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Third Stage of Labour Management Approaches in Midwife-led Units

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Third Stage of Labour Management Approaches in Midwife-led Units (Part 2)

Appendices

School of Human and Health Sciences
University of Huddersfield
January 2020
Resubmitted 22nd September 2020-major amendments
### Appendix 1: Critical Appraisal of Cochrane Systematic Reviews using CASP (2018a) tool - Critical appraisal table

<table>
<thead>
<tr>
<th>CASP (2018a) Checklist Systematic Review</th>
<th>Did the study ask a clearly focused question?</th>
<th>Did the authors look for the right type of papers?</th>
<th>Do you think all the important, relevant studies were included?</th>
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<th>Were all important outcomes considered?</th>
<th>Are the benefits worth the harms and costs?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prendiville, Elbourne, McDonald (2000) This version of the Cochrane review informed RCOG (2009) prevention of PPH recommendations.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes See thesis regarding RCT and cause and effect analysis See thesis regarding cohort studies and cause and effect analysis, examining associations or relationships between variables. All RCT investigating the package of AM versus EM. Types of participants: All women who expected a vaginal delivery. *Bagley: Ireland *Rodgers: UK *Prendiville: UK Bristol</td>
<td>Yes</td>
<td>No</td>
<td>EM only suitable for women at low risk of PPH (who have had a normal physiological birth)</td>
<td>For women at low risk of PPH</td>
<td>High risk</td>
<td>Mixed risk- Prendiville and Khan should not have been given EM- in a RCT comparing AM versus EM. Khan RCT included women with multiple pregnancies and breech presentations. The oxytocin in AM, epidural, oxytocin for IOL. Women in Bagley: Ireland Rodgers identified as low risk but had women in who were high risk.</td>
<td>All women</td>
<td>High and low risk</td>
<td>Regarding blood loss and PPH and need for further uterotonic drugs treatment of PPH Compared to EM AM was associated with a reduction in PPH &gt; 500mls 4 studies Khan, Begley, Prendiville, Rogers 6284 women RR 95% CI 0.38 [0.32, 0.46] Severe PPH clinically &gt; 1000mls 4 studies Khan, Begley, Prendiville, Rogers 6284 RR 95% CI 0.33 [0.21, 0.51] Mean blood loss 2 studies Begley, Prendiville, Rogers 2941 Mean Difference (95% CI) -79.33 [-94.29, -64.37] Maternal Hb &lt; 9 g/dl 24 - 48 hours post partum 4 studies Thilaganath, Begley Prendiville, Rogers 4255 RR 95% CI 0.40 [0.29, 0.55] Blood transfusion 5 studies Khan, Thilaganath, Begley, Prendiville, Rogers 6477 RR 95% CI 0.34 [0.22, 0.53] Therapeutic oxytocics 5 studies Khan, Thilaganath, Begley, Prendiville, Rogers</td>
</tr>
</tbody>
</table>
Thilaganathan UK Brighton

Khan (1997) Mix Iran Management verse AM not AM verse EM

Prendiville study secondary analysis not enough info. Given regarding this group of women identified by then as at low risk?

AM and EM have variable definitions in different settings.

Begley RCT used ergometrine, Rogers and Prendiville used syntometrine.

AM was routine practice in all RCT except Rodgers RCT.

Rogers RCT both AM and EM practised, but more confident in AM. Also Harding questionnaire midwives more confident in EM.

6477 Risk Ratio (M-H, Fixed, 95% CI) 0.20 [0.17, 0.25] maternal blood loss (weighted mean difference -79.33 millilitres, 95% confidence interval -94.29 to -64.37); PPH ≥ 500 RR 0.38, 95% CI0.32 to 0.46; prolonged third stage of labour 9.77 minutes, 95% CI10.00 to -9.53).

AM was associated with an increased risk of maternal nausea RR 1.83, 95% CI1.51 to 2.23 vomiting and raised blood pressure.

No advantages or disadvantages were apparent for the baby. Meta-analyses of data from these RCTs provides convincing evidence that blood loss and the risk of PPH will be reduced in women offered AM. This applies to all women, and also specifically to women considered to be at low risk of 3rd stage complication. AM should be routine for women expecting a vaginal delivery in a maternity hospital. There is no evidence to suggest that this should not also include home births and MLU in a developed country.

[0.49, 0.74] -Therapeutic oxytocics. 4- Begley, Prendiville, Rogers Thilaganath 3809 women RR95% CI 0.16 [0.12, 0.21]

-Sub-group of women who were at low risk of PPH (ie excluding those women at higher risk in the Prendiville RCT and RCT by Khan).

The conclusions did not differ substantially from those derived from all women, except that the reduction in manual removal of the placenta was statistically significant at the 5% level.

-There was, however, considerable heterogeneity between the trials for this outcome.
<table>
<thead>
<tr>
<th>CASP (2018a) Checklist</th>
<th>Systematic Review</th>
<th>Did the study ask a clearly focused question?</th>
<th>Did the authors look for the right type of papers?</th>
<th>Do you think all the important, relevant studies were included?</th>
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<th>Were all important outcomes considered?</th>
<th>Are the benefits worth the harms and costs?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begley, Gyte, Murphy, Devane, McDonald, McGuire, (2010).</td>
<td>To compare the effectiveness of AM versus EM on severe primary PPH, blood loss and other maternal and infant outcomes. To compare variations in the packages of AM and EM on severe primary PPH, haemorrhage, blood loss and other maternal and infant outcomes.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>7 RCTs (829 women) compared AM versus EM (Begley 1990; Prendiville 1988; Rogers 1998; Thilaganathan 1993), 1x RCT (1657 women) compared AM versus M.M.(Khan 1997). In all trials, participants were healthy pregnant women expected to give birth vaginally.</td>
<td>Summary, AM reduced blood loss at the time of birth (and concomitant treatments required) but increased hypertension, pain and discomfort and increased return to hospital due to postnatal bleeding following. Also if decreased the baby’s birthweight. No statistically significant reduction or increase in severe PPH for women at low risk to bleeding. Number of women was insufficient to assess this outcome with confidence. AM resulted in a lower birthweight and an increase in the incidence of postpartum diastolic BP greater than 90 mmHg, after pains, need for postpartum analgesia in the labour ward, and having to return to hospital as an in or outpatient because of bleeding. All women AM in hospitals in high-income countries led to a reduction in: Severe primary PPH greater than 1000mls Begley Prendiville Rogers -Maternal Hb less than 9 g/dl at 24 to 48 hours Prendiville, Thilaganath -primary blood loss &gt; 500 ml Prendiville, Rogers.</td>
<td>Indices of maternal blood loss were also Signify, improved:Mean Hb was higher by 0.5 g/dl in the AM. This result may not be clinically significant, as routine blood donation reduces hb levels by prox. 0.6 g/dl (Burnley 2006) without ill effects and postnatal women undergo a diuresis postnatally that reverses the haemodilu. of pregnancy, thus increasing their hb levels within a few days after birth (Hytten 2001; Taylor 1981). There was no difference seen in the numbers of women needing uterotonic tmt. between 24 hours and 6 weeks postnatal! This would appear to show that, treating excess bleeding when it occurs is as effective as giving uterotonic prophylaxis, while avoiding the potential adverse effects of the interventions used in active management. No difference was found in maternal Hb, less than 9 g/dl post discharge and up to six weeks, which may reflect either the beneficial effects of blood transfusions given to those women who were identified as having low hb.</td>
<td>No</td>
<td>Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches. Different birth settings- All RCT in hospital obs-led units Women at low risk of PPH.</td>
<td>Limited generalisability to women at low risk birthing in MLU cared for by midwives experienced in both AM and EM.</td>
</tr>
</tbody>
</table>
AM versus EM

Thilaganath -mean maternal blood loss (average mean difference Begley, Rogers -maternal blood transfusion Begley, Prendiville, Rogers Thilaganath -iron therapy in the puerperium Rogers -therapeutic uterotonics postpartum Begley, Prendiville, Rogers, Thilaganath -secondary blood loss > 500 ml (clinically estimated or measured after 24 hours and before six weeks) (> 500 ml) Begley mean birthweight (average MD in g -76.90 -postnatal maternal Hb (outcome not pre-specified) (average MD 0.52. -postnatal diastolic blood pressure > 90 mmHg up to discharge from labour ward -postnatal oral or rectal analgesia to discharge from labour ward -postnatal opiate analgesia to discharge from labour ward -return to hospital as an in or outpatient because of bleeding and after pains There was no statistically significant difference identified in: • mean length of third stage in minutes (MD -0.30, 95% CI -1.87 to 1.27, one study, 1429 women, -manual removal of placenta RR 1.78, 95% CI 0.57 to 5.56, four studies, 4829 women, -uterotonic treatment > 24 hours and < 6 weeks (RR 3.08, 95% CI 0.32 to 29.55, one study, 1429 women,
### CASP (2018a) Checklist

**Systematic Review**

<table>
<thead>
<tr>
<th>Did the study ask a clearly focused question?</th>
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</thead>
<tbody>
<tr>
<td><strong>Begley, Gyte, Devane, McGuire, &amp; Weeks, (2011a).</strong> This version of the Cochrane review informed the RCOG (2016) and WHO (2012; 2018) third stage of labour guidelines</td>
<td>To compare the effects of AM versus EM of the third stage of labour on severe primary PPH and other maternal and infant outcomes.</td>
<td>Yes</td>
<td>We searched the Cochrane Pregnancy and Childbirth Group Trials Register (15 February 2011).</td>
<td>Same as Begley et al (2010)- see above</td>
<td>Results same as Begley 2010 Cochrane review-see above</td>
<td>No</td>
<td>Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches.</td>
<td>Limited generalisability to women at low risk birthing in MLU cared for by midwives experienced in all AM and EM.</td>
<td></td>
</tr>
<tr>
<td>CASP (2018a) Checklist Systematic Review</td>
<td>Did the study ask a clearly focused question?</td>
<td>Did the authors look for the right type of papers?</td>
<td>Do you think all the important, relevant studies were included?</td>
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<td>-----------------------------------------------</td>
</tr>
</tbody>
</table>
| Begley, Gye, Devane, McGuire, & Weeks (2015) | **Objective**
To compare the effectiveness of active versus expectant management of the third stage of labour. | **Yes**
See thesis regarding RCT and cohort studies
Randomised and quasi-randomised controlled trials comparing active versus expectant management of the third stage of labour.
- Included 7 studies involving 8247 women (Begley 1990; Jangsten 2011; Jerbi 2007; Khan 1997; Prendiville 1988; Rogers, 1998; Thilaganathan 1993) Studies conducted in the UK (Prendiville 1988; Rogers 1998, Thilaganathan 1993), Ireland (Begley 1990), Sweden (Jangsten 2011), Tunisia (Jerbi 2007) Abu Dhabi (Khan 1997). | **Same as Begley et al. (2010)**- see above | **Same as Begley et al. (2010)**- see above | **Results same as Begley 2010 Cochrane review-see above** | **Results same as Begley 2010 Cochrane review-see above** | **No**
Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches.
Different birth settings: All RCT in hospital obst-led units
Women at low risk of PPH. | **Confidence and experience of midwife in both approaches.**
Different birth settings: All RCT in hospital obst-led units
Women at low risk of PPH. | Limited generalisability to women at low risk birthing in MLU cared for by midwives experienced in both AM and EM. | **Confidence and experience of midwife in both approaches.**
Different birth settings: All RCT in hospital obst-led units
Women at low risk of PPH. | Limited generalisability to women at low risk birthing in MLU cared for by midwives experienced in both AM and EM. |
All studies took place in hospital settings. 4 studies (4829 women) compared active versus expectant management (Begley 1990; Prendiville 1988; Rogers 1998; Thilaganathan 1993) - 3 studies (3418 women) compared active versus mixed management (Jangsten 2011; Jerbi 2007; Khan 1997). In all trials, participants were healthy pregnant women expected to give birth vaginally. 3 studies included only women classified as being at low risk of bleeding or its effects (Begley 1990; Rogers 1998; Thilaganathan 1993), 4 studies (Jangsten 2011; Jerbi 2007; Khan 1997; Prendiville 1988) included women irrespective of their risk of bleeding.
<table>
<thead>
<tr>
<th>CASP (2018a) Checklist Systematic Review</th>
<th>Did the study ask a clearly focused question?</th>
<th>Did the authors look for the right type of papers?</th>
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<tbody>
<tr>
<td>Begley, Gyte, Devane, McGuire, Weeks, Biesty, (2019).</td>
<td><strong>Objective</strong> To compare the effectiveness of AM versus EM of the third stage of labour.</td>
<td>Yes See thesis regarding RCT and cohort studies</td>
<td>Randomised and quasi-randomised controlled trials comparing AM versus EM. Cluster randomised trials were eligible for inclusion, but none were identified - 8 studies, involving analysis of data from 8892 women. The studies were all undertaken in hospitals, 7 in higher income countries and 1 in a lower-income country. 4 compared AM versus EM. Begley 1990; Prendiville 1988; Rogers -Women at low risk.</td>
<td>Same as Begley et al. (2010)- see above</td>
<td>Results same as Begley 2010 Cochrane review-see above</td>
<td>Results same as Begley 2010 Cochrane review-see above</td>
<td>Results same as Begley 2010 Cochrane review-see above</td>
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<td>Results same as Begley 2010 Cochrane review-see above</td>
</tr>
</tbody>
</table>
Risk of PPH

3 RCTs
Begley (1990)
Rogers et al. (1998)
Thilaganath et al. (1993)

- AM verses MM
4 Jangsten 2011; Jerbi 2007; Khan 1997; (Yildirim 2016)

- 2 review authors independently assessed the studies for inclusion,
assessed risk of bias, carried out data extraction and assessed the quality of the evidence using the GRADE approach.

completeness of data collection.
There was an absence of high-quality evidence according to GRADE assessments for our primary outcomes.

Women at low risk
3 RCTs
Begley (1990)
Rogers et al. (1998)
Thilaganath et al. (1993)
Appendix 2 - Critical (2018b) appraisal table Studies involving women included in Cochrane Systematic reviews and/or NICE (2017) guideline comparing active management versus expectant management

CASP RCT (2018b) Checklist

<table>
<thead>
<tr>
<th>Study</th>
<th>Did the study ask a clearly focused question?</th>
<th>Was the assignment of patients to treat randomised?</th>
<th>Were all of the patients who entered the trial properly accounted for at its conclusion?</th>
<th>Were patients, health workers and study personnel ‘bind’ to treatment?</th>
<th>Were groups similar at the start of the trial?</th>
<th>Aside from the experimental interventions were the groups treated equally?</th>
<th>How large was the treatment effect?</th>
<th>How precise was the est. of the TMT effect?</th>
<th>Can the results be applied to the local population or in your context?</th>
<th>Were all the clinically important outcomes considered?</th>
<th>Are the benefits worth the harms and cost?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begley (1990)</td>
<td>Yes</td>
<td>Yes</td>
<td>AM-705 EM-724</td>
<td>Low risk of PPH however some women had risk factors for PPH- syntocihon infusion in labour-AM 194 (27%) EM 197 (27%) (did not have normal physiological birth), increased risk of PPH EM not appropriate episiotomy/tear sutured does not differentiate AM-144 20% EM144 20% Effect of episiotomy on woman’s hormones.</td>
<td>Yes</td>
<td>No</td>
<td>Not possible OBSERVER BIAS, practitioner bias, midwives less experienced in expectant management. PPH rate fell EM I during the study from 21% in the pilot study and 12% over the first 4 months, to 7% in the last 6 months, as midwives developed their skill.</td>
<td>Yes</td>
<td>AM verse EM and incidence of PPH. 3 women in EM group needed blood transfusion-1 had received ergo before placenta delivered (converted)) 1 in AM group.</td>
<td>Yes</td>
<td>-Increased incidence of PPH in EM group but no increase in blood transfusions. None of 60 women in -None in EM who had PPH had any complications postnatally. -4 of 14 women in AM did. 3 within first 5 days and 1 within first 6 weeks.</td>
</tr>
</tbody>
</table>
A policy of EM would result in higher PPH at time of delivery but women do not appear to suffer any further consequences. A PPH of 501-750mls does not cause problems for normal healthy women with Hb >10.6.

