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

CASP (2018a) Checklist Systematic Review	Did the study ask a clearly focused question?	Did the authors look for the right type of papers?	Do you think all the important, relevant studies were included?	Did the review's authors do enough to assess quality of the included studies?	If the results of the review have been combined, was it reasonable to do so?	What are the overall results of the review?	How precise are the results?	Can the results be applied to the local population?	Were all important outcomes considered?	Are the benefits worth the harms and costs?
Prendiville, Elbourne, McDonald (2000) This version of the Cochrane review informed RCOG (2009) prevention of PPH recommendations.	**Yes** To compare the effects of AM versus EM on blood loss and other maternal and perinatal complications of the 3rd stage.	**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. *Begley: Ireland *Rodgers: UK Hinchingbrooke *Prendiville :UK Bristol	**Yes** appropriate for that time 2000 Search strategy developed for the Pregnancy and Childbirth Group as a whole. All women Khan 5 RCT Thilaganath et al. (1993) Begley (1990) Prendiville et al. (1989) Rogers et al. (1998) Women at low risk 4 RCTs Begley (1990) Rogers et al. (1998) Prendlville (1989) RCT 2nd analyses Thilaganath et al. (1993)	**yes** Trials under consideration were evaluated for methodological quality and appropriateness for inclusion, without consideration of their results. Further information was sought from individual authors. Included trial data were processed as described in Clarke 1999.	**N0** EM only suitable for women at low risk of PPH (who have had a normal physiological birth) For women at low risk of PPH High risk Mixed risk-Preniville 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 oxytocic in AM, epidural, oxytocin for IOL Women in Begley: Ireland Rodgers identified as low risk but had women in who were high risk.	All women High and low risk 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 ≥500mls 4 studies Khan, Begley, Prendiville, Rogers 6284 women RR 95% CI 0.38 [0.32, 0.46] Severe PPH clinically ≥ 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 < 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	Women at low risk PPH Regarding blood loss and PPH and need for further uterotonic drugs and treatment of PPH PPH est. blood loss ≥ -500mls 3- Begley, Prendiville, Rogers 3616 women RR 95% CI 0.34 [0.27 to 0.43]. -Severe PPH loss ≥ 1000mls 3- Begley, Prendiville, Rogers 3616 women RR 95% CI 0.47 [0.27, 0.82] -Mean blood loss 2- Begley, Rogers 2941 women Mean Difference 95% CI -79.33 [-94.29, -64. 37] -Hb < 9 g/dl 24 - 48 hours post-partum 4 – Begley, Rogers, Prendlville Thilaganath 3417 women RR 95% CI 0.29 [0.19, 0.44] -Blood transfusion 4- Begley, Rogers, Thilaganath Prendiville, 3809 women RR95% CI 0.27 [0.13, 0.55] -Iron tablets during the Puerperium, 1 -Rogers 1447 women RR 95% CI 0.60	**No** Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches.	Confidence and experience of midwife in both approaches. Different birth settings- All RCT in hospital obs-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.

		*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 erogometrine, 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 $\geq$ 500 RR 0.38, 95% CI0.32 to 0.46); prolonged third stage of labour 9.77 minutes, 95% CI 10.00 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, Prendlville, 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.			

CASP (2018a) Checklist Systematic Review	Did the study ask a clearly focused question?	Did the authors look for the right type of papers?	Do you think all the important, relevant studies were included?	Did the review's authors do enough to assess quality of the included studies?	If the results of the review have been combined, was it reasonable to do so?	What are the overall results of the review?	How precise are the results?	Can the results be applied to the local population?	Were all important outcomes considered?	Are the benefits worth the harms and costs?
Begley, Gyte, Murphy, Devane, McDonald. McGuire, (2010).	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 ackages of AM and EM on severe primary PPH haemorrhage, blood loss and other maternal and infant outcomes**.**	**Yes** **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.** Randomised and quasi-randomised controlled trials comparing active versus expectant management of the third stage of labour.	**Yes** Cochrane Pregnancy and Childbirth Group Trials Register (May 2010). All women 5 studies (6486 women), Khan 5 RCT Thilaganath et al. (1993) Begley (1990) Prendiville (Rogers et al. (1998) All undertaken in hospitals in high-income countries. 4 compared AM versus EM Thilaganath et al. (1993) Begley (1990) Prendiville Rogers et al. (1998) 1 compared AM versus a Mix M. Khan 3 compared	Yes 2 authors independently assessed the studies for inclusion, assessed risk of bias and carried out data extraction. All metaanalyses used random-effects meta-analyses due to the clinical heterogeneity involved. For a number of outcomes, there was very little heterogeneity found (T2 = 0 and IU =0%), so there appears to be a single common treatment effect for these outcomes.	. 4 RCTs (4829 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. **3 RCTs only women classified as being at low risk to bleeding or its effects (Begley 1990; Rogers, 1998; Thilaganathan 1993.** 2x (Khan 1997; Prendiville 1988) included women irrespective of their risk of bleeding	**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 it 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, afer 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 > 500 ml Prendiville, Rogers,	**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 pprox. 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.	**No** Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches.	Confidence and experience of midwife in both approaches. Different birth settings- All RCT in hospital obs-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.

