PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A prospective cohort study of the morbidity associated with operative vaginal deliveries performed by day and at night
AUTHORS	Murphy, Deirdre; Butler, Katherine; Ramphul, Meenakshi; Dunney, Clare; Farren, Maria; McSweeney, Aoife; McNamara, Karen

VERSION 1 - REVIEW

REVIEWER	Dr Alyson Hunter Maternal and Fetal Medicine, Royal Jubilee Maternity Hospital Grosvenor Road Belfast BT12 6BB
REVIEW RETURNED	5-Aug-2014

GENERAL COMMENTS	Thank you for asking me to review this important and timely paper. In light of the drive by the DOH and RCOG in the UK to have 24 hour cover in delivery suite its findings shed doubt on the cost effectiveness of 24 hour Consultant led care on the labour wArd. It is very well written and clearly states its aims, methodology and findings. However, I have some minor criticisms 1. As an obstetrician I find the thread of the argument clear enough but I think that the authors should more clearly stress that, although the risks of OVD in inexperienced hands are potentially high, so are the other risks out of hours of unnecessary c section during the first stage of labour and the quality of care to other labour ward emergencies such as postpartum haemorrhage, APH, twin delivery,shoulder dystocia etc and this paper does not deal with those issues. Indeed, perhaps the authors may also have this information, which would be very useful, and if , as they suggest, this work leads to an RCT throughout UK & Irish units I would suggest that the study will not only look at OVD outcomes but should include unnecessary CS in first stage etc. 2. The Consultant supervision in general appears to be low and would be lower than many Uk units (7.3% day 3.4% night, Table 3) but yet outcomes are still good. Are trainees much more intensely trained in Dublin- can their training be compared to rest if UK? Were there many locums- many Uk units rely heavily on locums at night- did LOCUM care have an impact on outcomes? 3. Private patients on delivery suites is a common occurrence in many parts of the world including Ireland but not UK- any precise record of how often the private practice consultants were consulted for advice re OVD when in the labour ward at night- could this make a significant difference? 4. Amazing that only 1-2 trainees can run a DS of 9,000 deliveries- but 15% deliveries were private day and night- suggests a greater consultant presence on labour ward compared to most UK units.

	Could this suggest this type of mixed public private care may be advantageous ? 5. Consultants present for all second stage CS and trials of OVD in theatre. What was the mean percentage of time after midnight when a consultant was present to supervise/help junior doctors with OVD? If considerable does this perhaps mean consultant should be paid to be called in/paid to live in with the day off afterwards? After all, junior doctor do not work day after night on call, although younger etc. I completely agree with the authors that this and further studies are greatly needed before a huge amount of money is spent on 24 hour consultant led cover, in obstetrics and other specialties.

REVIEWER	Jane Sandall King's College, London
REVIEW RETURNED	08-Sep-2014

GENERAL COMMENTS	This is an important topic and a well written paper. I have some small queries and comments. Page 8 line 3 is Apgar score < 7 or less than and equal to 7. Page 8 was a power calculation conducted? Is the lack of difference due to inadequate power? Page 8 Is it essential to mention another study in this paper, or does it confuse? I would like the authors to provide enough information on the context in order for readers to determine generalisability to their own setting. What % are private patients, how often are obstetricians on premises at night in a private capacity? Did guidelines exist? I would like to see the authors discuss in more depth why they think that mid grade operators performed less OVDs in the day and why shoulder dystocia occurred more in the day.

REVIEWER	Helena Lindgren Karolinska Institutet, Sweden
REVIEW RETURNED	18-Sep-2014

GENERAL COMMENTS	Thank you for the opportunity to review the manuscript entitled ”A prospective cohort study of the morbidity associated with operative vaginal deliveries performed by day and night – implications for safe care on the labor ward”. The manuscript is interesting and I have also contacted my colleague associate professor Cecilia Ekéus at the Karolinska Institutet for her expertise regarding this subject. The study provides information that is reassuring when it comes to organization of care but adds no new knowledge regarding instrumental deliveries. Comments: Title: The last part “implications for safe care on the labor ward” should be excluded since the study is not about the safety of care but about the potential differences in outcome comparing day and nighttime among OVD. Abstract: It is not clear in the abstract what the primary outcome is.