-Should definition of PPH be reviewed?

CI 0.38-0.62

After pains

AMSD 8

EMSD1

P<0.02

Stat/sig.

CI 0.002-0.018

no longer used in AM.

Important

Effect of mixed management-more in EM received mixed management.

- increases risk of PPH.

EM-14% received ergo. (reason excessive blood loss or relaxed uterus). However 66% received CCT.

My conclusion

AM did result in lower blood loss, incidence of PPH>500 mL and a lower drop in Hb postnatally. Did not have any adverse effect from it, however, AM did results in higher BP and after pains.

I agree with conclusion of study- see above.

Issues with reliability, validity of study influencing generalisability of study.

<table>
<thead>
<tr>
<th>de Groot, van, Roosmale n., van Dongen, Borm, (1996)</th>
<th>Did the study ask a clearly focused question?</th>
<th>Was the assignment of patients (Pt.s) to treat randomised?</th>
<th>Were all of the patients who entered the trial properly accounted for at its conclusion?</th>
<th>Were patients, health workers and study personnel ‘bind’ to treatment?</th>
<th>Were groups similar at the start of the trial?</th>
<th>Aside from the experimental interventions were the groups treated equally?</th>
<th>How large was the treatment effect?</th>
<th>How precise was the est. of the TMT. effect?</th>
<th>Can the results be applied to the local population or in your context?</th>
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<th>Are the benefits worth the harms and cost?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study is a double blind multicentre trial of oral ergometrine versus placebo. Women at low risk of PPH randomised to 0.4mg ergometrine tablets, placebo</td>
<td>YES</td>
<td>YES</td>
<td>No- Not possible OBSERVER BIAS, practitioner bias, midwives less experienced in expectant management.</td>
<td>YES</td>
<td>YES</td>
<td>Not assessed as Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendiville et al (2000) to investigate AM verse EM.</td>
<td>Not assessed as Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendiville et al (2000) to investigate AM verse EM.</td>
<td>NO Did not compare AM with EM. This study compared IM oxytocin or a placebo. No other component of AM or EM was reported. Oral ergometrine no longer used as</td>
<td>Not assessed as Not generalisable to this women at low risk birthing at MLU. compare AM with EM. This study compared IM oxytocin or a placebo. No other component of AM or EM was reported. Oral ergometrine no longer used as</td>
<td>Not assessed as Not generalisable to this women at low risk birthing at MLU. compare AM with EM. This study compared IM oxytocin or a placebo. No other component of AM or EM was reported. Oral ergometrine no longer used as</td>
<td>Not generalisable to this study Did not compare AM with EM. This study compared IM oxytocin or a placebo. No other component of AM or EM was reported. Should not have been used by the National Collaborating Centre for Women’s and Children’s Health (2014) to inform NICE’s (2017) 3rd stage of labour practice guidelines comparing AM verse EM.</td>
</tr>
</tbody>
</table>

CASP (2018b) RCT Checklist

Study

- Included in NICE (2017) guidelines
<table>
<thead>
<tr>
<th>Study</th>
<th>Did the study ask a clearly focused question?</th>
<th>Was the assignment of patients (Pt.s) to treat randomised?</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Khan et al. (1997)</td>
<td>Yes</td>
<td>Yes</td>
<td>No-consisted of women at high and low risk of PPH. Women who were breech, had an epidural</td>
<td>No-consisted of women at high and low risk of PPH. Women who were breech, had an epidural</td>
<td>Yes</td>
<td>No-consisted of women at high and low risk of PPH. Women who were breech, had an epidural</td>
<td>Not assessed as did not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendiville et al (2000) to investigate AM versus EM.</td>
<td>Not assessed as did not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendiville et al (2000) to investigate AM versus EM.</td>
<td>No did not compare AM with EM. This study compared AM with mixed managemen t (AM versus minimal intervention)</td>
<td>Not assessed as did not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendiville et al (2000) to investigate AM versus EM.</td>
<td></td>
</tr>
<tr>
<td>Included in the Prendiville et al. (1988) Included in Prendiville et al. (2000) Cochrane</td>
<td>Yes</td>
<td>Yes</td>
<td>No-consisted of women at high and low risk of PPH. Women who were breech, had an epidural</td>
<td>No-consisted of women at high and low risk of PPH. Women who were breech, had an epidural</td>
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<td></td>
</tr>
</tbody>
</table>

National Collaborating Centre for Women’s and Children’s Health (2014) graded the quality of evidence very low or low quality (de Groot et al., 1996; Prendiville et al. 1988; Rodgers et al. 1998). This was as a result of the risk of bias, inconsistencies and indirectness in the studies.

- ≥ 500 ml-Low quality
- 1000 ml-Very low quality
- Need for further intervention: blood transfusion-Very low quality.
- Need for further intervention: therapeutic uterotonics-Very low quality.
<table>
<thead>
<tr>
<th>Systematic Reviews examining AM verse EM.</th>
<th>not have been included in RCT.</th>
</tr>
</thead>
</table>

**CASP (2018b) RCT Checklist Study**

**Did the study ask a clearly focused question?**
- Yes
- No

**Was the assignment of patients (PLs) to treat randomised?**
- Yes
- No

**Were all of the patients who entered the trial properly accounted for at its conclusion?**
- Yes
- No

**Were patients, health workers and study personnel ‘bind’ to treatment?**
- Yes
- No

**Were groups similar at the start of the trial?**
- Yes
- No

**Aside from the experimental interventions were the groups treated equally?**
- Yes
- No

**How large was the treatment effect?**
- Yes
- No

**How precise was the est. of the TMT. effect?**
- Yes
- No

**Can the results be applied to the local population or in your context?**
- Yes
- No

**Were all the clinically important outcomes considered?**
- Yes
- No

**Are the benefits worth the harms and cost?**
- Yes
- No

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<table>
<thead>
<tr>
<th>Study</th>
<th>Included in NICE (2017) guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Prendivill, Harding, Elbourne, Stirrat (1988)- Bristol third stage trial</td>
</tr>
<tr>
<td>No</td>
<td>Secondary analysis</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Yes</th>
<th>Main RCT EM 849 AM 846</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Not possible OBSERVER BIAS, practitioner bias, midwives less experienced than in expectant management. AM normal at hospital. Few experienced in EM initially, but did receive training 6 weeks before RCT.</td>
</tr>
</tbody>
</table>


| Low risk 1st and 2nd stages EM 335/541 |
|---|---|
| Low risk 1st and 2nd stage AM 340/538 |


| Secondary analysis data grouped according to whether the 1st and 2nd stages were classified as low risk in relation to the 3rd stage. Defined as low risk if: spontaneous onset of labour, Augmentation and epidural were not needed, labour lasted less than 12 hours. Delivery spontaneous. ITT. - 4.4% incident primary PPH in AM group compared with 16.1% incident Primary PPH in EM group. |
|---|---|
| Treatment | Power calculated, done for main study and primary outcome primary analysis Stat sig results >500ml: EM 152 AM 50 Odds ratio 3.13 CI 2.34-4.20 >1000ml: EM 26 AM 7 Odds ratio 3.13 CI 1.62 to 6.42 |
| Blood transfusion | EM 48 AM 18 Odds ratio 2.56 CI |


| Study used as evidence for NICE (2017) used results of all the study not just women the secondary analysis. Fully study included women at increased risk of PPH. Secondary analysis- including only women defined as low risk of PPH. Contained women with risk factors for PPH. History of PPH, Hb 9, episiotomy. |
|---|---|
| No | Confidence and experience of practitioners on third stage management approach outcomes not assessed. |


| Main conclusion from study: A policy of AM in hospital is justified. In terms of reducing blood loss greater than 500mls, although not necessary dangerous in healthy women. -However, AM compared with EM reduces blood loss of greater than 1000mls and the need for blood transfusions. However, needs to be tested out in environment in which AM is not the normal. -National Collaborating Centre for Women's and Children's Health (2014) graded the quality of evidence for the whole study- ≥ 500 ml-Low Blood transfusion- Moderate Therapeutic uterotonic- Moderate vomiting- Moderate Hypertension- Moderate Diastolic blood pressure > 100 |
|---|---|
Missing data for some comes 19% of Hb results missing in AM 18% in EM. 25% of antenatal and / or postnatal Hb results (used to calculate drop in mean Hb) missing in AM and 26% EM

States no women were excluded after randomisation but 182 are described as having not entered in the trial due to cord being cut early for fetal reasons. The envelop must have been opened before any neonatal need for attention became apparent

midwives responding to a questionnaire regarding this study, 30 (61%) conducted EM. Among the remaining 19, only one had practised EM as defined in the report (Harding 1989)

received-. AM 99% compared with nearly half women who).

Results of secondary analysis- AM preferable regardless of these first and second stage criteria. -However, AM increased incidents of vomiting, hypertension. -EM advantageous in terms of reducing vomiting and reducing neonatal packed cell volumes of less than 0.5.

2.56
Therap.
Oxytocic
EM 252
AM 54
Odds ratio
4.83
CI
3.77 to 6.18
Vomiting
EM 55
AM 102
Odds ratio
0.52
CI
0.37 to 0.72

Results for 2nd analysis
PPH EM
16.1%
AM 4.4%
Odds ratio
3.6,
95% CI
2.2 to 5.9)

Should not have been in study or received EM. -RCT conducted in hospital obstetric units. Effect on woman’s hormones, midwives more experienced in AM. -Reliability-components of EM different (noncompliance), women had risk factors for PPH should not have received EM, questioning validity of the study. -Women also birth in a hospital unit. - Many variations in AM and EM, women received mixed manag. more women in EM received this.

mmHg)- Moderate Maternal Hb ≤ 9 at 24-48 hours postpartum-
Low-Low and very low was as a result of the risk of bias, inconsistencies and indirectness in the study.

My conclusion- Not enough information provided to critically appraise secondary analysis thoroughly. -Medicalised approach to childbirth including 3rd stage, setting obs. Unit, study dated, practitioner’s not as experienced and confidence with EM; non-compliance by practitioners in the EM group.

-Questioning validity of study and reliability of results, questioning generalisability of findings to women at low risk of PPH with birth in MLU.
<table>
<thead>
<tr>
<th>Study</th>
<th>Did the study ask a clearly focused question?</th>
<th>Was the assignment of patients (Pt.s) to treat randomised?</th>
<th>Were all of the patients who entered the trial properly accounted for at its conclusion?</th>
<th>Were patients, health workers and study personnel ‘bind’ to treatment?</th>
<th>Were groups similar at the start of the trial?</th>
<th>Aside from the experimental interventions were the groups treated equally?</th>
<th>How large was the treatment effect?</th>
<th>How precise was the est. of the TMT. effect?</th>
<th>Can the results be applied to the local population or in your context?</th>
<th>Were all the clinically important outcomes considered?</th>
<th>Are the benefits worth the harms and cost?</th>
</tr>
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<tbody>
<tr>
<td>Rogers, Wood, McCandlish, Ayers, Truesdale, Elbourne (1998)</td>
<td>Yes</td>
<td>Yes</td>
<td>NO</td>
<td>Yes</td>
<td>YES (less than 0.5% attrition, equal losses in both groups). At 6 week follow up less than 5% attrition.</td>
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<tr>
<td>Begley et al. (2010, 2011, 2015, 2019)</td>
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<td>EM 764 AM 748</td>
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</table>
management styles. Midwives less confidence with EM than AM. PPH slightly higher in women attended by midwives initially less confident in EM. Treatment received: PPH was lowest in fully AM 8% and 11% in fully – EM. Highest rate 21% in MMG (more women had MM in EM group).

RR 0.51 (0.36–0.72) p 0.0002
Vomting RR 0.35 (0.21–0.61) p 0.0002
Raised BP Not stat signifi.

CASP (2018b)

RCT Checklist

Study

Did the study ask a clearly focused question?
Was the assignment of patients (Pt.s) to treat randomised?
Were all of the patients who entered the trial properly accounted for at its conclusion?
Were patients, health workers and study personnel ‘bind’ to treatment?
Were groups similar at the start of the trial?
Aside from the experimental interventions were the groups treated equally?
How large was the treatment effect?
How precise was the est. of the TMT. effect?
Can the results be applied to the local population or in your context?
Were all the clinically important outcomes considered?
Are the benefits worth the harms and cost?

Thilagana than B; Cutner Latimer, Beard (1993)

Yes To compare AM with EM in women at low risk of PPH. To determine whether EM results in increased blood loss in women at low risk of PPH
Yes- 193 women completed the study. AM-103 EM-90
However, not described when randomisation occurred.

No Not clear how many women initially randomised. States total of 193 women. Spont. Vaginal birth completed the study and all had results available for complete allocated analysis.

No Practitioner bias- does not say if midwives less experienced in expectant management.

Yes Yes

193 women completed the study. AM-103 EM-90
Main results- EBL no significant difference. Changes in Hb. mean Hb level dropped in the women with presumed PPH (EBL >500mls was 2.0g/dl) - mean Hb level dropped in the women with blood loss of < 500mls

No sign in est. Blood loss, haem drop p<0.5

No power calculation had been performed and the stated hypothesis was not a null one.
Bias due to unclear randomisation process.
It also had selected reporting bias as PPH

Overall impression- small scale study, reduced reliability and validity as Limited details regarding random Process.
Does not say if midwives equally experienced in both approaches
Also RCT conducted in hospital setting reducing generalisibility to women birthing in MLU.
Women included low proportion of women

National Collaborating Centre for Women’s and Children’s Health (2014) graded the quality of evidence very low or low quality. This was as a result of the risk of bias, inconsistencies and indirectness in the studies
Blood transfusion- Moderate
Therapeutic uterotonics- Moderate
Fall in haemoglobin (reported postpartum)- Low
Proportion of women
This might mean a larger number of women were included but some of the results were missing and as a result these women were excluded from the study. This might cause significant bias. Very unlikely all women received allocated tmt. yet this information not given. Number of women were withdrawn after randomisation not given.

was 0.6. - Overall significant correction between EBL and Hb drop. - AM and EM compared no significant difference in intrapartum haemorrhage, postpartum Hb or drop in Hb. -5 women in EM and 1 in AM had postpartum Hb of < 9. Difference not significant. -3rd stage longer in EM group. - Low complication rate in study. - Retained placenta EM 0 AM 1 -blood transfusion EM 0 AM 1 -Further oxytocics -EM 7 AM 1 rates were not presented and mean blood loss figures were rounded this was also heighted by Begley (2010).

with haemoglobin < 9 g/dl postpartum- very low.
Cochrane 2019- study at high risk of bias for complete data not clear how many women were randomised, and an unknown number of women were withdrawn following randomisation

My conclusion- Small RCT. Women in study at low risk of PPH.
## Appendix 3: Literature Review One Database search results Stage 2- Studies that appeared to meet the study selection criteria those that were ambiguous and screening them in full against the inclusion criteria.