			AM versus EM Begley (1990) Rogers et al. (1998) Thilaganath et al. (1993**)** 4 conducted in UK(Prendiville 1988; Rogers 1998; Thilaganathan 1993), Ireland (Begley 1990) 1 Abu Dhabi (Khan 1997).			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, rendiville, 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 > 24hours and < 6 weeks (RR 3.08, 95% CI 0.32 to 29.55, one study, 1429 women,				

CASP (2018a) Checklist Systematic Review	Did the study ask a clearly focused question?	Did the authors look for the right type of papers?	Do you think all the important, relevant studies were included?	Did the review's authors do enough to assess quality of the included studies?	If the results of the review have been combined, was it reasonable to do so?	What are the overall results of the review?	How precise are the results?	Can the results be applied to the local population?	Were all important outcomes considered?	Are the benefits worth the harms and costs?
Begley, Gyte, Devane, McGuire, & Weeks, *(2011a).* **This version of the Cochrane review informed the RCOG (2016) and WHO (2012; 2018) third stage of labour guidelines**	**To compare the effects of AM versus EM of the third stage of labour on severe primary PPH and other maternal and infant outcomes.** **2. To compare variations in the packages of active and expectant management of the third stage of labour on severe primary PPH and other maternal and infant outcomes**	**Yes** See thesis regarding RCT and cohort studies Included studies 7 studies involving 8247 women Begley 1990; Jangsten 2011; Jerbi 2007; Khan 1997; Prendiville 1988; Rogers AM versus EM Begley (1990) Rogers et al. (1998) Thilaganath et al. (1993) Prendiville Women at low risk of PPH 3 RCTs Begley (1990) Rogers et al. (1998) Thilaganath et al. (1993) AM verses MM Jangsten 2011; Jerbi 2007; Khan 1997;	We searched the Cochrane Pregnancy and Childbirth Group Trials Register (15 February 2011). Data collection and analysis Two review authors independently assessed the studies for inclusion, assessed risk of bias and carried out data extraction.	**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** AM compared with EM for women at low risk of bleeding, the benefits seen: Reduction in number of blood transfusions -Reduced primary blood loss greater than 500 mL, but less than 1000 mL. The negative Sequelae: -Decreased baby's birthweight, --increased hypertension -postpartum pain Return to hospital due to postnatal bleeding following discharge. The outcomes "blood loss" and "number of blood transfusions are susceptible to bias, due to the lack of blinding of clinicians. When expectant management is used, it is important that the option of using a uterotonic (non-ergot based initially) as treatment at any time is available if excess bleeding occurs.	**Results same as Begley 2010 Cochrane review-see above**	**No** Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches.	Confidence and experience of midwife in both approaches. Different birth settings- All RCT in hospital obs-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.

CASP (2018a) Checklist **Systematic Review**	**Did the study ask a clearly focused question?**	**Did the authors look for the right type of papers?**	**Do you think all the important, relevant studies were included?**	**Did the review's authors do enough to assess quality of the included studies?**	**If the results of the review have been combined, was it reasonable to do so?**	**What are the overall results of the review?**	**How precise are the results?**	**Can the results be applied to the local population?**	**Were all important outcomes considered?**	**Are the benefits worth the harms and costs?**
Begley, Gyte, Devane, McGuire, & Weeks *(2015)* This version of the Cochrane review informed the RCM (2018) third stage of labour practice recommendations.	**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).	Searched the Cochrane Pregnancy and Childbirth Group Trials Register (30 Sept2014) and reference lists of retrieved studies.	**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.	Confidence and experience of midwife in both approaches. Different birth settings- All RCT in hospital obs-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. T **-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.								

CASP (2018a) Checklist Systematic Review	Did the study ask a clearly focused question?	Did the authors look for the right type of papers?	Do you think all the important, relevant studies were included?	Did the review's authors do enough to assess quality of the included studies?	If the results of the review have been combined, was it reasonable to do so?	What are the overall results of the review?	How precise are the results?	Can the results be applied to the local population?	Were all important outcomes considered?	Are the benefits worth the harms and costs?
Begley, Gyte, Devane, McGuire, Weeks, Biesty, (2019).	**Objective** To compare the effectiveness of AM versus EM of the third stage of labour.	**Yes** See thesis regarding RCT and cohort studies 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**	Searched Cochrane Pregnancy and Childbirth's Trials Register, ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP), on 22 January 2018, and reference lists of retrieved study We used a random-effects model in the analyses because of clinical heterogeneity 3 studies as having low risk of bias in the main aspects of sequence generation, allocation concealment and	**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**	**Results same as Begley 2010 Cochrane review-see above** **No** Low risk spontaneous vaginal birth MLU Care provide by midwives experience in both approaches.	Confidence and experience of midwife in both approaches. Different birth settings- All RCT in hospital obs-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.