	Main outcome measures include many different variables and the authors need to clarify which is the primary outcome and secondary outcome. In the methods section it is explained that the study has statistical power to detect differences in maternal hemorrhage, 3d and 4th degree tears and admission to NICU. Introduction: informative and clear. Results: Illustrative and well written. There is no information regarding the indication for OVD which and I think this should be added. If the delivery is completed by OVD because of asphyxia in the fetus or because of exhaustion may play a role in the outcome of the newborn. Discussion: The important findings are discussed and the conclusion is adequate. When discussing the health of the newborn one new reference should be added to include some new findings on this subject: Vacuum assisted birth and risk for cerebral complications in term newborn infants: a population-based cohort study.Ekéus C, Högberg U, Norman M. BMC Pregnancy Childbirth. 2014 Jan 20;14:36. doi: 10.1186/1471-2393-14-36. PMID: 24444326 [PubMed - in process)

VERSION 1 – AUTHOR RESPONSE

Reviewer Name: Dr Alyson Hunter

1. As an obstetrician I find the thread of the argument clear enough but I think that the authors should more clearly stress that, although the risks of OVD in inexperienced hands are potentially high, so are the other risks out of hours of unnecessary c section during the first stage of labour and the quality of care to other labour ward emergencies such as postpartum haemorrhage, APH, twin delivery,shoulder dystocia etc and this paper does not deal with those issues. Indeed, perhaps the authors may also have this information, which would be very useful, and if, as they suggest, this work leads to an RCT throughout UK & Irish units I would suggest that the study will not only look at OVD outcomes but should include unnecessary CS in first stage etc.

Response: We agree entirely with the reviewer that OVD is only one of the important obstetric decisions/interventions that take place out of hours and that decisions around caesarean section and emergency care are equally important. However, the purpose of this study was to focus specifically on one skill set and to compare outcomes by day and by night. We will clarify this point further in the discussion but a research paper addressing all aspects of obstetric care would be too complex and would likely confuse the question we have attempted to address. We have emphasized the relevance of our approach to other centres, other disciplines and indeed other aspects of obstetric care.

2. The Consultant supervision in general appears to be low and would be lower than many Uk units (7.3% day 3.4% night, Table 3) but yet outcomes are still good. Are trainees much more intensely trained in Dublin- can their training be compared to rest if UK? Were there many locums- many Uk units rely heavily on locums at night- did LOCUM care have an impact on outcomes?

Response: We have a very limited reliance on locum obstetric services and an analysis based on this would not be possible. Our trainees do have an intense workload and this has been described in the methods section to allow comparisons with other settings. One could argue whether this is a good or bad thing in terms of high exposure and accelerated experience versus fatigue and compromised decision-making. Undoubtedly high volume exposure is of benefit in terms of acquiring and maintaining clinical skills. This point will be highlighted further.

3. Private patients on delivery suites is a common occurrence in many parts of the world including

Ireland but not UK- any precise record of how often the private practice consultants were consulted for advice re OVD when in the labour ward at night- could this make a significant difference?

Response: Unfortunately data on informal requests for support or advice are not recorded. We relied exclusively on the robust data recording who was present at the delivery, who was the operator and who was the supervising clinician, as these data were recorded systematically by day and at night.

4. Amazing that only 1-2 trainees can run a DS of 9,000 deliveries- but 15% deliveries were private day and night- suggests a greater consultant presence on labour ward compared to most UK units. Could this suggest this type of mixed public private care may be advantageous ?

Response: In keeping with the two previous points it is difficult to quantify precisely what additional contribution the presence of consultant attendance for private patients accrued for the overall provision of care. We prefer to avoid speculating beyond the limits of the data but have highlighted the point that a consultant is often present in the hospital at night and will provide support if required, irrespective of whether or not they are the dedicated on-call consultant.