<table>
<thead>
<tr>
<th>Study</th>
<th>Database</th>
<th>Included</th>
<th>Reason excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Amelink-Verburg, M P; Verloove-Vanhorick, S P; Hakkenberg, R M A; Veldhuijzen, I M E; Bennebroek Gravenhorst, J; Buitendijk, S E (2008). Evaluation of 280,000 cases in Dutch midwifery practices: a descriptive study. <em>BJOG : an international journal of obstetrics and gynaecology</em>; vol. 115 (no. 5); 570-578.</td>
<td>Medline</td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and associated blood loss.</em>&lt;br&gt;<em>Did not examine MLU</em></td>
<td></td>
</tr>
<tr>
<td>3. Benjamin Y; Walsh D; Taub N (2001). A comparison of partnership caseload midwifery care with conventional team midwifery care: labour and birth outcomes. <em>Midwifery</em>; vol. 17 (no. 3); p. 234-240.</td>
<td>CINAHL&lt;br&gt;Medline</td>
<td></td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</em>&lt;br&gt;<em>Did not examine blood loss and third stage of labour.</em>&lt;br&gt;Increased rate of EM in MLU. Did not examine blood loss</td>
</tr>
<tr>
<td>4. Bernitz, Stine; Aas, Eline; Øian, Pål. (2012). Economic evaluation of birth care in low-risk women. A comparison between a midwife-led birth unit and a standard obstetric unit within the same hospital in Norway. A randomised controlled trial. <em>Midwifery</em>; vol. 28 (no. 5); p. 591-599.</td>
<td>BNI</td>
<td></td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</em></td>
</tr>
<tr>
<td>5. Bais JM; Eskes M; Pel M; Bonsel GJ; Bleker OP. (2004). Postpartum haemorrhage in nulliparous women: incidence and risk factors in low and high risk women. A Dutch population based cohort study on standard (&gt; or = 500 ml) and severe (&gt; or = 1000 ml) postpartum haemorrhage. <em>European journal of obstetrics, gynecology, and reproductive biology</em>; vol. 115 (no. 2); p. 166-172.</td>
<td>PubMed</td>
<td></td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</em>&lt;br&gt;<em>Place of birth not identified.</em></td>
</tr>
<tr>
<td>6. Bolten N.; de Jonge A.; Klomp T.; Geerts C.C.; Zwagerman E.; Zwagerman P.; Zwart J.J. (2016). Effect of planned place of birth on obstetric interventions and maternal outcomes among low-risk women: A cohort study in the Netherlands. <em>BMC Pregnancy and Childbirth</em>; vol. 16 (no. 1)</td>
<td>EMBASE&lt;br&gt;PubMed&lt;br&gt;CINAHL&lt;br&gt;Medline</td>
<td></td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</em>&lt;br&gt;<em>Examined birth outcomes including PPH for women planning to have home birth with hospital birth. Does not say they were cared for in a birth centre/midwifery led unit.</em></td>
</tr>
</tbody>
</table>


11. David, K V; Pricilla, R A; Venkatesan, S; Rahman, S P M F; G S, Yeshvanth Kumar; Vijayaseelvi, R (2012). Outcomes of deliveries in a midwife-run labour room located at an urban health centre: results of a 5-year retrospective study. The National medical journal of India; 2012; vol. 25 (no. 6); p. 323-326

12. Davis D; Baddock S; Pairman S; Hunter M; Benn C; Anderson J; Dixon L; Herbison P. (2012). Risk of severe postpartum hemorrhage in low-risk childbearing women in new zealand: exploring the effect of place of birth and comparing third stage management of labor. Birth; vol. 39 (no. 2); p. 98-105.


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<tr>
<th>Reference</th>
<th>Source</th>
<th>Hand Searching</th>
<th>Notes</th>
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<tbody>
<tr>
<td>De Jonge, A; van der Goes, BY; Ravelli, ACJ; Amelink-Verburg, MP; Mol, BW; Nijhus, JG; Gravenhorst, J Bennebroek; Buitendijk, SE (2009). Perinatal mortality and morbidity in a nationwide cohort of 529 688 low-risk planned home and hospital births. BJOG; vol. 116 (no. 9); p. 1177.</td>
<td>BNI</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Place of birth was home or hospital.</td>
<td></td>
</tr>
<tr>
<td>Dixon, Tracy, Guilliland, Fletcher, Hendry, Pairman (2013) Outcomes of physiological and active third stage labour care amongst women in New Zealand. Midwifery. 29: 67-74.</td>
<td>Hand searching</td>
<td>*It does not further analysis active and expectant management and its associated blood loss in relation to different places of birth. *Women who birthed at home or with primary unit (MLU) more likely to have expectant management. *Increased PPH with active management.</td>
<td></td>
</tr>
<tr>
<td>Eide B.I.; Rasmussen S.; Nilsen A.B.V. (2009). Births in two different delivery units in the same clinic - A prospective study of healthy primiparous women. BMC Pregnancy and Childbirth; vol. 9,</td>
<td>EMBASE</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did not examine blood loss as an outcome.</td>
<td></td>
</tr>
<tr>
<td>Fahy K; Hastie C; Bisits A; Marsh C; Smith L; Saxton A (2010). Holistic physiological care compared with active management of the third stage of labour for women at low risk of postpartum haemorrhage: A cohort study. Women and Birth : Journal of the Australian College of Midwives; vol. 23 (no. 4); p. 146-152</td>
<td>EMBASE</td>
<td>Included</td>
<td></td>
</tr>
<tr>
<td>Gidaszewski B; Khajehei M; Gibbs E; Chua SC. (2019). Comparison of the effect of caseload midwifery program and standard midwifery-led care on primiparous birth outcomes: A retrospective cohort matching study. Midwifery; vol.69 p10-15</td>
<td>EMBASE</td>
<td>Included</td>
<td></td>
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<tr>
<td>Gottvall, Karin; Waldenström, Ulla; Tingstig, Charlotta; Grunewald, Charlotta (2011). In-hospital birth center with the same medical guidelines as standard care: A comparative study of obstetric intervention and outcomes. Birth: Issues in Perinatal Care; vol. 38 (no. 2); p. 120-128.</td>
<td>Pubmed</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</td>
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<td></td>
<td>Medline</td>
<td>*Did not examine active compared to expectant management of the third stage of labour and the associate blood loss.</td>
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<td>Citation</td>
<td>Database(s)</td>
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<tr>
<td>24. Grigg CP; Tracy SK; Tracy M; Daellenbach R; Kensington M; Monk A; Schmied V. (2017). Evaluating Maternity Units: a prospective cohort study of freestanding midwife-led primary maternity units in New Zealand clinical outcomes. BMJ open; vol. 7 (no. 8); p. e016288.</td>
<td>PubMed Medline</td>
<td>* examine active in obs unit compared to expectant management in MLU Increased rate of expectant management</td>
<td></td>
</tr>
<tr>
<td>25. Hermus MAA; Boesveld IC; Hitzert M; Franx A; de Graaf JP; Steegers EAP; Wiegers TA; van der Pal-de Bruin (2017). Defining and describing birth centres in the Netherlands - a component study of the Dutch Birth Centre Study. BMC pregnancy and childbirth; vol. 17 (no. 1); p. 210.</td>
<td>PubMed</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</td>
<td></td>
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<tr>
<td>26. Hitzert, Marit; Hermus, Marieke A.A.; Scheerhagen, Marisja; Boesveld, Inge C.; Wiegers, Therese A.; van den Akker-van Marle, M. Elske; van Dommelen, Paula; van der Pal-de Bruin, Karin M.; de Graaf, Johanna P. (2016). Experiences of women who planned birth in a birth centre compared to alternative planned places of birth. Results of the Dutch Birth Centre Study. Midwifery; vol. 40 (no. 0); p. 70-78.</td>
<td>BNI</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</td>
<td></td>
</tr>
<tr>
<td>27. Hiraizumi Y; Suzuki S. (2013). Perinatal outcomes of low-risk planned home and hospital births under midwife-led care in Japan. The journal of obstetrics and gynaecology research; vol. 39 (no. 11); p. 1500-1504.</td>
<td>PubMed Medline</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. Hospital birth and home births not MLU</td>
<td></td>
</tr>
<tr>
<td>29. Jiang XM; Chen QY; Guo SB; Jin LZ; Huang XX; Liu XW; Hong JX; Qu HB; Hu RF. (2018). Effect of midwife-led care on birth outcomes of primiparas. International Journal of Nursing Practice; vol. 24 (no. 6); p. e12686.</td>
<td>PubMed CINAHL Medline</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</td>
<td></td>
</tr>
<tr>
<td>30. Jolles, Diana R.; Langford, Rae; Stapleton, Susan; Cesario, Sandra; Koci, Anne; Alliman, Jill. (2017). Outcomes of childbearing Medicaid beneficiaries engaged in care at Strong Start birth center sites between 2012 and 2014. Birth: Issues in Perinatal Care; vol. 44 (no. 4); p. 298-305.</td>
<td>PsychoINFO</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</td>
<td></td>
</tr>
<tr>
<td>31. Jonge, A; Geerts, CC; Goes, BY; Mol, BW; Buitendijk, SE; Nijhuis, JG. (2015). Perinatal mortality and morbidity up to 28 days after birth among 743 070 low-risk planned home and hospital births: a cohort study based on three merged national perinatal databases. BJOG; Apr 2015; vol. 122 (no. 5); p. 720.</td>
<td>BNI</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did not examine MLU (home or hospital)</td>
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<tr>
<td>Reference</td>
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<tr>
<td>32. Karolinski A; Micone P; Mercer R; Gibbons L; Althabe F; Belliz JM; Messina A; Lapidus A; Correa A; Taddeo C; Lambruschini R; Bertin M; Dibiase L; Montes Varela D; Laterra C; AMBA Perinatal Network Research Group. (2009). Evidence-based maternal and perinatal healthcare practices in public hospitals in Argentina. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics; vol. 105 (no. 2); p. 118-122.</td>
<td>PubMed</td>
<td></td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</td>
</tr>
<tr>
<td>33. Kataoka, Yaeko; Eto, Hiromi; Iida, Mariko (2013). Outcomes of independent midwifery attended births in birth centres and home births: A retrospective cohort study in Japan. Midwifery; Aug 2013; vol. 29 (no. 8); p. 965-972.</td>
<td>EMBASE</td>
<td></td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</td>
</tr>
<tr>
<td>34. Kataoka, Yaeko; Masuzawa, Yuko; Kato, Chiho; Eto, Hiromi (2018). Maternal and neonatal outcomes in birth centers versus hospitals among women with low-risk pregnancies in Japan: A retrospective cohort study. Japan Journal of Nursing Science; vol. 15 (no. 1); p. 91-96.</td>
<td>CINAHL</td>
<td></td>
<td>INCLUDED -</td>
</tr>
<tr>
<td>36. Li, Y; Townend, J; Rowe, R; Brocklehurst, P; Knight, M; Linsell, L; Macfarlane, A; McCourt, C; Newburn, M; Marlow, N; Pasupathy, D; Redshaw, M; Sandall, J; Silverton, L; Hollowell, J (2015). Perinatal and maternal outcomes in planned home and obstetric unit births in women at 'higher risk' of complications secondary analysis of the Birthplace national prospective cohort study. BJOG; vol. 122 (no. 5); p. 741</td>
<td>BNI</td>
<td></td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. Compared home birth with obs unit.</td>
</tr>
<tr>
<td>37. Loewenberg Weisband, Yiska; Klebanoff, Mark; Gallo, Maria F.; Shoben, Abigail; Norris, Alison H (2018). Birth Outcomes of Women Using a Midwife versus Women Using a Physician for Prenatal Care. Journal of Midwifery &amp; Women's Health; vol. 63 (no. 4); p. 399-409.</td>
<td>CINAHL</td>
<td></td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.</td>
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<tr>
<td>40. Maillefer, Françoise; de Labrusse, Claire; Cardia-Vonèche, Laura; Hohfeld, Patrick; Stoll, Beat (2015). Women and healthcare providers' perceptions of a midwife-led unit in a Swiss university hospital: a qualitative study. BMC Pregnancy and Childbirth; vol. 15 (no. 56); p. 11.</td>
<td>BNI</td>
<td>*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</td>
<td></td>
</tr>
<tr>
<td>41. Monk A; Tracy M; Foureur M; Grigg C; Tracy S. (2014). Evaluating Midwifery Units (EMU): a prospective cohort study of freestanding midwifery units in New South Wales, Australia. BMJ open; vol. 4 (no. 10); p. e006252.</td>
<td>PubMed Yes</td>
<td>*Included</td>
<td></td>
</tr>
<tr>
<td>42. Monk, Amy R.; Tracy, Sally K.; Foureur, Maralyn; Tracy, Mark. (2013). Evaluating midwifery units (EMU): Lessons from the pilot study. Midwifery; vol. 29 (no. 8); p. 845-851.</td>
<td>BNI</td>
<td>*pilot study Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</td>
<td></td>
</tr>
<tr>
<td>45. Overgaard, Charlotte; Møller, Anna Margrethe; Fenger-Gran, Morten; Knudsen, Lisbeth B; Sandall, Jane (2011). Freestanding midwife unit versus obstetric unit: a matched cohort study of outcomes in low-risk women. BMJ open; vol. 1 (no. 2); p. e000262.</td>
<td>PsycoINFO</td>
<td>*Reduced incidence of PPH in MLU. Did not compare active management verse expectant management of the third stage of labour and the associate blood loss.</td>
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<tr>
<td>Reference</td>
<td>Title</td>
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<td>Schroeder, Elizabeth; Petrou, Stavros; Patel, Nishma; Hollowell, Jennifer; Puddicombe, David; Redshaw, Maggie; Brocklehurst, Peter (2012).</td>
<td>Cost effectiveness of alternative planned places of birth in woman at low risk of complications: evidence from the Birthplace in England national prospective cohort study.</td>
<td>BMJ: British Medical Journal (Online); vol. 344 ; p. n.</td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</em></td>
</tr>
<tr>
<td>Sutton F; McLauchlan M; Virtue C. (2002).</td>
<td>Primary maternity care outcomes in New Zealand: a comparison of midwife and medical practitioner care.</td>
<td>New Zealand College of Midwives Journal; vol. 26 ; p. 5-8.</td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</em></td>
</tr>
<tr>
<td>Kellie; Nickel, Nathan; Prior, Heather J.; Banerjee, Ankona; Morris, Margaret; Robinson, Kristine. (2016).</td>
<td>Maternity outcomes in Manitoba women: A comparison between midwifery-led care and physician-led care at birth.</td>
<td>Birth: Issues in Perinatal Care; vol. 43 (no. 2); p. 108-115.</td>
<td><em>Did stated birth setting</em></td>
</tr>
<tr>
<td>Van Wagner, Vicki; Osepchook, Claire; Harney, Evelyn; Crosbie, Colleen; Tulugak, Mina (2012).</td>
<td>Remote midwifery in Nunavik, Québec, Canada: outcomes of perinatal care for the Inulitsivik Health Centre, 2000-2007.</td>
<td>Birth; vol. 39 (no. 3); p. 230-237.</td>
<td><em>Did not examine active compared with expectant management of the third stage of labour and the associate blood loss</em></td>
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<tr>
<td>Reference</td>
<td>PubMed</td>
<td>Medline</td>
<td>CINAHL</td>
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</table>
| *No statistically significant differences in postpartum haemorrhage.  
*Birth took place tertiary hospital not MLU |
| *Did not examine active compared with expectant management of the third stage of labour and the associate blood loss  
*Did not state birth setting |
| 57.Walsh D; Downe SM (2004). Outcomes of free-standing, midwife-led birth centers: a structured review. Birth (Berkeley, Calif.); vol. 31 (no. 3); p. 222-229 | PubMed | | | |
| *Did not examine active compared with expectant management of the third stage of labour and the associate blood loss |
| 58.Yiska Loewenberg Weisband; Klebanoff, Mark; Gallo, Maria F; Shoben, Abigail; Norris, Alison H. (2018). Birth Outcomes of Women Using a Midwife versus Women Using a Physician for Prenatal Care. Journal of Midwifery & Women's Health; vol. 63 (no. 4); p. 399. | BNI | | | |
| *Did not examine active compared with expectant management of the third stage of labour and the associate blood loss |
| *Intrapartum care in a hospital not MLU  
*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss |
Appendix 4

PRISMA Flow Diagram for Structured Literature Review One

Records identified through database searching (n=672)

Additional records identified through other sources (n=14)

Records after duplicates removed (n=451)

Stage 1 (n=451)

Excluded (n=392)

Stage 2

Full-text articles assessed for eligibility (n=59) (n=5)

Excluded with reason given (n=50)

Studies included in quantitative synthesis (meta-analysis) (n=9)
## Appendix 5 - Structure Literature Review: One Critical appraisal table using CASP (2018b, c) tool