		<u>risk of PPH</u> 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 **Study**	***Did the study ask a clearly focused question?***	**Was the assignment of patients 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 trail?**	**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?**
Begley (1990) -Included in Prendiville, et al (2000) and Begley et al. (2010, 2011,2015, 2019) Cochrane Systematic Reviews	***Yes*** .	**Yes** AM-705 EM-724 Low risk of PPH however some women had risk factors for PPH- syntocinon 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.	**Yes**	**No-** Not possible OBSERVER BIAS, practitioner bias, midwives less experienced in expectant management. PPH rate fell EM l 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.	**Yes**	**Yes**	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. **-I**ncreased 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.	**Power caluation?** AM verse EM **Blood loss** AM-Mean-148.9ml SD 127-10 EM-Mean-234ml SD 223-90 **P<0.000005** **Stat/sig.** **PPH >500ML** AM-SD-14 EM-SD-60 **P <0.0005** **Stat/sig.** **P/N Hb** <10gm AM-SD 8 EM-SD 60 P<0.0002 **Stat/sig.** **CI 0.04-0.09** **BP >95mmHg** AM-SD-35 EM-SD-5 P<0.0001 **Stat/sig.**	**No-** Contained women with risk factors for PPH-syntocinon infusion in labour episiotomy (did not have normal physiological birth), increased risk of PPH EM not appropriate RCT conducted in hospital obstetric units. Effect on woman's hormones, midwives more experienced in AM. Ergometrine used as uterotonic	**No-** effect of confidence and experience of practitioners on third stage management approach outcomes. -If midwife confident and experienced in an approach blood loss reduced, more confident in active management initially. When became confident in EM PPH reduced. In RCT-AM usual approach. PPH rates for EM group decreased considerably after first 4 months. Difference significant first 4 months 12%, Last 8 ½ months 7%. PPH rates highest in pilot study 21% and decreased to 2-10% for the last 8 ½ months of the RCT. *experience of midwife	**No** **Conclusion from study:** Routine AM is not necessary for women at low risk of PPH. -A policy of EM would result in higher blood loss and PPH >500mL at time of delivery. Lower Hb postnatally but women do not appear to suffer any further consequences. **AM**- Higher incidence of after pains and raised BP with AM compared to EM. -appropriateness of **RCT**-Questions best answered by RCT relate to interventions, mainly concerned with therapy or prevention. **However**, a cohort study would have reflected more accurately what is going on in practise than an experimental study.

							-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 low 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.**
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 trail?**	**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?**
de Groot, van, Roosmalen., van Dongen, Borm, (1996) -Included in NICE (2017) guidelines	Study is a double blind multicenter trial of oral ergometrine versus placebo. Women at low risk of PPH randomised to 0.4mg ergometrine tablets, placebo	**YES**	**YES**	**No-** Not possible OBSERVER BIAS, practitioner bias, midwives less experienced in expectant management.	**YES**	**YES**	**Not assessed as** Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al (2000) to investigate AM verse EM.	**Not assessed as** Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al (2000) to investigate AM verse EM.	**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 erogmentine no longer used as	**Not assessed as** Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al (2000) to investigate AM verse EM.	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.

	tablets, or 51U oxytocin								prophylactic drug in AM. Does not compare AM versus EM. Both third stage approaches are M. manage.		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 Need for further intervention: blood transfusion-Very low quality. Need for further intervention: therapeutic uterotonics-Very low quality
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 trail?**	**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?**
Khan et al. (1997) **Included in the** Prendiville et al. (1988) Included in Prendiville, et al (2000) Cochrane	Yes Consisted of high risk and low risk women. Women at high risk should not have had EM should have had AM should	**Yes**	**Yes**	**No-** Not possible OBSERVER BIAS, practitioner bias, midwives less experienced in expectant management.	No consisted of women at high and low risk of PPH. Women who were breech, had an epidural	**Yes**	**Not assessed as** Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al (2000) to investigate AM verse EM.	**Not assessed as** Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al	**NO** Did not compare AM with EM. This study compared AM with mixed management (AM verse minimal intervention)	**Not assessed as** Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al (2000) to investigate AM verse EM.	Not generalisable to this women at low risk birthing at MLU. compare AM with EM. Should not have been used by Prendivilleet al (2000) to investigate AM verse EM.