5. Consultants present for all second stage CS and trials of OVD in theatre. What was the mean percentage of time after midnight when a consultant was present to supervise/help junior doctors with OVD? If considerable does this perhaps mean consultant should be paid to be called in/paid to live in with the day off afterwards? After all, junior doctor do not work day after night on call, although younger etc. I completely agree with the authors that this and further studies are greatly needed before a huge amount of money is spent on 24 hour consultant led cover, in obstetrics and other specialties.

Response: The attendance of consultants at night is recorded in the figures for grade of operator/supervising operator. We were not in a position to do a formal economic analysis but as suggested by the reviewer this is a very important consideration and should be addressed in relevant research addressing service reconfiguration.

Reviewer Name: Jane Sandall

1. Page 8 line 3 is Apgar score < 7 or less than and equal to 7.

Response: <7 in keeping with the criteria used for cerebral palsy risk assessment. However, it the I minute Apgar score has been corrected to ≤3.

2. Page 8 was a power calculation conducted? Is the lack of difference due to inadequate power?

Response: The study was adequately powered for the outcomes PPH, anal sphincter tear and NICU admission (important more commonly occurring adverse outcomes of OVD), which has been stated. We have acknowledged that the study is under-powered for rare outcomes such as maternal/perinatal mortality, hypoxic-ischaemic encephalopathy etc.

3. Page 8 Is it essential to mention another study in this paper, or does it confuse?

Response: We agree that it is potentially confusing and have removed this.

4. I would like the authors to provide enough information on the context in order for readers to determine generalisability to their own setting. What % are private patients, how often are obstetricians on premises at night in a private capacity? Did guidelines exist? I would like to see the

authors discuss in more depth why they think that mid grade operators performed less OVDs in the day and why shoulder dystocia occurred more in the day.

Response: Further detail has been provided. The proportion of private patients is reported in table 1 and is in keeping with the overall distribution of public/private patients. As with the first reviewer we do not have reliable data on ad hoc support by consultants attending private patients but have recorded all operators and supervising operators and their grades. We have mentioned the use of guidelines based on RCOG best practice (referenced). We have added further detail on the unexpected finding re shoulder dystocia.

Reviewer Name: Helena Lindgren

1. Title: The last part “implications for safe care on the labor ward” should be excluded since the study is not about the safety of care but about the potential differences in outcome comparing day and nighttime among OVD.

Response: We are happy to amend accordingly although we do think the “implications” is relevant.

2. Abstract: It is not clear in the abstract what the primary outcome is. Main outcome measures include many different variables and the authors need to clarify which is the primary outcome and secondary outcome. In the methods section it is explained that the study has statistical power to detect differences in maternal hemorrhage, 3d and 4th degree tears and admission to NICU.

Response: As this was a cohort study rather than an RCT we did not have a single primary outcome. The “main” outcomes of interest were postpartum haemorrhage, anal sphincter tear and neonatal unit admission. The study was powered to address these outcomes. Many other less common adverse outcomes have also been addressed with the acknowledgement that the study was under-powered to exclude potential differences in rare outcomes. This has been clarified in the abstract.

3. Introduction: informative and clear. Results: Illustrative and well written. There is no information regarding the indication for OVD which and I think this should be added. If the delivery is completed by OVD because of asphyxia in the fetus or because of exhaustion may play a role in the outcome of the newborn.

Response: Table 2 includes the main indications for OVD – prolonged second stage of labour (>2 hours), fetal malposition, pathological CTG and low pH on FBS. We have presented both maternal and fetal criteria for OVD as there is often an overlap in the indications for obstetric intervention in the second stage of labour.

4. Discussion: The important findings are discussed and the conclusion is adequate. When discussing the health of the newborn one new reference should be added to include some new findings on this subject: Vacuum assisted birth and risk for cerebral complications in term newborn infants: a population-based cohort study.Ekéus C, Högberg U, Norman M. BMC Pregnancy Childbirth. 2014 Jan 20;14:36. doi: 10.1186/1471-2393-14-36. PMID: 24444326 [PubMed - in process)

Response: We are happy to include this reference as suggested.