<table>
<thead>
<tr>
<th>CASP (2018b) RCT Checklist</th>
<th>Did the study ask a clearly focused question?</th>
<th>Was the assignment of patients to treat randomised?</th>
<th>Were all of the patients who entered the trial properly accounted for at its conclusion?</th>
<th>Were patients, health workers and study personnel ‘bind’ to treatment?</th>
<th>Were groups similar at the start of the trial?</th>
<th>Aside from the experimental interventions, were the groups treated equally?</th>
<th>How large was the treatment effect?</th>
<th>How precise was the estimated of the treatment effect?</th>
<th>CI</th>
<th>Can the results be applied to the local population?</th>
<th>Were all the clinically important outcomes considered?</th>
<th>Are the benefits worth the harms and cost?</th>
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<tbody>
<tr>
<td>Begley, Devane, Clarke, McCann, Hughes, Reilly, et al. (2011b).</td>
<td>Yes</td>
<td>Involved 1653 women whom were randomised to midwife-led care or consultant-led care. If they were randomised to MLC they were expected to birth on the MLU. If they were randomised to consultant-led care they were expected to birth on the obstetric unit 1,101 women were randomised midwifery led care and 552 were randomised to consultant led care.</td>
<td>Yes Randomised process explained in paper.</td>
<td>Not possible</td>
<td>Yes</td>
<td>Analysis by ITT by type of care received. Findings Despite an increase in EM in the MLU compared to obstetric units (12.4%, 137 of 1101 versus 0.2%, 1 of 552; RR 68.69 no stat. significant difference in estimated mean blood loss during the 3rd stage of labour or shortly after (323 mL (SD 317 mL) vs 324 mL (SD 401 mL); MD 6.17, 95% CI 32.12, 44.46) incidence of PPH (13.1%, 144 of 1101 versus 13.6%, 75 of 552; RR 0.96, 95% CI 0.74, 1.25), small CI.</td>
<td>The sample size required was 1,539, taking account of the two to one randomisation ratio and based on two-tailed tests. This assumed a criterion for significance (alpha) of 0.05, and sufficient power (at ≥ 0.80) to detect differences of at least 6% between consultant-led care and midwife-led care in MLUs in rates of PPH (&gt; 500: (8% to 4%); High level of reliability and validity.</td>
<td>Conclusion: Good level of reliability and validity. RCT high level of evidence, Power calculation performed to ensure Generalisability: can be applied to study population-women at low risk, birthing in MLU. However, does not directly examine AM versus EM and PPH. It examined intended place of birth and PPH and intended place of birth and 3rd stage of labour Mange. (AM or EM). However, from the results of the study it can be implied that despite the lack of direct comparison of outcomes in the two management styles, as little effect on incidence of PPH observed in obstetric-led units and MLU.</td>
<td>Suggests that EM reasonable option for women at low risk and intending to birth in MLU.</td>
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<tr>
<td>CASP (2018c) Cohort Study Checklist</td>
<td>Did study address a clearly focused issue?</td>
<td>Was the cohort recruited in an acceptable way?</td>
<td>Was the exposure accurately measured to minimize bias?</td>
<td>-Was the outcome accurately measured to minimize bias?</td>
<td>Have the authors identified all important confounding factors?</td>
<td>What are the results of this study?</td>
<td>Do you believe the results?</td>
<td>Can the results be applied to the local population?</td>
<td>Do the results of the study fit other available evidence?</td>
<td>What are the implications of this study for practice?</td>
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<td>Davis, Baddock, Pairman, Hunter, Benn, Anderson, Dixon, Herbison, (2012)</td>
<td>Yes</td>
<td>Retrospective</td>
<td>The study analysed data collected from the New Zealand College of Midwives' research database for women giving birth in 2006 and 2007 who were classified as at low risk of PPH when labour commenced. The New Zealand College of Midwives' research database holds data for approximately 32% of all the births in New Zealand. Data was obtained for 39,677 births, of which 16,453 (41.5%) births met the study</td>
<td>Unable to blind</td>
<td>Subject measures</td>
<td>Objective measurement- Visual estimation of blood loss. Most common method for measuring blood loss in clinical practice. There are various checks and balances built into the system that ensures data is entered accurately and appropriately</td>
<td>Analysis</td>
<td>AM and AM with treatment were combined under the classification “active management” -EM and EM And with treatment were combined under the classification EM -Analysis Was planned With multinomial Logistic regression Controlling for Maternal age, parity, ethnicity, smoking, augmentation of labour, mode of birth, episiotomy, perineal trauma, and newborn birthweight greater than 4,000 g. In the analysis of place of birth, adjustments were also made for mode of third</td>
<td>Yes</td>
<td>The proportion of women who had a severe PPH was higher in the women who received AM compared to those who received EM in all birth settings, which included the primary units (midwifery units). This difference was statistically significant (RR: 2.14, 95% CI: 1.42–3.22). Additionally, in the primary level units women who received AM more than twice as likely to have a severe PPH, as women who received EM (1.7%, 23</td>
<td>No power calculation</td>
<td>CI given for overall birth settings not just MLU.</td>
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<td>CASP (2018c) Cohort Study Checklist</td>
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<td>Have the authors identified all important confounding factors?</td>
<td>Have they taken account of the confounding factors in the design and/or analysis?</td>
<td>Was the following up of subjects complete enough?</td>
<td>Was the follow-up of subjects long enough?</td>
<td>What are the results of this study?</td>
<td>How precise are the results?</td>
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</table>
| Dixon, Fletcher, Tracy, Guilliland, Pairman, Hendry, (2009). | Yes | Unable to blind participants. Participants practice both AM and EM. | Subject measures Visual estimation of blood loss. Most common method for measuring blood loss in clinical practice. There are various checks and balances built into the system that ensures data is entered accurately and appropriately | Characteristics of cohort presented with regards to Ethnicity and pain relief management And third stage approach outlined. | Yes | Findings primary level units (MLU) reduction in amount of PPH, despite an increased proportion in the use of EM (EM 57.8%) compared to AM (AM rate 42.2%). In comparison the 2nd 3rd level units (obstetric No power calculation P values provided for: women who had EM , 96.3% (15,020) had a blood loss of <500mls compared to 93.1% (15,787) of women who had AM (Z=12.7, p=0.05). statistically significant | Finding runs counter to some of the findings from RCT and Cochrane reviews who analyses women at for women at mixed risk and at low risk of PPH 2000, 2010, 2011, 2015, 2019 -found significant increase in AM compared to EM for blood loss 500-1000 Statistically significant | No significant difference between

Outcomes of the study were attributed to the planned place of birth at the onset of labour. All analyses were performed using Stata V11 (12). Intention to treat- Outcomes were attributed to the planned place of birth at the onset of labour rather than actual place of birth.妇女 versus 0.6%, 9 women). Although twice as many women in the EM group went on to have further (uterotonics) treatment for excessive blood loss compared with those in the AM(14.0% vs 7.3%).

Did study address a clearly focused issue? Retrospective Analysed data collected from the New Zealand College of Midwives' research database for women giving birth in from 2004 to 2008. 33,752 women met the study inclusion criteria. Outcomes of the study were attributed to the planned place of birth at the onset of labour.

Unable to blind participants. Participants practice both AM and EM.

Characteristics of cohort presented with regards to Ethnicity and pain relief management And third stage approach outlined.
Once the inclusion/exclusion criteria applied study cohort reduced to 33,752. All women who had a normal vaginal birth (spontaneous onset of labour after 37 weeks cephalic presentation of a single live baby) between the years 2004 to 2008 inclusive, and had data provided to the MMPO database by a midwife during this time, were included in the sample.

Women were excluded if had a multiple pregnancy, history of previous PPH, a previous caesarean section, breech birth, intrauterine death, instrumental or operative birth, induction or augment of labour.

| AM and EM for blood loss greater than 1,000 mL although the trend favours AM. | Not statistically significant |
| Dixon study fits with findings from Davis et al (2012) study. | The results of this research suggest that AM stage following a physiological labour and birth results in higher blood loss when compared to EM. |

| Generalisability Study sample can be applied to women at low risk of PPH birthing in a MLU. | Overall birth settings not just MLU. For women who had a blood loss of > 500mls and <1000mls, a significant higher proportion fell into the AM 5.3% (n=903) than in the EM 3.1% (n=484); Z=9.9, p< 0.001). Statistically significant overall birth settings not just MLU. (p values given overall birth settings and not just MLU). |

| Overall birth settings not just MLU. For women who had a blood loss of > 500mls and <1000mls, a significant higher proportion fell into the AM 5.3% (n=903) than in the EM 3.1% (n=484); Z=9.9, p< 0.001). Statistically significant overall birth settings not just MLU. (p values given overall birth settings and not just MLU). |

| Units) had an increased proportion of AM (63.7% and 65.5% respectively) compared to EM (36.3% and 34.1 respectively). The proportion of blood loss of 501-1000mL was 4.1% and 0.99% for a blood > 1000mL at the primary level units; whilst at the secondary and tertiary level units (obstetric-led units) the proportions of blood loss of 501-1000 mL were 4.2% and 5.2% respectively. For a blood loss greater than 1000mL they were 1.2% and 1.5% respectively. |
| Dixon, Tracy, Guilliland, Fletcher, Hendry.Pairman . (2013). | Analysed further the data from their 2009 study (Dixon et al., 2009). | Yes | Retrospective | Unable to blind participants. How practice both AM and EM. | Subject measures Visual estimation of blood loss. Most common method for measuring blood loss in clinical practice. There are various checks and balances built into the system that ensures data is entered accurately and appropriately. | Exclusion criteria outline to ensure women were low risk | Yes | Women who had EM compared with AM received more treatment for excessive blood loss, consisting of the use of an uterotonic drug, after birth. RR of having treatment for excessive blood loss if a woman had EM was 70% higher than if she had AM (RR 1.7, 95% CI: 1.6–1.8). -However, once given uterotonic drug to treat excessive blood loss, those in the EM group were less at risk of a PPH compared with the AM group (RR: 0.54, No power calculation CI given overall birth settings not just MLU. | Conclusion | Good level of reliability. Validity to women at low risk birth in MLU, reduced As p values not given for AM and EM and PPH in MLU but birth settings overall. However, trend slightly lower in MLU compared to obs unit. Generalisability Study sample can be applied to women at low risk of PPH birthing in a MLU. This finding runs counter to some of the findings from RCT and Cochrane reviews who analyses women at low risk of PPH 2000, 2010, 2011, 2015, 2019 -found significant increase in AM compared to EM for blood loss 500-1000 No significant difference between AM and EM for blood loss greater than 1,000 mL although the trend favours AM. Fits with findings from Davis et al (2012) study. The results of this research suggest that AM stage following a physiological labour and birth results in higher blood loss when compared to EM. |
CASP (2018c) Cohort Study Checklist

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<td>Yes</td>
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<tr>
<td>What are the following up of subjects complete enough?</td>
<td>Yes</td>
</tr>
<tr>
<td>What was the precision of the results?</td>
<td>Yes</td>
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<tr>
<td>Do you believe the results?</td>
<td>Yes</td>
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<tr>
<td>Can the results be applied to the local population?</td>
<td>No</td>
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<tr>
<td>Do the results of the study fit other available evidence?</td>
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</tr>
<tr>
<td>What are the implications of this study for practice?</td>
<td>No</td>
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</table>

Fay, Hastis, Bisits, Marsh (2010)

Is ‘holistic psychophysiological care’ in the third stage of labour safe for women at low risk of PPH?

Expectant management was mainly practised at the freestanding midwifery unit and midwives who worked there received extra training in expectant management.

Fahy et al. (2010) study reported that there were wide variations in how AM and holistic psychophysiological (EM) third stage care was provided, resulting in a number of the women receiving mixed management. However, the number of women who received

Subject measures


In practice clinical decisions are made on practitioners’ estimated of blood loss.

Exclusion criteria outline to ensure women were low risk

Women exclude who were at high risk of PPH or who went on in labour to develop risk factors for PPH

Fahy study fits with findings from Davis et al (2012)
Active management was the intention at the tertiary level unit and expectant management was the intention at the free standing midwifery unit.

Mixed management is unknown, as the study was conducted retrospectively and the researchers did not have control over the interventions being investigated.

The total number of women who gave birth at the tertiary unit during the study 9,313, of 67% (6,240) were excluded due to identified risk factor for PPH. The total number of women who birthed on freestanding MLU 431 of which 16.2% (70) were excluded for risk factors for PPH. The total number of women who met the study criteria was 3,436, consisting of 3,073 at the tertiary level unit and 361 at the freestanding MLU.

361 women) for EM intended 3rd stage management approach at the MLU. This increased incidence of PPH with Am versus EM was statistically significant (OR 4.4, 95% CI: 2.3 to 8.4).

- At MLU TmT received analysis found increased PPH (500 mL or more) rate with AM (12.5%; 6 of 48 women) compared to EM (1.3%; 4 of 313 women).
- lower blood loss and incidence of PPH (500 mL or more) associated with EM compared to AM in women at low risk of PPH in all birth settings. This blood loss and incidence of PPH lower in the MLU regardless of 3rd stage approach.

compared to AM was over 27 times smaller (107 versus 2968).

Despite the high numbers of women in this study who received AM the low numbers of women who received EM will limit precision of estimates and power of this study, reducing its validity and generalisability.

Generalisability Reduced see above.

The results of this research suggest that AM stage following a physiological labour and birth results in higher blood loss when compared to EM.
### CASP (2018) Cohort Study Checklist

<table>
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<th>Was the cohort recruited in an acceptable way?</th>
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<tbody>
<tr>
<td>To compare maternal and neonatal birth outcomes and morbidities associated with the intention to give birth in a MLU or tertiary level obstetric-led maternity hospital (TMH) in Canterbury New Zealand.</td>
<td>Unable to blind participants. However, practice both AM and EM.</td>
<td>Subject measures Visual estimation of blood loss. Most common method for measuring blood loss in clinical practice In practice clinical decisions are made on practitioners' estimated of blood loss.</td>
</tr>
<tr>
<td><strong>Prospective cohort study.</strong> The study consisted of 407 women who intended to give birth in a midwifery unit and 285 women who intended to give birth at the obstetric unit in 2010–2011. All of the women planning to birth at the obstetric unit were low risk and 29 of the women planning to birth at the midwifery unit had identified risk factors. Women were able to join the study any time after hospital booking and before labour.</td>
<td><strong>Criteria for study outlined-low risk criteria outlined Demographic differences between the groups were presented. There were some significant differences between the 2 cohorts. The women who planned to give birth in a PMU were younger, heavier, more likely to have given birth before, to be Māori and to live rurally, than the women who planned to give birth in the TMH. After adjusting for confounding factors – confounding factor and place of birth. Not 3rd stage management and incidence of PPH.</strong> Number of women who had EM but then converted to EM not examined.</td>
<td><strong>Women’s outcomes were analysed by stated intention to give birth either in a PMU or TMH at the time of admission to study. EM was higher in the women who intended to birth in MLU compared with obstetric unit (41.8% versus 19.3%). Despite this increase in EM the MLU compared with obstetric unit, both groups of women had similar overall rates of PPH. At the MLU 17.4% of women had a PPH defined as a blood loss of 500-999 mL.</strong> <strong>No power calculation given.</strong></td>
</tr>
<tr>
<td>Women had a PPH</td>
<td></td>
<td><strong>Conclusion</strong> Reliability Small study size which prevented strongly powered statistical analysis of clinical outcomes, reflected in CI. Not knowing the ‘risk status on admission in labour’ of participants-increasing confounders. However, some confounding factors adjusted for in analysis Validity reduced value because of above. Does not examine AM versus EM and PPH. It examined Intended place of birth and PPH and intended place if birth and</td>
</tr>
<tr>
<td><strong>This finding runs counter to some of the findings from RCT and Cochrane reviews who analyses women at low risk of PPH 2000, 2010, 2011, 2015, 2019 - found significant increase in AM compared to EM for blood loss 500-1000 mL.</strong> Same as RCT and Cochrane reviews who analyses women at low risk of PPH 2000, 2010, 2011, 2015, 2019 No significant difference between AM and EM for blood loss greater than 1,000 mL although the trend favours AM. <strong>Grigg study also found this.</strong> The results of this research suggest a trend in a reduction of PPH 500-1000mls with EM compared to AM following a physiological labour.</td>
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Grigg, Tracy, Tracy, Daeilenbach, Kensington, Monk, Schmied, (2017)
### Confounding factors
- Maternal age, smoking status, parity, term, augmentation, induction, excludes elective caesarean section, was not significantly different between the cohorts.
- Not knowing the 'risk status on admission in labour' of participants-increasing confounders.