Systematic Reviews examining AM verse EM..	not have been included in RCT.							(2000) to investigate AM verse EM.			
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 trail?**	**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?**
Prendiville, Harding, Elbourne, Stirrat (1988)- Bristol third stage trial -Included in Prendiville et al. (1988) Included in Prendiville , et al (2000) and Begley et al. (2010, 2011, 2015, 2019) Cochrane Systematic Reviews. -Included in NICE (2017) guidelines	**Yes** Primary analysis All women High and low risk of PPH. Secondary analysis-including only women defined as low risk of PPH.	**No** Secondary analysis No description of randomisation given	**Yes** **Main RCT EM 849** **AM 846** RCT-protocol modified due to increased PPH in EM and none compliance with EM (women having mixed M) and women increased risk of PPH having EM. Low risk 1st and 2nd stags EM 335/541 Low risk 1st and 2nd stage AM 340/538	**No-** Not possible OBSERVER BIAS, practitioner bias, midwives less experienced in expectant management. AM normal at hospital Few experienced in EM initially but did receive training 6 weeks before RCT. Only six (13%) said that they were very confident in using EM before the study started and 22 (46%) afterwards. In addition, of 49	**Yes**	**Yes**	**Secondary analysis data grouped according to whether the 1st and 2nd stages were classified as low risk in relation to the 3rd stage.** **<u>Defined as low risk if:</u>** spontaneous onset of labour, Augmentationand epidural were not needed, labour lasted less than 12 hours Delivery spontaneous. ITT- **<u>4.4% incident primary PPH in AM group compared with 16.1% incident Primary PPH in EM group.</u>** Treatment	P*ower calculat. done for main study and primary outcome primary analysis* <u>Stat sig results</u> <u>></u>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 ration 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 . -If midwife confident and experienced in an approach blood loss reduced, more confident in active management initially. When became confident in EM PPH reduced. In RCT-AM usual approach. Effect of mixed management	<u>Main conclusion from study-</u> 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 ≥ 1000 ml-Very low Blood transfusion-Moderate Therapeutic uterotonics-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%) conduced 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 generaliability of findings to women at low risk of PPH with birth in MLU.

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 trail?**	**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?**
Rogers, Wood, McCandlish, Ayers, Truesdale, Elbourne (1998) -included in Prendiville, et al (2000) and Begley et al. (2010, 2011, 2015, 2019) Cochrane Systematic Reviews. -Included in NICE (2017) guidelines 976 women eligible for RCT declined 504 stated wanting EM.	***Yes*** RCT to compare the effects of AM and EM of rd stage maternal and neonatal morbidity	**Yes**	**YES** (less than 0.5% attrition, equal losses in both groups). At 6 week follow up less than 5% attrition. **EM 764** **AM 748**	**NO** Not possible - OBSERVER BIAS, practitioner bias, midwives However, when the studies was conducted says practitioner's experience and confidence with AM and EM. However, the questionnaire administered to 92 of the 153 midwives prior to the study commencement showed that, whereas 84% felt "very confident" of active management, only 41% were "very confident" of expectant	**Yes**	**Yes**	**PPH-rate** 11.7%. 126 (16.5%) in EM 51 (6.8%) in AM **Blood loss of ≥500mls** EM (13.9%) AM 38 (5.1%). **Blood loss of ≥1000mls** EM 20 (2.6%) AM 13 (1.7%). **postnatal Hb ≤ 10g/dl** EM 204 (28.4%) AM 107 (15.2%). **Blood transfusions** EM 20 women (2.6%), AM 4 women (0.5%). **Use of iron tablets** delivery to six weeks. EM 205 (28%) AM 121 (16.9%) **EM increased** used of therapeutic uterotonic and 3rd stage longer than 30 minutes. **EM reduced** incidence of nausea and vomiting. **Women felt satisfied with both**	**PPH-rate** RR 2.42 (95%CI 1.78-3.30) **Blood loss of >1000** P=0.32 Not stat signifi. **postnatal Hb ≤ 10g/dl** RR 1.86 (1.51-2.30)P= 0.0001 Stat. Signify. **Blood transfusions** RR 4.9 (1.68-14.25)p 0.0024, Stat. Signify **Used of therap. Uteroton**.RR 6.25 (4.33-9.96)p 0.00001 Stat. Signify **nausea and vomit.**	women as low risk of PPH-although contained women at risk of PPH **Episiotomy-** EM-89 11.6% AM-92 12.3% -Effect of episiotomy on woman's hormones. Medicalised approach to childbirth and 3rd stage. Non-compliance by pract. fully AM 95.9% fully EM 64.2%. Many variations in AM.and EM.	**No contained women at high risk of PPH.** **Variation in AM and EM approaches.** **More women in EM group had mixed management** **Mixed management more PPH**	AM compared to EM reduced risk of PPH. No evidence that differential effects of EM were evident beyond short term. National Collaborating Centre for Women's and Children's Health (2014) graded the quality of evidence ≥ 500mL low ≥ 1000 ml very low blood transfusion moderate therapeutic uterotonics moderate nausea-moderate This was as a result of the risk of bias, inconsistencies and indirectness in the studies

				management			**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).**	RR0.51 (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 trail?**	**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?**
Thilaganathan B; Cutner Latimer, Beard (1993) -Included in Prendiville, et al (2000) and Begley et al. (2010, 2011, 2015, 2019) Cochrane Systemati	***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**	193women completed the study. AM-103 EM-90 **<u>Main results-</u>** EBL no significant difference. **-** Changes in Hb- mean Hb level dropped in the women with presumed PPH (EBL <u>></u>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 generalisibity to women birthing in MLU. Women included low	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

c Reviews. -Included in the NICE (2017) guidelines			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. ? 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).	risk of PPH	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.

