performing more caesareans than required to protect babies from harm, the authors have decided to make a more specific and targeted statement:
"Electronic fetal monitoring does not enable prevention of cerebral palsy, but EFM and expert testimony that contradicts evidence of good medical quality in "birth injury" litigation contribute to our high rate of caesarean deliveries."
Since they wish to express this opinion in a peer reviewed medical journal they would be expected to
1. Describe the increase in caesarean delivery rates
2. Quantify the proportion of caesareans which are performed in labour as a result of an abnormal CTG. The authors state "EFM is not the only factor contributing to the excess of surgical deliveries, but it is clearly a significant factor." (Page 8, lines 4 and 5). This is not a sufficient attempt to deal with the contributions of increasing rates of elective caesarean section, the increasing numbers of pregnant women who have undergone a previous caesarean delivery. It would be better if there was discussion of the proportion of current caesareans performed in labour, and in those cases, the proportion which are performed for fetal distress. One of the references (Reference 23 Narber et al) does analyse this, and finds that the main contributor to the increase in caesarean rates at one academic hospital was in fact the increase in repeat caesarean deliveries (50% of the increase). By comparison, fetal distress accounted for 16% of the increase. In Reference 22 (Sachs), whilst making the case that medico-legal considerations were a major contributor to the increase in caesarean rates, found that fetal distress was ranked third in contribution to the rising caesarean rate, behind repeat caesarean and dystocia.
3. At least attempt to show that excess caesareans are more likely to occur in countries with relatively high rates if medico-legal claims compared to similar countries with lower rates of medico-legal claims. This would add weight to the claim that medico-legal considerations are implicated in the increase in caesarean section rates. For example, countries with statutory compensations schemes and/or low litigation rates (eg Netherlands, New Zealand, Scandinavian countries) tend to have lower caesarean rates then USA, Britain and Australia.

The authors should acknowledge that about 16% of cerebral palsy is attributable to birth asphyxia in term babies (Ref 22 Sachs). Are the authors saying that we should not use Electronic Fetal Monitoring at all? It is one thing to make the valid point that EFM is overused, and inappropriately used in low risk labours; it is another to suggest it has no place at all in modern obstetrics. The studies to which the authors refer are studies of routine use of EFM in all labours. I am not aware of studies which show EFM is of no benefit in high risk labours. In addition, College guidelines (RCOG, RANZCOG ACOG) state clearly that EFM should only be used in high risk pregnancies with specific indications. Perhaps if these guidelines were better adhered to we would have less of a problem with unnecessary EFM induced caesarean sections. This would be worthy of mention.
Reference 3 is a media article based on the JAMA study (reference 4) and probably does not merit separate citation in an academic journal. The JAMA study is used to support the statement that "caesarean rates are too high for optimal health of mothers and infants" yet that study actually shows no further trend towards lower maternal or perinatal mortality rates when national caesarean rates rise above 20%. The study makes no comment on maternal infant health outcomes beyond perinatal death rates, and therefore is not directly relevant to an article discussing Cerebral Palsy as the main outcome.
The discussion "Is there a way forward" I think is a valuable contribution to the issues raised regarding the problem which arises when compensation/assistance for long term neurological disability is determined by litigation on civil courts. Perhaps it might also be helpful to discuss the place for statutory compensation/disability assistance schemes.
Overall I feel this is a valuable article but requires some revision to bring it to the standard expected in a high quality peer reviewed journal

Additional Questions:

Please enter your name: Andrew Pesce

Job Title: Consultant Obstetrician and Gynaecologist

Institution: Westmead Hospital, Westmead NSW Australia

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

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If you have any competing interests (please see BMJ policy) please declare them here:

Reviewer: 2

Recommendation:

Comments:
Dear BMJ Editors

I congratulate the authors on a balanced and detailed review. The topic of the role of EFM as a method to improve fetal/neonatal survival and neurological outcome is highly charged with serious implications for medico-legal cases seeking to establish negligence.

I believe the importance of this review justifies publication with your journal.

I have some minor suggestions which may improve the paper.

Line 16 page 5: ref 3 is data from ref 4 can be deleted.

Line 18 page 5 "exceedingly high" could be changed to "extremely high" as used in in the text in reference 5.

The sentence "Although electronic monitoring has no demonstrated value for preventing CP, it may thus have other applications and is less expensive than one-on-one auscultation" lines 36-40 page 7 should be referenced or deleted. I am not aware of comparative cost data in this area.

Lines 20 to 27 page 8: "Surgical delivery increases risks to mothers, immediate and long-term.[25,26] Maternal death (adjusted for confounders) was 3.6 times more frequent after cesarean than vaginal delivery, [27] Operative deliveries increase risks of maternal haemorrhage, infection, and thromboembolism, and respiratory depression in the neonate" The use of word Operative in the second sentence could be clarified. Does this refer to all - cesarean and/or instrumental vaginal delivery?

The sentence on page 8 lines 28-32 "Complications in subsequent pregnancies include a high rate of repeat cesarean delivery, abnormally invasive placentation with potential for catastrophic haemorrhage, and uterine rupture." This is a critical issue of maternal morbidity and should be referenced.

The quoted sentence lines 24 to 26 page 9 "There is overwhelming evidence that part of the recent rise in the cesarean section rate in this country is the result of the medical-legal environment." [21] can the authors please check this as it appears to be from reference 22 not 21. The quote is the first sentence in the summary page 54 of ref 22.

The sentence on page 9 line 55 – 57 "The current medico legal approach is expensive, irrational and highly inefficient, and benefit to disabled children and their families is minimal" should be referenced if possible (undoubtedly true but would be strengthened with a reference).

I would ask the authors to consider a sentence or two about the forthcoming INFANT study due to be published soon. The protocol "A study of an intelligent system to support decision making in the management of labour using the cardiotocograph – the INFANT study protocol" DOI: 10.1186/s12884-015-0780-0 details the planned enrolment 46,000 women judged to require continuous EFM during labor. So far the abstract has been presented at two international conferences in the UK – but no sign of the publication which is bound to be controversial.

Dr Mark Tracy

Additional Questions:
Please enter your name: Dr Mark Tracy

Job Title: Senior Newborn Intensive Care Specialist and Clinical Senior Lecturer

Institution: Westmead NICU WSLHD

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

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If you have any competing interests (please see BMJ policy) please declare them here: None

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