### Comparison
- Compared to 20.1% at obstetric unit
- Slightly higher in obs unit
- Additionally, at the MLU unit 5.9% of women had a severe PPH (defined as blood loss 1000 or over) compared to 4.6% at women at obstetric unit.

### Blood Loss
- Included Japan hospitals in MLUs and gave birth in women who were low risk of obstetric unit.
- Defined as at 4.6% at MLU compared to 5.9% of women in MLU.

### Analysis
- The majority of women who delivered in these hospitals had a low-risk pregnancy with no major complication during pregnancy and received AM.
- The Cesarean section rate was 16.8%. The inclusion criteria were:
  - Observations were analysed according to actual place of birth and used logistic regression analysis to compare outcomes at the birth centres with hospital obstetric units, where women received AM.

### Results
- Number of women who had a PPH over 500 mL or over 1000 mL was higher in the MLU than the MLU where the women received EM compared to the hospital obstetric units, where women received AM.

### Power calculation given
- For the comparison of MLU with the hospitals
  - Adjusted odds ratios (a ORs) for the MLU outcomes were estimated by using a logistic regression model.

### Odds ratio
- Number of cases and controls were estimated.

### Generalisability
- Provides some evidence for women at low risk of PPH similar in MLU and OB unit.

### Conclusion
- The finding was not significant despite the lack of direct comparison of outcomes in the two management styles, the rates of PPH similar in MLU and OB unit.

### CASP (2018) Cohort Study Checklist

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<td>- Did they use subjective or objective measurements?</td>
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<td>Was the outcome measured to minimize bias?</td>
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### Visual estimation of blood loss
- The Cesarean section rate was 16.8%. The inclusion criteria:
  - Observations were analysed according to actual place of birth and used logistic regression analysis to compare outcomes at the birth centres with hospital obstetric units, where women received AM.

### Number of cases and controls
- Number of women who had a PPH over 500 mL or over 1000 mL was higher in the MLU than the MLU where the women received EM compared to the hospital obstetric units, where women received AM.

### Adjusted odds ratios
- Adjusted odds ratios (a ORs) for the MLU outcomes were estimated by using a logistic regression model.

### Generalisability
- Provides some evidence for women at low risk of PPH similar in MLU and OB unit.

### Conclusion
- The finding was not significant despite the lack of direct comparison of outcomes in the two management styles, the rates of PPH similar in MLU and OB unit.
women at risk of a PPH, midwives can use uterotonicss under the direction of obstetricians. The data of this current study were collected before the guidelines were revised, so the risk to women who deliver at MLU since then should not be overestimated.

Included: vaginal delivery, gestation at ≥22 weeks, singleton, and cephalic presentation. Exclusion criteria: transportation to other facilities, Caesarean section, and twin pregnancies. Outcomes assessed logistic regression analysis to compare outcomes at the birth centres with hospital outcomes, adjusting for age, parity, mode of delivery, and number of gestational weeks.

This difference was statistically significant for a blood loss 500 mL; 22.1% compared with 18.4% (OR 1.47, 95% CI: 1.31 to 1.64, \( P < 0.001 \)); and for a blood loss of over 1000 mL, 3.6% compared with 2.4% (OR 1.77, 95% CI: 1.35 to 2.33, \( P < 0.001 \)).

Analysis, adjusting for age, parity, mode of delivery, and number of gestational weeks, with 95% CI.

Many women with risk factor for PPH and received EM in MLU had PPH. However, Kataoka, found that this difference was statistically significant.

Generalisability: AM reduced risk PPH. However, risk of EM and PPH in MLU should not be overestimated due to change in guideline since study.
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<td><strong>Laws, Xu, Welsh, Tracy, Sullivan (2014).</strong></td>
<td>To examine maternal morbidity related to birth center care (MLU) for women in New South Wales. Maternal.</td>
<td>Large scale matched pairs retrospective cohort study. This study consisted of women defined as at low risk of PPH. The maternal outcomes for these women, who intended to birth in New South Wales birth centres (MLU), were matched with women who intended to give birth in alongside hospitals obstetric units.</td>
<td>Data was collected from computerised maternity notes of 15,742 women between 2001 and 2009 inclusive who met the study criteria. MLU Data also collected from the computerised maternity notes of 66,190 women who intended to give birth in the alongside hospital’s labour ward during the same period.</td>
<td>Subject measures Visual estimation of blood loss. Most common method for measuring blood loss in clinical practice In practice clinical decisions are made on practitioners’ estimated of blood loss.</td>
<td>Criteria: All women intending to give birth in NSW birth centres, to singleton babies at 37 or more weeks’ spontaneous onset of labour, born between January 2001, and December 31, 2009, Adjusted odds ratios were calculated, controlling for: maternal age, Australian/over seas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, To control for confounders such as institutional and staffing factors, women were matched on the following conditions: intended place of birth of same hospital, same date of birth (plus or minus 1 day). The matched ratio was 1 (birth centre); 2 (co-located hospital labour ward) and 44,121 women were included—14,707 in the birth centre group and 29,414 in the hospital group.</td>
<td>For the 1st stage of analyses, all women who intending to birth at MLU (“non-matched”) were included. For 2nd stage, matched-pair analysis, hospital women were included who could be matched with MLU Unadjusted OR majority of outcomes were significant different between the MLU and hospital groups of women, in favour of MLU. PPH (8.6 vs 10.6%, OR 0.79 [95% CI 0.74–0.85]).</td>
<td>No power calculation Unadjusted OR majority of outcomes were significant different between the MLU and hospital groups of women, in favour of MLU. PPH (8.6 vs 10.6%, OR 0.79 [95% CI 0.74–0.85]).</td>
<td>Conclusion Reliability Does not examine AM versus EM and PPH. It examined Intended place of birth and PPH and intended place of birth and 3rd stage of labour Mange. (AM or EM). Generalisability: provides some evidence for women at low risk planning to birth at MLU. From the results of the study it can be implied that despite the lack of direct comparison of outcomes in the two management styles and PPH the PPH rates were higher in obs unit.</td>
<td>This finding runs counter to some of the findings from RCT and Cochrane reviews who analyses women at low risk of PPH 2000, 2010, 2011, 2015, 2019 -found significant increase in AM compared to EM for blood loss 500-1000. The results of this research suggest that AM stage following a physiological labour and birth results in higher blood loss when compared to EM.</td>
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</table>
### CASP (2018c) Cohort Study Checklist

<table>
<thead>
<tr>
<th>Did study address a clearly focused issue?</th>
<th>Was the cohort recruited in an acceptable way?</th>
<th>Was the exposure accurately measured to minimize bias?</th>
<th>Have the authors identified all important confounding factors?</th>
<th>Was the following up of subjects complete enough?</th>
<th>What are the results of this study?</th>
<th>Do you believe the results?</th>
<th>Can the results be applied to the local population?</th>
<th>Do the results of the study fit other available evidence?</th>
<th>What are the implications of this study for practice?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigating specified maternal and neonatal outcomes in women at low risk of obstetric complications.</td>
<td>New South Wales, Australia</td>
<td>Data was collected from the computerised maternity notes of women who booked to give birth at the freestanding MLU and the tertiary-level units from 2010 over a 17-month period and who met the study criteria.</td>
<td>The number of eligible women was 3,651, of whom 494 planned to birth on the freestanding MLU and 3,157 planned to birth on the tertiary-level units.</td>
<td>Analysis of data was by intention-to-treat with outcomes attributed to planned place of birth at the time of booking.</td>
<td>PPH 500-999 MLU 9.7% compared with 15.4% at obs unit. P= 0.031 Stat sign! 1000 MLU 3.6 compared with 4.4 at obs unit P=0.168 not stat sign</td>
<td>Overall prevalence of PPH (500 mL or over) in the free standing MLU was 13.4% and 3.6% for severe PPH. Reliability Good level of reliability. Study was powered to detect a clinically relevant fall of 21% in the rate of women requiring a caesarean section from 29% to 23%, with 90% power and a significance level of P=0.05. These numbers were also sufficient to detect a clinically significant reduction of 4.0 percentage points in the rate of instrumental birth (forceps/ventouse) from 11% to 7% with 90% power and a significance level of P=0.05. However, study does not exam. AM versus EM and PPH.</td>
<td>Good level of reliability. Study was powered to detect a clinically relevant fall of 21% in the rate of women requiring a caesarean section from 29% to 23%, with 90% power and a significance level of P=0.05.</td>
<td>Generalisability: provides some evidence for women at low risk planning to birth at MLU. From the results of the study it can be implied that despite the lack of direct comparison of outcomes in the two management styles and PPH the PPH rates were higher in obs unit.</td>
<td></td>
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<tr>
<td>Investigated specified maternal and neonatal outcomes in women at low risk of obstetric complications.</td>
<td>Participants had low risk, singleton pregnancies and were at less than 28 weeks gestation at the time of booking. Inclusion and exclusion criteria defined</td>
<td>Data was collected from the computerised maternity notes of women who booked to give birth at the freestanding MLU and the tertiary-level units from 2010 over a 17-month period and who met the study criteria.</td>
<td>The number of eligible women was 3,651, of whom 494 planned to birth on the freestanding MLU and 3,157 planned to birth on the tertiary-level units.</td>
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<td>Good level of reliability. Study was powered to detect a clinically relevant fall of 21% in the rate of women requiring a caesarean section from 29% to 23%, with 90% power and a significance level of P=0.05.</td>
<td>Generalisability: provides some evidence for women at low risk planning to birth at MLU. From the results of the study it can be implied that despite the lack of direct comparison of outcomes in the two management styles and PPH the PPH rates were higher in obs unit.</td>
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</table>

Monk, Tracy Foureur Grigg Tracy. (2014). Investigated specified maternal and neonatal outcomes in women at low risk of obstetric complications. It compared women giving birth in one of 2 freestanding MLUs in regional and urban areas, with women intending to give birth in one of 2 tertiary level units (obstetric units). The tertiary level units were the referral hospitals for the freestanding MLU. Midwives in the MLU worked in small groups.
| and provided 24 hour on-call midwifery care. | 1000 mL or more. This likely reduction in PPH for women booked for the freestanding MLU was despite a higher incidence of EM for these women compared with women booked at the tertiary-level units (37.5% compared with 2.9%). | It exam. Intended place of birth and PPH and intended place of birth and 3rd stage of labour Mange. (AM or EM). |
## Appendix 6- Structure Literature Review Two database search table

<table>
<thead>
<tr>
<th>References</th>
<th>Database</th>
<th>Included</th>
<th>Reason Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Begley CM; Gyte GM; Devane D; McGuire W; Weeks A; Biesty LM . (2019). Active versus expectant management for women in the third stage of labour. The Cochrane database of systematic reviews; Feb 2019; vol. 2 ; p. CD007412</td>
<td>PubMed</td>
<td></td>
<td>Did not explore midwives experiences, regarding the third stage of labour.</td>
</tr>
<tr>
<td>2. Begley, Cecily M; Guilliland, Karen; Dixon, Lesley; Reilly, Mary; Keegan, Caroline,(2012). Irish and New Zealand midwives’ expertise in expectant management of the third stage of labour: the 'MEET' study. Midwifery; Dec 2012; vol. 28 (no. 6); p. 733-739.</td>
<td>Medline</td>
<td>YES</td>
<td>STUDY: Explores the views of expert midwives in Ireland and New Zealand of the skills they employ in expectant management of the third stage of labour (EMTSL).</td>
</tr>
<tr>
<td>3. Davis, Deborah; Baddock, Sally; Pairman, Sally; Hunter, Marion; Benn, Cheryl; Anderson, Jacqui; Dixon, Lesley; Herbison, Peter (2012). Risk of Severe Postpartum Hemorrhage in Low-Risk Childbearing Women in New Zealand: Exploring the Effect of Place of Birth and Comparing Third Stage Management of Labor. Birth: Issues in Perinatal Care; Jun 2012; vol. 39 (no. 2); p. 98-105</td>
<td>CINAHL</td>
<td></td>
<td>Did not explore midwives experiences, regarding the third stage of labour.</td>
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<tr>
<td>Reference</td>
<td>Database(s)</td>
<td>Summary</td>
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<tr>
<td>De Groot, A N; van Roosmalen, J; van Dongen, P. (1996).</td>
<td>Medline</td>
<td>Studied the standard practice during the third stage of labour of Dutch midwives and obstetricians. The practice was elucidated by a questionnaire mailed to all Dutch midwives and obstetricians. Midwives were more likely to use expectant management compared to obstetricians. Did not explore midwives' views regarding third stage approaches or factors that midwives feel influence their practice during the third stage of labour.</td>
<td></td>
</tr>
<tr>
<td>Dencker, Anna; Smith, Valerie; McCann, Colette; Begley, Cecily. (2017).</td>
<td>CINAHL</td>
<td>Did not explore midwives' experiences regarding the third stage of labour.</td>
<td></td>
</tr>
<tr>
<td>Fahy K; Hastie C; Bisits A; Marsh C; Smith L; Saxton A (2010).</td>
<td>CINAHL</td>
<td>Did not explore midwives' experiences regarding the third stage of labour.</td>
<td></td>
</tr>
<tr>
<td>Farrar, Diane; Tuffnell, Derek; Airey, Rebecca; Duley, Lelia. (2010).</td>
<td>Medline</td>
<td>Examines current UK practice during the third stage of labour. A postal survey of 2230 fellows and members of the Royal College of Obstetricians and Gynaecologists (RCOG) and 2400 members of the Royal College of Midwives was undertaken. Respondents were asked about care during the third stage of labour. Midwives were more likely to use expectant management than obstetricians. Did not explore midwives' views regarding third stage of labour or factors that midwives feel influence their practice during the third stage of labour.</td>
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<td>Reference</td>
<td>Database(s)</td>
<td>Notes</td>
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<tr>
<td>10. Fullerton JT; Hollenbach KA; Wingard DL (1996). Practice styles. A comparison of obstetricians and nurse-midwives. Journal of nurse-midwifery; 1996; vol. 41 (no. 3); p. 243-250</td>
<td>PubMed; CINAL</td>
<td>Study explored similarities and differences between obstetricians and nurse midwives in specific processes in the management of perinatal care in order to assist women to choose from among the options of childbirth provider and birth setting that have become available to them. Did not explore midwives experiences, regarding the third stage of labour, only what management approaches they use.</td>
<td></td>
</tr>
<tr>
<td>11. Hammah, Juliana; Donkor, Ernestina Safoa. (2013). Assessment of Practising Midwives on the Management of the Third Stage of Labour. African Journal of Midwifery and Women's Health; 2013; vol. 7 (no. 2); p. 59-64.</td>
<td>BNI</td>
<td>Did not explore midwives experiences, regarding the third stage of labour. Also a low income country-</td>
<td></td>
</tr>
<tr>
<td>13. Jangsten, Elisabeth; Hellstrom, Anna-Lena; Berg, Marie. (2010). Management of the third stage of labour focus group discussions with Swedish midwives. Midwifery; Dec 2010; vol. 26 (no. 6); p. 609-614</td>
<td>Medline; CINAHL; EMBASE; PubMed</td>
<td>YES*</td>
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<td></td>
<td></td>
<td>Explored Swedish midwives’ experiences of management of third stage of labour.</td>
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<td>Reference</td>
<td>Database</td>
<td>Type</td>
<td>Description</td>
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<tr>
<td>14. Levy, V; Moore, J (1-85). The midwife's management of the third stage of labour. Nursing times; 1985; vol. 81 (no. 39); p. 47-50.</td>
<td>Medline</td>
<td></td>
<td>Did not explore factors that midwives feel influence their practice during the third stage of labour.</td>
</tr>
<tr>
<td>15. Noseworthy, D Ann; Phibbs, Suzanne R; Benn, Cheryl A (2013). Towards a relational model of decision-making in midwifery care. Midwifery; Jul 2013; vol. 29 (no. 7); p. e42</td>
<td>Medline</td>
<td>Yes</td>
<td>Factors such as identity projects, individual practices, the organisation of maternity care, local hospital cultures, medicalised childbirth, workforce shortages, funding cuts and poverty shape the way in which care decisions are made.</td>
</tr>
<tr>
<td>18. Schorn, Mavis N.; Dietrich, Mary S.; Donaghey, Beth; Minnick, Ann F. (2018). Variables That Influence US Midwife and Physician Management of the Third Stage of Labor. Journal of Midwifery &amp; Women's Health; Jul 2018; vol. 63 (no. 4); p. 446-454.</td>
<td>CINAHL</td>
<td>EMBASE</td>
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<td>Study Type</td>
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<tr>
<td>Schorn, Mavis N.; Dietrich, Mary S.; Donaghey, Beth; Minnick, Ann F. (2017). US Physician and Midwife Adherence to Active Management of the Third Stage of Labor International Recommendations. Journal of Midwifery &amp; Women's Health; Jan 2017; vol. 62 (no. 1); p. 58-67.</td>
<td>CINAHL EMBASE BNI PubMed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schorn, Mavis N.; Minnick, Ann; Donaghey, Beth (2015). An Exploration of How Midwives and Physicians Manage the Third Stage of Labor in the United States. Journal of Midwifery &amp; Women's Health; Mar 2015; vol. 60 (no. 2); p. 187-198.</td>
<td>CINAHL EMBASE PsycINFO BNI PubMed</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Smit, M; van Stralen, G; Wolterbeek, R; van Dillen, J; van Roosmalen, J; Slootweg, Y. (2013). Survey of prophylactic use of uterotonics in the third stage of labour in the Netherlands. Midwifery; Aug 2013; vol. 29 (no. 8); p. 859-862</td>
<td>Medline CINAHL</td>
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</table>