Study	Database	Included	Reason excluded
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. *BJOG : an international journal of obstetrics and gynaecology;* vol. 115 (no. 5); 570-578.	Medline		*Did not examine active compared with expectant management of the third stage of labour and associated blood loss. *Did not examine MLU
2.Begley C.; Clarke M.; Devane D.; McCann C.; Gormally S.; Hughes P.; Reilly M.; Finan A.; Maguire R.; Higgins S.; Doyle M. (2011). Comparison of midwife-led and consultant-led care of healthy women at low risk of childbirth complications in the Republic of Ireland: A randomised trial. Comparison of midwife-led and consultant-led care of healthy women at low risk of childbirth complications in the Republic of Ireland: a randomised trial. *BMC pregnancy and childbirth*; vol. 11; p. 85.	EMBASE CINAHL Medline PubMed	**Yes**	*Examine active compared with expectant management of the third stage of labour and the associated blood loss. **Increased rate of EM in MLU.** **No difference in PPH rates.**
3.Benjamin Y; Walsh D; Taub N (2001). A comparison of partnership caseload midwifery care with conventional team midwifery care: labour and birth outcomes. Midwifery; vol. 17 (no. 3); p. 234-240.	CINAHL Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did not examine blood loss and third stage of labour. Increased rate of EM in MLU. Did not examine blood loss
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. Midwifery; vol. 28 (no. 5); p. 591-599.	BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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 (> or = 500 ml) and severe (> or = 1000 ml) postpartum haemorrhage. European journal of obstetrics, gynecology, and reproductive biology; vol. 115 (no. 2); p. 166-172.	PubMed		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss *Place of birth not identified.
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. BMC Pregnancy and Childbirth; vol. 16 (no. 1)	EMBASE PubMed CINAHL Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *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.

7.Bernitz S.; Aas E.; Oian P. (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. Midwifery; Oct 2012; vol. 28 (no. 5); p. 591-599.	EMBASE		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did not examine blood loss
8.Birthplace in England Collaborative Group (2011). Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study**. BMJ :** British Medical Journal (Online); vol. 343 ; doi: https://doi.org/10.1136/bmj.d7400 BMJ 2011;343:d7400.			*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did not examine blood loss
9.Campbell R; Macfarlane A; Hempsall V; Hatchard K. (1999). Evaluation of midwife-led care provided at the Royal Bournemouth Hospital. Midwifery; Sep 1999; vol. 15 (no. 3); p. 183-193.	PubMed CINAHL Medline		*Did not examine active or expectant management of the third stage of labour. *Did not examine blood loss
10.Cheung, N; Mander, R; Wang, X. (2011). Clinical outcomes of the first midwife-led normal birth unit in China: a retrospective cohort study. Midwifery; Oct 2011; vol. 27 (no. 5); p. 582-587.	BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *China middle income country
11.David, K V; Pricilla, R A; Venkatesan, S; Rahman, S P M F; G S, Yeshvanth Kumar; Vijayaselvi, 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	Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Study conducted in Indian. Medium income country
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.	**PubMed**	**Yes**	**Included**
13.Dencker A.; Begley C.; Smith V.; McCann C.(2017). Midwife-led maternity care in Ireland - a retrospective cohort study BMC Pregnancy and Childbirth; vol. 17 (no. 1).	EMBASE PubMed CINAHL Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did not examine blood loss ***More women had expectant management**
14.De Jonge A.; Mannien J.; Mesman J.A.J.M.; Van Roosmalen J.; Zwart J.J.; Buitendijk S.E.; Van Dillen J.. (2015). Severe adverse maternal outcomes among women in midwife-led versus obstetrician-led care at the onset of labour in the Netherlands: A nationwide cohort study. PLoS ONE; vol. 10 (no. 5).	EMBASE PubMed Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss

15.De Jonge, A; van der Goes, BY; Ravelli, ACJ; Amelink-Verburg, MP; Mol, BW; Nijhuis, 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.	BNI		*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.
16.Dixon, L; Fletcher, L.; Tracy, S; Guilland, K.; Pairman, S; Hendy, C.(2009). Midwives care during the Third Stage of Labour: An analysis of the New Zealand College of Midwives Midwifery Database 2004-2008. New Zealand College of Midwives Journal. Issue 41, p20-25.	Hand searching	**Yes**	* Does not further analysis active and expectant management and its associated blood loss and its relation to different places of birth. ***More likely to have expectant management in alternative institutional birth settings and reduced *Incidence of PPH compared with obstetric-led hospital units.**
17.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.	Hand searching Yes	**Yes**	*It does not further analysis active and expectant management and its associated blood loss it 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.**
18.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,	EMBASE		*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.
19.Eto H.; Hasegawa A.; Kataoka Y.; Porter S.E. (2017). Factors contributing to postpartum blood-loss in low-risk mothers through expectant management in Japanese birth centres. Women and Birth; vol. 30 (no. 4).	EMBASE CINAHL		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Examined expectant management and blood loss.
20.Faison J.B.; Pisani B.J.; Douglas R.G.; Cranch G.S.; Lubic R.W.. (1979).The childbearing center: An alternative birth setting. Obstetrics and Gynecology; vol. 54 (no. 4); p. 527-532. .	EMBASE		*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.
21.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	**EMBASE PubMed CINAHL Medline**	**Yes**	**Included**
22.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 ;p10-16	PubMed Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
23.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.	PsycoINFO		*Did not examine active compared to expectant management of the third stage of labour and the associate blood loss

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.	PubMed Medline	**Yes**	* examine active in obs unit compared to expectant management in MLU **Increased rate of expectant management**
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.	PubMed		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	PubMed Medline		*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
28.Huitfeldt, Anette Schaumburg; Voldner, Nanna; Blix, Ellen (2016). Outcomes of care at 'Føderiket Midwifery Unit' 2007-2011, a freestanding midwifery-led unit in Oslo, Norway: A prospective cohort study. Nordic Journal of Nursing Research; vol. 36 (no. 1); p. 38-43.	CINAHL		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	PubMed CINAHL Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	PsycoINFO		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	BNI		*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)

32.Karolinski A; Micone P; Mercer R; Gibbons L; Althabe F; Belizan 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.	PubMed		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	EMBASE BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.
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.	CINAHL Medline	**Yes**	**INCLUDED -**
35.Laws, Paula J.; Xu, Fenglian; Welsh, Alec; Tracy, Sally K.; Sullivan, Elizabeth A. (2014). Maternal Morbidity of Women Receiving Birth Center Care in New South Wales: A Matched-Pair Analysis Using Linked Health Data. Birth: Issues in Perinatal Care; vol. 41 (no. 3); p. 268-275.	**Medline**	**Yes**	***Included**
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	BNI		*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.
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 & Women's Health; vol. 63 (no. 4); p. 399-409.	CINAHL		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.
38.Low LK; Bailey JM; Sacks E; Medina L; Piñeda HO . (2008). Postpartum hemorrhage prevention: a case study in northern rural Honduras. Journal of midwifery & women's health; vol. 53 (no. 1); p. e1.	PubMed		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss. *Low income country

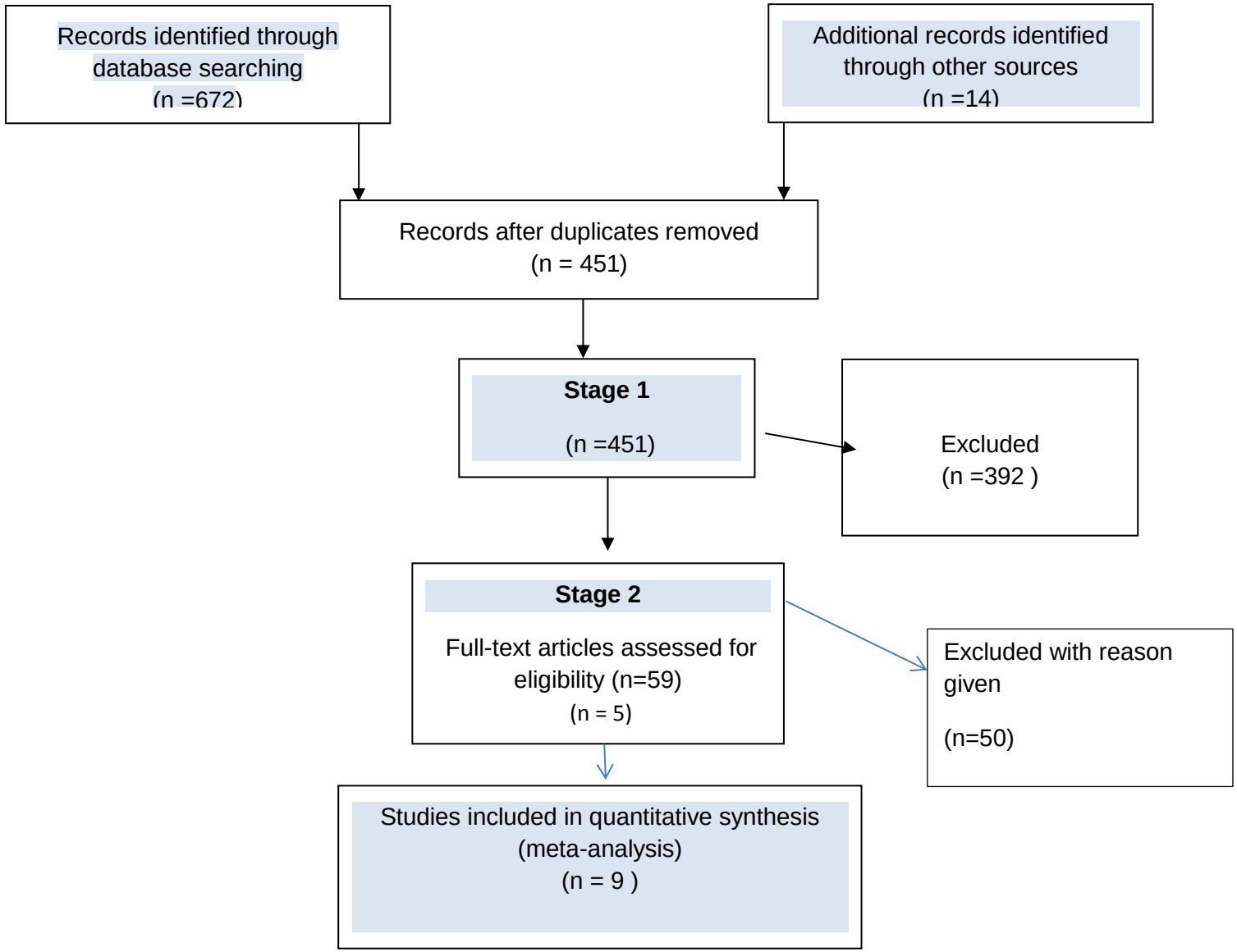
39.Mahmood T.A.. (2003). Evaluation of an experimental midwife-led unit in Scotland. Journal of Obstetrics and Gynaecology; vol. 23 (no. 2); p. 121-129.	EMBASE PubMed		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
40.Maillefer, Françoise; de Labrusse, Claire; Cardia-Vonèche, Laura; Hohlfeld, 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.	BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
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.	**PubMed**	**Yes**	***Included**
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.	BNI		* pilot study Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
43.Nethery, Elizabeth; Gordon, Wendy; Bovbjerg, Marit L.; Cheyney, Melissa (2017). Rural community birth: Maternal and neonatal outcomes for planned community births among rural women in the united states, 2004-2009. Birth: Issues in Perinatal Care; p. No.	PsycoINFO BMI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
44.Tokiko Oish iA, B PhD, MPH, RN, CNM • Tomoko TamuraC PhD, RN, CNM, PHN Utako YamamotoD.(2017). Outcomes of blood loss post physiological birth with physiological management in the third stage of labour at a maternity home in Japan. Midwifery, New Zealand College of Midwives Journal • Issue 53. 23-25.	Searching		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.
45.Overgaard, Charlotte; Møller, Anna Margrethe; Fenger-Grøn, Morten; Knudsen, Lisbeth B; Sandall, Jane (2011). Freestanding midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women. BMJ open; vol. 1 (no. 2); p. e000262.			*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.
46.Offerhaus, Pien M.; Hukkelhoven, Chantal W. P .M.; de Jonge, Ank; van der Pal-de Bruin, Karin M.; Scheepers, Peer L. H.; Lagro-Janssen, Antoine L. M.(2013). Persisting rise in referrals during labor in primary midwife-led care in the Netherlands. Birth: Issues in Perinatal Care; vol. 40 (no. 3); p. 192-201.	PsycoINFO		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss.