<table>
<thead>
<tr>
<th>Title</th>
<th>Database</th>
<th>Country</th>
<th>Summary</th>
</tr>
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<tbody>
<tr>
<td>How do physicians and midwives manage the third stage of labour?</td>
<td>CINAHL, BNI, PsycINFO, PubMed</td>
<td>British Columbia</td>
<td>This study is a survey of maternity practitioners in usual practice settings in British Columbia. All 199 obstetricians, all 82 midwives, and a random sample of family physicians practicing intrapartum maternity care (one-third, or 346) were surveyed. The three main outcome measures by discipline were the method preferred in managing third-stage labor, the reasons given for the chosen method, and views on the appropriateness of the current third-stage labor guideline. Results: Conclusions: A major difference was found between physicians and midwives in the management of third stage labor. Physicians routinely implemented active management of the third stage of labor; midwives preferred expectant approaches, principally based on women's preference. Did not explore views regarding third stage management of labour or factors that midwives feel influence their practice during the third stage of labour.</td>
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<thead>
<tr>
<th>Title</th>
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<th>Country</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetric care providers' knowledge, practice and associated factors towards active management of third stage of labor in Sidama Zone, South Ethiopia.</td>
<td>CINAHL</td>
<td></td>
<td>Did not explore views regarding third stage management of labour or factors that midwives feel influence their practice during the third stage of labour.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Title</th>
<th>Database</th>
<th>Country</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey of prophylactic use of uterotonics in the third stage of labour in the Netherlands.</td>
<td>EMBASE, BNI, PubMed</td>
<td></td>
<td>Did not explore midwives views regarding third stage management approaches or factors that midwives feel influence their practice during the third stage of labour.</td>
</tr>
</tbody>
</table>

Words used “midwives”, “midwife”, third stage of labour” “study”
<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwife/midwives experience of third stage approaches of labour</td>
<td>Any other outcome examined</td>
</tr>
<tr>
<td>Midwives practising in high income countries</td>
<td>Midwives practising in low income countries</td>
</tr>
<tr>
<td>Factors midwives/midwife feel influence their practice during the third stage of labour</td>
<td></td>
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</tbody>
</table>

Words used for database search “midwives”, “midwife”, third stage of labour” “study”.

Then inclusion exclusion criteria used.

Midwife/midwives experience of third stage of labour management approaches.

Factors midwives feel influence their practice during the third stage of labour.
Appendix 7

PRISMA Flow Diagram - Structure Literature review Two

Records identified through database searching (n = 329)

Additional records identified through other sources (n = 2)

Records after duplicates removed (n = 231)

Records excluded (n = 206)

Records screened (n = 231)

Full-text articles assessed for eligibility (n = 25)

Full-text articles excluded, (n = 20)

Studies included in qualitative synthesis (n = 5)
### Appendix 8- Structure Literature Review Two Critical appraisal table using CASP (2018d) tool

<table>
<thead>
<tr>
<th>Evaluation criteria for qualitative research</th>
<th>Was there a clear statement of the aims</th>
<th>Is qualitative methodology appropriate</th>
<th>Design appropriate to address aim</th>
<th>Appropriate recruitment Strategy</th>
<th>Appropriate data collection</th>
<th>Appropriate consideration of researcher/ participant role?</th>
<th>Ethical issues/ Funding?</th>
<th>Sufficient rigour of data analysis?</th>
<th>Clear statement of findings?</th>
<th>How valuable is the research?</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASP (2018d) Study</td>
<td>Yes</td>
<td>Yes (Mixture of interviews and focus groups. All 11 individual interviews and 1 focus-group with 7 participants.)</td>
<td>Yes (Purposive sample Chosen because of expertise in EM. Experienced in EMTS. All volunteers met inclusion criteria: Registered midwife; self-employed and/or government-funded midwife in New Zealand or employed in one of the Irish MLUs; used EMTSL for at least 30% of births facilitated in the past 2 years; had an average PPH rate, for all EMTSLs, of less than 4%).</td>
<td>Yes (Data collection transparent. Semi-structured, recorded, interviews undertaken by the lead author experienced in interview technique, pre-tested interview guide developed from literature. Brief field-notes also written after interview.)</td>
<td>Yes (Interviewer known by New Zealand participants; Known by reputation by all Irish participants, and was personally known, although not closely, by 3 of them. Outline their position regarding EM and influence of this on EM.)</td>
<td>Yes (Paper states ethical approval gained.)</td>
<td>Yes (Rigours data analysis allowing transparency. Clear account of analytic process from coding to developing of themes. Findings tested against further interviews, peer debriefing and informant validation, with contradictory evidence sought.)</td>
<td>Yes (Theme developed discussed and related to other evidence. Credible findings. Thematic finding, four themes identified: ‘Going with the flow’, ‘Knowing it’s separated, ‘Coping with the abnormal’ ‘Letting it come.’)</td>
<td>Yes (Search process clearly documented.)</td>
<td>Yes (Researcher discusses contribution study makes to existing knowledge or understanding and possible further research.)</td>
</tr>
<tr>
<td>Begley, C., Guilliland, K., Dixon, L., Reilly, M., Keegan, C. (2012).</td>
<td>Yes To explore the views of expert midwives in Ireland and New Zealand as to why they use EMTSL and what skills they employ. Did not explore use of AM? Experience in worked in MLUs.</td>
<td>Yes (Advances of both methods.)</td>
<td>Yes (Purposive sample Chosen because of expertise in EM. Experienced in EMTS. All volunteers met inclusion criteria: Registered midwife; self-employed and/or government-funded midwife in New Zealand or employed in one of the Irish MLUs; used EMTSL for at least 30% of births facilitated in the past 2 years; had an average PPH rate, for all EMTSLs, of less than 4%).</td>
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<tr>
<td>Evaluation criteria for qualitative research (CASP, 2018d)</td>
<td>Was there a clear statement of the aims?</td>
<td>Is qualitative methodology appropriate?</td>
<td>Design appropriate to address aim?</td>
<td>Appropriate recruitment strategy?</td>
<td>Appropriate data collection?</td>
<td>Appropriate consideration of researcher/participant role?</td>
<td>Ethical issues/Funding?</td>
<td>Sufficient rigour of data analysis?</td>
<td>Clear statement of findings?</td>
<td>How valuable is the research?</td>
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<tr>
<td>Jangsten, Hellstrom and Berg (2010)</td>
<td>Yes</td>
<td>Qualitative approach, purposive sample midwives experienced in labour and third stage, data collection-focus groups, data analysis content analysis. Midwives practising on obs units not MLU? Different philosophy? Groups focus-difficult to discuss midwives reviews regarding 3d stage care (sensitive issues),</td>
<td>Study was conducted labour wards in 6 hospitals located south west to the north of Sweden; 3 University hospitals 3 provincial hospitals. Strategic selection aimed to capture diverse experiences. Criterion for participation experienced as a labour ward midwife, preferably &gt;15years. Participating midwives, to a large extent, adopted the recommendation of Prophylactic oxytocin administration but showed great variations in managing 3rd stage of labour. 6 focus groups took place in a conference room close to the labour ward at each hospital, at time chosen by participants. During the first 2 focus groups both a moderator and a facilitator present. Only a moderator in the others. Structure of focus group outlined. Lasted 40 and 70 minutes, tape-recorded and transcribed verbatim by the moderator. Value of focus groups on collecting sensitive information and discussing this in front of peers.</td>
<td>No</td>
<td>Doctorate study, so it is presumed the research supervisors were also involved in study. Researcher/Participant role in study not stated. Not reflexive, reducing credibility.</td>
<td>Ethical approval gained.</td>
<td>Confimrability-data collection and analysis outlined. Not as transparent as could have been. Analysis process was outlined and examples given. The analysis process was based on the content analysis principles. Data analysis described examples of data and coding given. However, researcher does not consider how their own role in research may influence findings or what they did to reduce this.</td>
<td>Yes</td>
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</table>

The study is trustworthy. Yes but less so than Begley et al. (2012) study. **Transferability:** yes but not as transferable as Begley et al. (2012) study. 
Relevance: yes Explored midwives regarding AM and EM but AM not same as in UK and midwives work in obs units not MLU. The study is trustworthy. Yes but less so than Begley et al. (2012) study.  

**Transferability:** yes but not as transferable as Begley et al. (2012) study. 
**Relevance:** yes 
Explored midwives regarding AM and EM but AM not same as in UK and midwives work in obs units not MLU. 

The study is trustworthy. Yes but less so than Begley et al. (2012) study.
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<th>Ethical issues/Funding?</th>
<th>Sufficient rigour of data analysis?</th>
<th>Clear statement of findings?</th>
<th>How valuable is the research?</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASP (2018d) Study</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| Noseworthy, Phibbs and Benn, (2013).        | Yes To explore issues around decision-making within childbirth in general and the third stage of labour in particular | Yes Interviews conducted with women and midwives. However, if women were present during the interviews it may have been difficult to discuss midwives reviews regarding 3d stage care may have under-emphasised institutions effects on practice, given the focus on midwife-mother relationships (sensitive issues). However, Noseworthy study had a different aim than mine so was suitable for their study. | Yes Methods interviews with women and midwives. Value of joint interviews? Ability to discuss sensitive subject with the other person present? | No Not discussed Transparent. Not has rigorous researcher does not consider how their own role in research may influence findings. However, transcripts and themes discussed with the other researchers. Reflexivity- not demonstrated | No Ethical consent gained, issues consider ed. | Yes Transcripts analysed using thematic analysis Braun and Clarke (2006) 6 stage guide. Analysis process discussed examples of data in the codes given. | Yes Ethical consent gained. Issues considered. | Yes Sufficient rigour of data analysis? | Yes How valuable is the research? | Yes Decision-making for women and midwives is influenced by complex human, contextual and political factors that shape the way in which care decisions are made. Relevance-yes explored issues around decision-making within childbirth in general and 3rd stage in particular. However, women involved in study present during interview may have been difficult to discuss midwives reviews regarding 3d stage care, may have under-emphasised institutions effects on practice. Also midwives provided case load care as did the New Zealand Midwives in Begley study, as a result may influence their views. Credibility-outline of analysis process and how quotes in interviews relate to themes more than one person contributed to this process. | Yes A range of relational, social and political factors not present within existing decision-making models were highlighted. | Yes The study is trustworthy.
<table>
<thead>
<tr>
<th>Evaluation criteria for qualitative research</th>
<th>Was there a clear statement of the aims</th>
<th>Is qualitative methodology appropriate</th>
<th>Design appropriate to address aim</th>
<th>Appropriate recruitment Strategy</th>
<th>Appropriate data collection</th>
<th>Appropriate consideration of researcher/participant role?</th>
<th>Ethical issues/Funding?</th>
<th>Sufficient rigour of data analysis?</th>
<th>Clear statement of findings?</th>
<th>How valuable is the research?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schorn, M. N.; Minnick, A. Donaghey, B. (2015)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Purposive sample of 22 participants among 4 groups. No certified midwives available to include.</td>
<td>4 provider-specific focus groups (certified nurse-midwives, certified professional midwives, obstetricians, and family practice physicians) were held using a nominal group technique. Nominal group technique structured method for group brainstorming encouraging contributions from everyone and enables quick agreement.</td>
<td>No Reflexivity: No Effect of researchers on study not discussed. However 2 researchers independently coded the transcriptions to enhance the rigor and minimize individual bias or error.</td>
<td>Yes Confirmability- Yes Data analysed by more than one researcher Data analysis process discussed in detail. Transcriptions and recordings were compared for accuracy. 2 researchers independently coded the transcriptions to enhance the rigor and minimize individual bias or error.</td>
<td>Yes**</td>
<td>Yes**</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Relevance-Although participants conducted births inclusion criteria- only needed to have conducted 1 in last 12 months. Only 1 worked in MLU Also USA very medicalised model of childbirth different to UK (more promotion of normal birth)-All Practitioners worked in USA hospital Obs-led unit Except CPM CPM=10 participants CNM=4 Obs=4 Family practitioners =4 CPM=1 worked in MLU Home=7 Group practice=2**

The study is trustworthy Yes but limited transferability to other settings outside USA and MLU..
# Appendix 8- Structure Literature Review Two Critical appraisal table using Greenhaugh (2019) tool

<table>
<thead>
<tr>
<th>Study</th>
<th>What was the research question and was a questionnaire appropriate for answering it?</th>
<th>Was the questionnaire used valid and reliable?</th>
<th>What did the questionnaire look like, and was it appropriate for target population?</th>
<th>Were the instructions clear?</th>
<th>Was the questionnaire adequately piloted?</th>
<th>What was the sample?</th>
<th>How was the questionnaire administered and was the response rate adequate?</th>
<th>How were data analysed?</th>
<th>What were the main results?</th>
<th>What were the key conclusions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harding, Elbourne and Prendiville (1989)</td>
<td>Yes. Assessed the views of mothers and midwives who had participated in Prendivilles et al. (1988) RCT (clinical trial) investigating AM versus EM of the 3rd stage of labour. The best way to find someone views out is to ask them. Mothers who took part in RCT asked to give their views about the time immediately after the birth via short questionnaire mainly multiple-choice questions, although open-ended comments invited. Midwives working obs-unit during RCT sent questionnaire Reliab. Limited validity/value as many consisted of multiple choice questions, with a short space to add comments.</td>
<td>Yes.</td>
<td>Yes.</td>
<td>No. Not stated</td>
<td>Study sample: Participants in Harding et al.’s study consisted of midwives who practised in hospital obstetric units and women who birthed their babies in this setting. 191 mothers (11% of the total number of women randomised in the RCT) 49 midwives. Psychometric instrument used to measure an aspect of human psychology.</td>
<td>Opportune sample. Women on postnatal wards whilst research on there.</td>
<td>Data collection: Data for the study was collected via administered questionnaire Both mothers and midwives commented negatively on the length of time EM took. Suggest the time a physiological third stage of labour takes is a factor that might affect a midwife’s use of and a woman’s request for EM. The majority of midwives thought women preferred AM, which management approach women wanted was also important to the midwives and this would influence the 3rd stage approach used. Also, assessing woman for any risk factors for PPH and any deviation from normal during labour was important to midwife. If any risk factors for PPH or any deviation from normal AM</td>
<td>Views of mother not taken into account regarding 3rd stage management. Generalisability limited Practice in obstetric-led units. Decay element. Views regarding pregnancy and birth changed. Medicalised approach. Experienced in AM, usually approach. Bias. Did not explore these views in any detail multiple choice question</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9: SREP approval for study One

Subject: 0764615 - Karen Baker (Prof Doc) - SREP Application (Low Risk) - APPROVED SUBJECT TO AMENDMENT - Outcomes of expectant (physiological) management compared to active management of the third stage of labour - SREP/2016/093

Dear Karen,

I am writing in connection with the above mentioned SREP Application.

Your application has been approved by SREP subject to one amendment.

The attached document contains the essential amendment which reflects concerns expressed by our reviewers (listed on the left of the document) – you are required to complete the relevant box on the right hand side of the document to explain how you have addressed the reviewers’ concerns. Please refer in the box to any additional documents you are revising in response to the amendments, and submit these documents too. There is no need to resubmit an amended version of your original SREP Application Form.

Please address the essential amendment (contained in the attached document) and complete the right hand side of the document to confirm any revisions you have made and email your completed form along with any necessary accompanying documents to me. I will then forward your amended application onto the reviewers of your application for their feedback.

Regards,

Kirsty
(SREP Administrator)

Kirsty Thomson
Research Administrator
Email
From: Anne-Marie Henshaw <Anne-Marie.Henshaw@cht.nhs.uk>
Sent: 01 December 2016 14:41
To: Karen Baker U0764615 <Karen.Baker@hud.ac.uk>
Subject: RE: Second and final part of Doctorate study: service evaluation consisting of a retrospective cohort study involving reviewing maternity computerised case notes

Hi Karen

I am absolutely delighted to support you to progress this study. As always, if I can be of any assistance please let me know.

We have undertaken some significant work in Division to try to reduce our rates of PPH, I would really appreciate your views on this work and whether we have any gaps in our plans and actions. Could we meet to discuss?

Kindest regards, and well done Anne-Marie

Dr Anne-Marie Henshaw Phd
Associate Director of Nursing and Head of Midwifery Families and Specialist Services Division
Calderdale and Huddersfield NHS Foundation Trust
Mobile number: 07500761250 Email anne-marie.henshaw@cht.nhs.uk
PA Amanda Holmes amanda.holmes@cht.nhs.uk (Please contact Amanda to arrange meetings)
Appendix 11: Explorative Phase Midwives Questionnaire (From Service Evaluation)

Midwives Questionnaire

1. Sex: Please circle which apply  male / female

2. Age: Please circle which apply :  21-30  31-35  36-40  41-45  46-50  50-55  56 and over

3. Year of qualification as a midwife

  __________________________________________________________

4. How long have you worked as a midwife?

  -------------------------------------------------------------------------------------

5. What areas have you worked in as a midwife and for how long?

  -------------------------------------------------------------------------------------
6. How long have you worked on the birth centres?


7. Active management of the third stage involves a package of care comprising of what components:

Please tick all that apply?

- [ ] No routine use of uterotonic drugs
- [ ] Routine use of uterotonic drugs
- [ ] No clamping of the cord until pulsation has stopped
- [ ] Deferred clamping and cutting of the cord
- [ ] Delivery of the placenta by maternal effort
- [ ] Controlled cord traction after signs of separation of the placenta.
8. Physiological management of the third stage involves a package of care that includes what components:

Please tick all that apply?

☐ No routine use of uterotonic drugs
☐ Routine use of uterotonic drugs
☐ No clamping of the cord until pulsation has stopped
☐ Deferred clamping and cutting of the cord
☐ Delivery of the placenta by maternal effort
☐ Controlled cord traction after signs of separation of the placenta.

9. Please tick one box below only which best describes how you feel about the following statement?

I feel experienced in supporting women who want to birth on the birth centre and want to have a normal birth.

<table>
<thead>
<tr>
<th>Very strongly agree</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
<th>Very strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
10. Please tick one box below only which best describes how you feel about the following statement?

I feel confident in conducting physiological management of the third stage of labour.

Very strongly agree  |  Strongly agree  |  Agree  |  Neither agree nor disagree  |  Disagree  |  Strongly disagree  |  Very strongly disagree
---|---|---|---|---|---|---

11. Please tick one box below only which best describes how you feel about the following statement?

I feel confident in conducting active management of the third stage of labour.

Very strongly agree  |  Strongly agree  |  Agree  |  Neither agree nor disagree  |  Disagree  |  Strongly disagree  |  Very strongly disagree
---|---|---|---|---|---|---

Thank you for your time.

Karen Baker
Registered midwife
Appendix 12 Interview Schedule for initial interviews

Interview Guide/Topic Guide for semi-structured interviews IRAS projection ID 203549

Study Title: Midwives’ understanding regarding factors they feel influence their use of third stage management approaches in midwifery-led units.

To explore factors midwives’ feel influence their use of third stage management approaches in midwife-led units.

Before recording the interviews

Stage 1: Introduction and context setting

a. Introduction to the researcher and study topic

My name is Karen Baker. I am a practising midwife within the NHS Trust. I am also a postgraduate researcher at the University of Huddersfield.

I have been given the Trust’s permission to conduct a research project within the Trust, exploring management approaches during the third stage of labour in women giving birth in birth centres.

b. Explanation of the aims and objectives of the study

The study aims to explore midwives’ understanding regarding factors they feel influence their use of third stage management approaches in midwife-led units.
The study consists of 6 semi-structured individual interviews with midwives experienced in practising in midwife-led units and experienced and skilful in active and expectant management third stage approaches. The interviews will be audio-recorded.

It is your views and experiences I am interested in and therefore there are no right or wrong answers. Furthermore, we are equal colleagues and not sub-ordinates so you should say what you think and not what you think I want to hear.

c. Explain confidentiality and anonymity

*Interviewer reading from the script again*

All information you disclose in the interview will be kept confidential except where legal obligations would necessitate disclosure by the researcher to appropriate personnel. The results of this study will be presented in the researcher’s thesis and it is anticipated that the research may, at some point, be published in a journal or report or presented at conferences. Therefore, to

minimise the risk of participants in the study being identified in the thesis, participant codes instead of names will be used. I will remove all names identified by participants in the study and replace them with pseudonyms. Furthermore, in publications and presentations I will also not identify the study site and will carefully choose verbatim extracts from the interviews. The interview will be recorded and it is likely to last around 30 minutes, though you may wish to talk for a shorter or longer time period than this.
d. What will happen to the information?

*Interviewer reading from the script again*

All information collected from you and about you during the interview will be kept secure in line with the University of Huddersfield’s procedures and the Data Protection Act (1998). It may be necessary to use your words in the presentation of the findings and your permission for this is included in the consent form.

e. Consent issues

*Interviewer reading from a script again*

Participation in the semi-structured interviews is entirely voluntary and you have the right to withdraw at any time. Any non-participation will not have any negative consequences. If you want to withdraw at any time from the interview the information you have already provided in the interview will be withdrawn also. If you decide at a later date that you want the information you have provided in the interview to be withdrawn from the study, this will only be possible before coding of the interview transcriptions has commenced.

f. Check whether they have any questions

g. Check whether they are happy to continue and sign the consent form.

Before recording, write down the participant’s name and identifiable number on a sheet of paper.

**Stage 2** Inform the participant that the interview is now being audio recorded; record the participant’s identifiable number on the audio recorder.
• **Opening topics: Easy opening questions**
  Ask participants:
• Where they work?
• How long have they worked there?
• Where they have worked before?
• How long they have worked as a midwife?
• How do they feel experienced in normal pregnancy, birth and the third stage of labour?
• How they gained this experience?

**Stage 3 Conceptual questions: Exploring key concepts**

To explore participants’ understanding of third stage management approaches

• What is your understanding of expectant management of the third stage of labour?
• What is your understanding of active management of the third stage of labour?
To investigate whether participants feel confident in third stage management approaches.

- Can you tell me how you feel about conducting expectant management of the third stage of labour?
- Can you tell me how you feel about conducting active management of the third stage of labour?

Exploring key concepts: To explore factors that affect midwives’ use of third stage management approaches.

Main theme questions (Key questions)

- When you are providing care for a woman in labour on the birth centre can you talk me through how you would approach third stage of labour care with her?

Possible Follow-up questions

- What if a woman had risk factors for PPH does that influence your third stage of labour care?
- Can you tell me what factors would influence your use of an active third stage of labour management approach?

- What if a woman had no risk factors for PPH would that influence your third stage of labour care?
- Can you tell me what factors would influence your use of an expectant third stage of labour management approach?

Main theme question (Key questions)

- Can you tell me whether you think where the woman births influences your use of active or expectant management of the third stage of labour?
• **Possible Follow-up question/probes**
  • In that way?

  **Main theme questions (Key questions)**

  **Believes regarding birth**

  • Can you tell me what are your beliefs regarding birth?

  • Can you tell me whether you feel these believes are important regarding providing care third stage of labour care?

  • **Follow-up questions**
    • How, in that way?

  • Can you tell me whether you think women are aware of the different third stage of labour management approaches?

  • **Stage 4**
    a. **Winding down: Summarising**

Thank you for your time. The interview will remain confidential. Participants are welcome to contact the research team to ask questions at a later date if they wish. If participants feel anxious about any aspect of the study and need support they can also speak to their supervisor of midwives. The findings of the study will be presented in the researcher’s dissertation. It is also anticipated that the findings from this report will be represented by the researcher at conferences, in publications within peer reviewed journals and at maternity user groups. Summary information about the study will also be provided to participants if requested.
Appendix 13: Interview schedule/ topic guide for semi-structured follow-up interviews  IRAS projection ID 203549

To explore midwives’ understanding regarding factors they feel influence their use of third stage management approaches in midwifery-led units.

Stage 1: Introduction and context setting
You raised some really interesting issues in your first interview and I would like to discuss these further.

a. Introduction to the researcher and study topic

My name is Karen Baker. I am a practising midwife within the NHS Trust. I am also a postgraduate researcher at the University of Huddersfield.

I have been given the Trust’s permission to conduct 2 research studies within the Trust. Study 1 is investigating management approaches during the third stage of labour (active and expectant) and the incidence of PPH during the third stage of labour or shortly after in women at low risk of PPH giving birth in the midwifery-led units.
b. **Explanation of the aim of the qualitative study and follow-up interview**

Study 2 aims to explore midwives’ understanding regarding factors they feel influence their use of third stage management approaches in midwifery-led units. The aim of this follow-up interview is to explore further some of the responses you gave in the initial interview further.

It is midwives’ views and responses that the researcher is interested in and, therefore, there are no right or wrong answers. Furthermore, midwives are equal colleagues to the researcher, not subordinates, so you should say what you think and not what you think the researcher wants to hear.

c. **Explain confidentiality and anonymity**

*Interviewer reading from the script again*

All information you disclose in the interview will be kept confidential except where legal obligations would necessitate disclosure by the researcher to appropriate personnel. The results of this study will be presented in the researcher’s thesis and it is anticipated that the research may, at some point, be published in a journal or report or presented at conferences. Therefore, to minimise the risk of participants in the study being identified in the thesis, participant codes instead of names will be used. I will remove all names identified by participants in the study and replace them with pseudonyms. Furthermore, in publications and presentations I will also not identify the study site and will carefully choose verbatim extracts from the interviews.

The interview will be recorded and it is likely to last around 20 minutes, though you may wish to talk for a shorter or longer time period than this.
d. Explain what will happen to the information

*Interviewer reading from the script again*

All information collected from you and about you during the interview will be kept secure in line with the University of Huddersfield’s procedures and the Data Protection Act (1998). It may be necessary to use your words in the presentation of the findings and your permission for this is included in the consent form.

e. Explain consent issues

*Interviewer reading from the script again*

Participation in the semi-structured interviews is entirely voluntary and you have the right to withdraw at any time. Any non-participation will not have any negative consequences. If you want to withdraw at any time from the interview the information you have already provided in the interview will be withdrawn also. If you decide at a later date that you want the information you have provided in the interview to be withdrawn from the study, this will only be possible before coding of the interview transcriptions has commenced.

f. Check whether they have any questions


g. Check whether they are happy to continue and sign the consent form
Issues to explore with each participant:

**Participant 1** – You raised some really interesting issues in your first interview about the importance of the midwife being confident in third stage management approaches and I would like to discuss this further.

Can you tell me more about how you gained confidence in these third stage approaches?
What was the effect of this confidence on your practice?

**Participant 2** - You raised some really interesting issues in your first interview about the importance of the midwife being confident in third stage management approaches and about the importance of the woman making an informed choice regarding third stage management and I would like to discuss these issues further.

Can you tell me more about how you gained this confidence in third stage management approaches?
Can you tell me more about what was the effect of this confidence on your practice?

Can you tell me more about the woman making an informed choice regarding her management during the third stage of labour?
When does the woman make this informed choice?
Can you tell me more about what factors will influence her choice?
Can you tell me more about what does the midwife need to do to enable this informed choice?

**Participant 3** - You raised some really interesting issues in your first interview about the importance of the confidence of the midwife in third management approaches, empowering women to make an informed choice regarding the third stage of labour management and the effect the birth centre being busy on third stage of labour care, and I would like to discuss these further.
Can you tell me more about how you gained confidence in these third stage approaches?
Can you tell me more about what was the effect of this confidence on your practice?
Can you tell me more about empowering women to make an informed choice regarding her management during the third stage of labour?
Can you tell me how does the woman become empowered?
Can you tell me more about when does the woman become empowered?
Can you tell me about what factors will influence the woman becoming empowered?

Can you tell me what affect does the birth centre being busy have on you providing for the woman during the third stage of labour? Does it influence the information you give to the woman or how you give it?

**Participant 4** - You raised some really interesting issues in your first interview about the importance of the confidence of the midwife in third management approaches, and the effect the birth centre being busy on third stage of labour care, and I would like to discuss these further.

Can you tell me more about how you gained confidence in these third stage approaches?
Can you tell me more about what was the effect of this confidence on your practice?

Can you tell me what affect does the birth centre being busy have on you providing for the woman during the third stage of labour? Does it influence the information you give to the woman or how you give it?
**Participant 5**- Confidence of midwife, informed choice
Can you tell me more about how you gained confidence in these third stage approaches?
Can you tell me more about what was the effect of this confidence on your practice?

Can you tell me more about the woman making an informed choice regarding her management during the third stage of labour?
When does the woman make this informed choice?
Can you tell me more about what factors will influence her choice?
Can you tell me more about what does the midwife need to do to enable this informed choice?

**Participant 6**- How you gained confidence in third stage management approaches.
Can you tell me more about how you gained confidence in these third stage approaches?
Can you tell me more about what was the effect of this confidence on your practice?

**Stage 3**

b. **Winding down: Summarising**

Thank you for your time. The interview will remain confidential. You are welcome to contact the research team to ask questions at a later date if you wish. If you feel anxious about any aspect of the study and need support you can also speak to your supervisor of midwives.
The findings of the study will be presented in the researcher's dissertation, at conferences, in publications within peer-reviewed journals and at maternity user groups.

Summary information will also be provided to participants if requested.

_During the interviews questions I was asking myself:_

*What does this data tell me regarding how midwives view the different third stage management approaches?*

*What are the factors that midwives perceive affect their use of active versus expectant management approaches?*

*What effect does working on a birth centre have on the use of these third stage management approaches?*
Your SREP Application - Karen Baker (Prof Doc Candidate) - Risks and benefits of physiological management compared to active management of the third stage of labour for women at low risk of...... (SREP/2015/82)

Kirsty Thomson  
Mon 21/12/2015 15:04

To: Karen Baker U0764615  
C: Rob Burton; Dawn Leeming; Rachel Armitage

Dear Karen,

Dr Dawn Leeming, SREP Deputy Chair, has asked me to contact you with regard to your SREP application as detailed above.