47.Offerhaus, Pien M.; Otten, Wilma; Boxem-Tiemessen, Jolanda C.G.; de Jonge, Ank; van der Pal-de Bruin, Karin, M.; Scheepers, Peer L.H.; Lagro-Janssen, Antoine L.M. (2015). Variation in intrapartum referral rates in primary midwifery care in the Netherlands: A discrete choice experiment. Midwifery; vol. 31 (no. 4); p. e69.	BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
48.Schroeder, Elizabeth; Petrou, Stavros; Patel, Nishma; Hollowell, Jennifer; Puddicombe, David; Redshaw, Maggie; Brocklehurst, Peter (2012). 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. BMJ : British Medical Journal (Online); vol. 344 ; p. n.	BNI		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
49.Seijmonsbergen-Schermers, A. E.; Zondag, D. C.; Nieuwenhuijze, M.; Van den Akker, T.; Verhoeven, C. J.; Geerts, C.; Schellevis, F.; De Jonge, A. (2018). Regional variations in childbirth interventions in the Netherlands: a nationwide explorative study. BMC Pregnancy & Childbirth; vol. 18 (no. 1).	CINAHL Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
50.Sutton F; McLauchlan M; Virtue C. (2002). Primary maternity care outcomes in New Zealand: a comparison of midwife and medical practitioner care. New Zealand College of Midwives Journal; vol. 26 ; p. 5-8.	CINAHL		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss
51.Suzuki S.; Hiraizumi Y.; Satomi M.; Miyake H. (2011). Midwife-led care unit for 'low risk' pregnant women in a Japanese hospital. Journal of Maternal-Fetal and Neonatal Medicine; vol. 24 (no. 8); p. 1046-1050.	EMBASE Medline PubMed		Did not examine blood loss AM compared with EM
52.Symon, Andrew G.; Paul, Jeanette; Butchart, Maggie; Dugard, Pat (2007). Self-rated "No-" and "Low-" risk pregnancy: A comparison of outcomes for women in obstetric-led and midwife-led units in England. Birth: Issues in Perinatal Care; vol. 34 (no. 4); p. 323-330.	PsycoINFO BNI		Did not examine blood loss Did examine active compared with expectant management of the third stage of labour and the associate blood loss.
53.Kellie; Nickel, Nathan; Prior, Heather J.; Banerjee, Ankona; Morris, Margaret; Robinson, Kristine. (2016). Maternity outcomes in Manitoba women: A comparison between midwifery-led care and physician-led care at birth. Birth: Issues in Perinatal Care; vol. 43 (no. 2); p. 108-115.	PsycoINFO BNI		**Lower rates of PPH if cared for by a midwife in labour.** Did examine active compared with expectant management of the third stage of labour and the associate blood loss. *Did stated birth setting
54.Van Wagner, Vicki; Osepchook, Claire; Harney, Evelyn; Crosbie, Colleen; Tulugak, Mina (2012). Remote midwifery in Nunavik, Québec, Canada: outcomes of perinatal care for the Inuulitsivik Health Centre, 2000-2007. Birth; vol. 39 (no. 3); p. 230-237.	BNI Medline		*Did not examine active compared with expectant management of the third stage of labour and the associate blood loss