Your application has been approved with minor amendments – approval is given on the understanding that you address the following essential amendments with your supervisors. There is no need to reply to SREP regarding these amendments unless you and your supervisors feel that you are unable to address these:

- Please clarify with your supervisors where will the locked cabinet for data storage be. The midwives consent form suggests this will be at the University of Huddersfield. Please amend if this will not be the case.
- You need to add ‘or interviews’ to the title of the Midwives consent form and within the Midwives’ study Invitation and Information Sheet’ as you suggest you may conduct focus groups or interviews.
- Section 2 in the IRAS form is not correctly completed – the mixed methods section should be selected. This section is used to generate the correct form so you may need to complete further information and some of the irrelevant sections will not be required.

With best wishes for the success of your research project.

Regards,

Kirsty
(on behalf of Dr Dawn Leeming, SREP Deputy Chair)

Kirsty Thomson  
Research Administrator  
01484 471156: K.Thomson@hud.ac.uk; www.hud.ac.uk
Appendix 15: Letter for HRA approval for Study Two initial interviews

Health Research Authority

Mrs Karen Clare Baker
12 Cotswold Ave, High Crompton
Alsop, Oldham
Greater Manchester
OL2 7RF

25 May 2016

Dear Mrs Baker,

Letter of HRA Approval

Study Title: Midwives perspectives of third stage management approaches- semi-structured interviews with midwives experienced in working in an alternative institutional birth setting

HRA project ID: 203549
Sponsor: University Of Huddersfield

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read Appendix B carefully, in particular the following sections:

- Participating NHS organisations in England - this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities.
- Confirmation of capacity and capability - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) - this provides details on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.
Appendix 16: Research and Development Approval for Study Two initial interviews

Email:
Please be aware that the R&D Department has a database containing study related information, and personal information about individual investigators e.g. name address, contact details etc. This information will be managed according to the principles established in The Data Protection Act. CC: Dr Anne-Marie Henshaw

Calderdale and Huddersfield NHS Foundation Trust
Research & Development Department
Old Library, Learning Centre Huddersfield Royal Infirmary

Lindley Huddersfield West Yorkshire

HD3 3EA
Telephone:
Email:
01484 343966 r&d@cht.nhs.uk
1 September 2016
Mrs Karen Clare Baker 12 Cotswold Ave, High Crompton Shaw, Oldham Greater Manchester OL2 7RF

Dear Mrs Baker

IRAS ID: 203549 Confirmation of Capacity and Capability at Calderdale & Huddersfield NHS Foundation Trust.

Full study title: Midwives perceptions of third stage management approaches: Semi-structured interviews with midwives experienced in working in alternative institutional birth settings

This letter confirms that Calderdale & Huddersfield NHS Foundation Trust has the capacity and capability to deliver the above
referenced study. Please find attached our agreed Statement of Activities as confirmation.

Our Trust follows the HRA process for study amendments and the sponsor maintains the responsibility to inform our site of any changes to the study. The study will be required to comply with our audit and monitoring procedures for research.

If you wish to discuss further, please do not hesitate to contact the R&D Office.

Yours sincerely

David Bukenhead

Dr David Birkenhead Director of Research and Development

VEABOU

Chairman: Andrew Haigh Chief Executive: Owen Williams

SON

INVESTORS IN PEOPLE

LED PEOPLE

compassionate care
Appendix 17: HRA approval for amendments to study 2: follow-up interviews

Email

From: PENISTONE, Helen (HEALTH RESEARCH AUTHORITY) <helen.penistone@nhs.net>
Sent: 02 August 2017 16:27
To: Karen Baker (Researcher) <Karen.Baker@hud.ac.uk>
Cc: Rob Burton <r.l.burton@hud.ac.uk>; jon.todd@cht.nhs.uk <jon.todd@cht.nhs.uk>; Lesley.Thomis@cht.nhs.uk <Lesley.Thomis@cht.nhs.uk>
Subject: RE: IRAS 203549 Amendment Categorisation and Implementation information - amendment assessed

Dear Karen,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Yours sincerely,
HRA Amendments

Helen Penistone
Assessor
Health Research Authority
3rd Floor, Barlow House | 4 Minshull Street | Manchester | M1 3DZ
T. 0207 104 8010
E. helen.penistone@nhs.net
Appendix 18: Research and Development approval for Study Two follow-up interviews

08 August 2017
Mrs Karen Care Baker
12 Cottonwood Ave, High Crompton
Shaw, Oldham
Greater Manchester
OL2 7BE

Dear Mrs Baker,

ID: 1266

Risks and benefits of physiological management compared to active management of the third stage of labour for women at low risk of postpartum haemorrhage. Semi-structured interviews with midwives experienced in normal pregnancy and birth.

IRAS ID: 203549
Protocol amendment No. 1

This amendment letter confirms that the Trust:
- Accepts that ICPRA standards relating to the legal and regulatory aspects of the study have been met, and
- Has the capacity to deliver the study as amended.

The following documents relating to this amendment have been reviewed:

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<tr>
<th>Document</th>
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<tr>
<td>Notification of Non-Substantial/Minor Amendments</td>
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<td>31 July 2017</td>
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<td>ICPRA Email Approval</td>
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Our Trust follows the ICPRA process for study amendments and the sponsor maintains the responsibility to inform our site of any changes to the study. The study will continue to be required to comply with our audit and monitoring procedures for research.

If you wish to discuss further, please do not hesitate to contact the R&D Office.

Chairman: Andrew Haigh
Chief Executive: Owen Williams

INVESTORS IN PEOPLE

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Appendix 19: Email Initial Midwives Study Invitation and Information sheets

Midwives’ Study Invitation Email

Midwives’ understanding regarding factors they feel influence their use of third stage management approaches.

My name is Karen Baker. I am a practising Midwife within the Trust, and I am also a postgraduate researcher at The University of Huddersfield.

I have been given the Trust’s permission to conduct a research project within the Trust, exploring management approaches during the third stage of labour in women at low risk of PPH, giving birth in midwifery-led units.

The study aims to explore midwives’ perspectives regarding factors they feel affect their use of third stage management approaches within midwifery-led units.

The study consists of 6 semi-structured individual interviews with midwives experienced in practising in midwife-led units and experienced and skilful in active and expectant management third stage approaches. The interviews will be digitally audio-recorded. Would you like to participate in the individual semi-structured interviews? However, before you decide whether you are interested in taking part in an interview it is important...
you understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with me if you wish. Please do not hesitate to ask if there is anything that is not clear or if you would like more information. If after reading the study information sheet you are interested in participating in the interviews please email the researcher back within 21 days of receiving this invitation, so a date and a time can be arranged to conduct the interview. It is anticipated that interviews will take place from 07/11/16 until 07/12/16.

**Study Information Sheet**

(Information Sheet attached to email)

**Why I have been approached?**

You have been asked to participate in the interviews because the researcher feels you would contribute particularly valuable information to the study.

**Do I have to take part in the study?**

It is your decision whether or not you take part. If decide to take part in the study you will be asked to sign a consent form at the beginning of the interview. You will be free to withdraw at any time without giving a reason.

**What will I need to do if I take part?**

The interview will consist of an informal discussion with me; acting in the role of a researcher, about what you feel affects your use of third stage management approaches within the birth centre setting.
The interviews will be audio recorded. You do not have to answer every question. It is anticipated they will be carried out from from 07/11/16 until 07/12/16. 6 semi-structured interviews will be conducted with 6 different midwives. They will be conducted within the Trust during your working day, away from the clinical area, in a private setting.

**Will my identity be disclosed?**

All information you disclose in the interview will be kept confidential except where legal obligations would necessitate disclosure by the researcher to appropriate personnel. The results of this study will be presented in the researcher’s thesis and it is anticipated that the research may, at some point, be published in a journal or report or presented at conferences. Therefore, to minimise the risk of participants in the study being identified in the thesis, participant codes instead of names will be used. I will remove all names identified by participants in the study and replace them with pseudonyms. Furthermore, in publications and presentations I will also not identify the study site and will carefully choose verbatim extracts from the interviews.

The interview will be recorded and it is likely to last around 30 minutes, though you may wish to talk for a shorter or longer time period than this.

**What will happen to the information?**

All information collected from you and about you during the interview will be kept secure in line with the University of Huddersfield’s procedures and the Data Protection Act (1998). It may be necessary to use your words in the presentation of the findings and your permission for this is included in the consent form.

**Withdrawal from the study**

If you want to withdraw at any time from the interview the information you have already provided in the interview will be withdrawn also. If you decide at a later date that you want the information you have provided in the interview to be withdrawn, this will only be possible before coding of the interview transcriptions has commenced.
When will the interviews take place?

If you are interested in participating in the interviews please email the researcher back within 21 days of receiving this invitation, so a date and a time can be arranged to conduct the interview, anticipate interviews dates from 07/11/16 until 07/12/16.

Who can I contact for further information?

If you require any further information about the research please contact the researcher, Karen Baker, Postgraduate Researcher, School of Human and Health Sciences, University of Huddersfield, email: karen.baker@hud.ac.uk

My project supervisor is Dr John Stephenson. Should you wish to contact him his details are: Dr John Stephenson PhD CMath MIMA FRSS, Senior Lecturer in Biomedical Statistics, School of Human and Health Sciences, University of Huddersfield, email: J.Stephenson@hud.ac.uk

Please email me an expression of interest to take part in the study within 14 days of receiving this email.

Thank you for your time  Karen Baker
Appendix 20: Midwifery Manager Study Information Email

Midwives’ understanding regarding factors they feel influence their use of third stage management approaches

My name is Karen Baker. I am a practising Midwife within the Trust, and I am also a postgraduate researcher at The University of Huddersfield.

I have been given the Trust’s permission to conduct a research project within the Trust, exploring management approaches during the third stage of labour in women at low risk of PPH, giving birth in midwifery-led units.

The study aims to explore midwives’ perspectives regarding factors they feel affect their use of third stage management approaches within midwifery-led units.

The study consists of 6 semi-structured individual interviews with midwives experienced in practising in midwife-led units and experienced and skilful in active and expectant management third stage approaches. The interviews will be digitally audio-recorded.

It is anticipated that interviews will take place from 07/11/16 until 07/12/16.


**Study Information Sheet for the Midwife Managers**

(Information Sheet attached to email)

**Why have certain midwives who work on the birth centre been approached to ask to participate in this study?**

They have been asked to participate in the interviews because the researcher feels they would contribute particularly valuable information to the study.

**Do they have to take part in the study?**

It is their decision whether or not they take part. If they agree to take part in the study they will be asked to sign a consent form at the beginning of the interview. They will be free to withdraw at any time without giving a reason.

**What will they need to do if I take part?**

The interview will consist of an informal discussion with me; acting in the role of a researcher, about what these midwives feel affects their use of third stage management approaches within the birth centre setting.

The interviews will be audio recorded. They do not have to answer every question. It is anticipated they will be carried out between 07/11/16 until 07/12/16. 6 semi-structured interviews will be conducted with 6 different midwives. They will be conducted within the Trust during your working day, away from the clinical area, in a private setting.

**Will their identity be disclosed?**

All information they disclose in the interview will be kept confidential except where legal obligations would necessitate disclosure by the researcher to appropriate personnel. The results of this study will be presented in the researcher’s thesis and it is anticipated that the research may, at some point, be published in a journal or report or presented at conferences. Therefore, to minimise the risk of participants in the study being identified in the thesis, participant codes instead of names will be used. I will remove all
names identified by participants in the study and replace them with pseudonyms. Furthermore, in publications and presentations I will also not identify the study site and will carefully choose verbatim extracts from the interviews. The interview will be recorded and it is likely to last around 30 minutes, though midwives may wish to talk for a shorter or longer time period than this.

**What will happen to the information?**

All information collected from the midwives during the interview will be kept secure in line with the University of Huddersfield’s procedures and the Data Protection Act (1998). It may be necessary to use midwives words in the presentation of the findings and their permission for this is included in the consent form.

**Withdrawal from the study**

If midwives want to withdraw at any time from the interview the information they have already provided in the interview will be withdrawn also. If they decide at a later date that they want the information they have provided in the interview to be withdrawn, this will only be possible before coding of the interview transcriptions has commenced.

**When will the interviews take place?**

If midwives are interested in participating in the interviews they have been asked to email the researcher back within 21 days of receiving this invitation, so a date and a time can be arranged to conduct the interview. It is anticipated that interviews will be conducted from 07/11/16 until 07/12/16.

**Who can I contact for further information?**

If you require any further information about the research please contact the researcher, Karen Baker, Postgraduate Researcher, School of Human and Health Sciences, University of Huddersfield, email: [karen.baker@hud.ac.uk](mailto:karen.baker@hud.ac.uk)

My project supervisor is Dr John Stephenson. Should you wish to contact him his details are: Dr John Stephenson PhD CMath MIMA FRSS, Senior Lecturer in Biomedical Statistics, School of Human and Health Sciences, University of Huddersfield, email: [J.Stephenson@hud.ac.uk](mailto:J.Stephenson@hud.ac.uk)
Appendix 21: Consent form

IRAS ID: Midwives understanding regarding third stage management approaches

Study Number: Study 2

Participant Identification Number for this Study:

CONSENT FORM

Title of Project:

Name of Researcher: Karen Baker

Please initial box

1. I confirm that I have read the information sheet dated..................... (version............) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or
from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

5. (If appropriate) I agree to my General Practitioner being informed of my participation in the study. / I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team.

6. (If appropriate) I understand that the information held and maintained by ________________________________ [(enter name of organisation(s) that will be providing you with data, including any NHS/HSC organisations)] may be used to help contact me or provide information about my health status.

I agree to take part in the above study.

______________________________  ________________________________  ________________________________
Name of Participant   Date   Signature

______________________________  ________________________________  ________________________________
Name of Person   Date   Signature

taking consent
Appendix 22: Reflective Narrative

I first became interested in the relationship between a woman’s birth setting, how she labours and births and how this birth setting may influence midwives’ practice when I started working as a midwife in a birth centre in 2010. Factors that influence midwives’ practice are important to study, as in the UK midwives provide care for women during pregnancy, childbirth and the postnatal period. If any deviations from the normal occur, midwives then refer women to the relevant healthcare professionals and work with them to meet the women’s needs. Midwives are also the lead carers for women defined as being at low risk of obstetric complications.

I was particularly interested in the relationship between midwife-led units, management approaches during the third stage of labour and the associated blood loss in women at low risk of PPH, and midwives’ practice during the third stage of labour. I developed a particular interest in this area of care as prior to working in a birth centre (midwife-led unit) I worked in an obstetric-led unit where the active management of the third stage of labour was the usual practice and recommended by midwives to all women. Although I was aware that expectant management was also an option, in the NHS Trust where I worked at the time practice guidelines recommended active management. The rationale for this was that research studies had shown an increase in PPH with expectant compared to active management. Consequently I had limited experience in conducting expectant management and limited exposure to it.

However, when I started work as a midwife at a midwife-led unit within another NHS Trust I became exposed to both active and expectant management. Although active management was still recommended in the NHS Trust’s practice guidelines, the midwives who worked at the midwife-led unit would discuss the different third stage management approaches with women, enabling them to make an informed choice. Additionally, if the woman was at low risk of PPH, some midwives would discuss with her initially having
expectant management and, if any risk factors for PPH occurred or the woman requested, then to convert to active management. This indicated to me that in different birth settings and between different healthcare professionals third stage management practices differ. This suggests that practices during the third stage of labour are likely to be influenced by a range of factors, not just findings from research studies. Moreover, it became evident to me that when women are offered expectant management of the third stage of labour as a reasonable option, they may choose it.

I also felt that working at a midwife-led unit enabled me to gain experience and confidence in both third stage approaches. I also felt that both third stage approaches were reasonable options for women at low risk of PPH and appreciated why midwives and women may want to choose one approach over the other.