55.Voon ST; Lay JTS; San WTW; Shorey S; Lin SKS . (2017). Comparison of midwife-led care and obstetrician-led care on maternal and neonatal outcomes in Singapore: A retrospective cohort study. Midwifery;vol. 53 ; p. 71-79.	PubMed Medline CINAHL		*No statistically significant differences in postpartum haemorrhage. *Birth took place tertiary hospital not MLU
56.Wagner, Vicki; Osepchook, Claire; Harney, Evelyn; Crosbie, Colleen; Tulugak, Mina (2012). Remote Midwifery in Nunavik, Québec, Canada: Outcomes of Perinatal Care for the Inuulitsivik Health Centre, 2000-2007. Birth: Issues in Perinatal Care; vol. 39 (no. 3); p. 230-237.	CINAHL		*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
59.Zu Sayn-Wittgenstein F.M.; Bauer N.H. (2010). The GERMAN multicenter study - Midwife-led-care. Journal of Maternal-Fetal and Neonatal Medicine; vol. 23 ; p. 267.	EMBASE		*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



Appendix 5-Structure Literature Review One Critical appraisal table using CASP (2018b, c) tool

CASP (2018b) RCT Checklist	*Did the study ask a clearly focused question?*	Was the assignment of patients 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 trail?	Aside from the experimental interventions, were the groups treated equally?	How large was the treatment effect?	How precise was the estimated of the treatment effect? CI	Can the results be applied to the local population? Were all the clinically important outcomes considered?	Are the benefits worth the harms and cost?
Begley, Devane, Clarke, McCann, Hughes, Reilly, et al. (2011b). **Outcome PPH above 500mls**	**Yes** Compared midwife-led care versus consultant-led care (obstetric care) for women at low risk of childbirth complication iin Ireland.	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.	**Yes** Randomised process explained in paper.	**Not possible**	**Yes**	**Yes**	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). mall CI-**	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 (> 500: (8% to 4%); **High level of reliability and validity.**	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.	**Suggests that EM reasonable option for women at low risk and intending to birth in MLU.**

CASP (2018c) Cohort Study Checklist	**Did study address a clearly focused issue?**	**Was the cohort recruited in an acceptable way?**	**Was the exposure accurately measured to minimize bias?**	**-Was the outcome accurately measured to minimize bias?** ***- Did they use subjective or objective measurements?***	**Have the authors identified all important confounding factors?** **Have they take account of the confounding factors in the design and/or analysis?**	**Was the following up of subjects complete enough?** **Was the follow-up of subjects long enough?**	**What are the results of this study?** **How precise are the results?**	**Do you believe the results?**	**Can the results be applied to the local population?**	**Do the results of the study fit other available evidence?** **What are the implications of this study for practice?**
Davis, Baddock, Pairman, Hunter, Benn, Anderson, Dixon, Herbison, (2012)	**Yes** **To investigate the effect of place of birth on the risk of PPH and the effect of mode of manag. of the 3rd stage of labour on severe PPH (≥1000ml)** **To test the hypothesis that place of birth affects the risk of PPH.**	**Yes** **Retrospective** 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	Unable to blind participants. Participants practice both AM and EM. .	**Unable to blind** **Subject measures** **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	Analysis 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, length 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	**Yes**	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**	**No power calculation** **CI given for overall birth settings not just MLU.** **RR given** Severe PPH was higher in the women who received AM compared to those who received EM statistically significant across all birth settings.	**Yes** **<u>Conclusion</u>** Good level of reliability. Validity to women at low risk birthing in MLU, reduced CI and RR provided over all birth settings. <u>Generalisability:</u> Study sample can be applied to women at low risk of PPH birthing in a MLU.	In this study of low-risk women, those having AM had twice the risk of severe PPH >1000ml than those having EM. 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 no significant difference between AM and EM for blood loss ≥1000 mL **although the trend favours AM, whilst Davis favours EM.** States- result of study is congruent with the experiences of midwives in New Zealand.

		criteria. Outcomes of the study were attributed to the planned place of birth at the onset of labour.			stage anagement. 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.		**women versus 0.6%, 9 women).** -Although twice as many women in the EM group went on to have further (uterotonic) treatment for excessive blood loss compared with those in the AM(14.0% vs **7.3%).**			
CASP (2018c) Cohort Study Checklist	**Did study address a clearly focused issue?**	**Was the cohort recruited in an acceptable way?**	**Was the exposure accurately measured to minimize bias?**	**Was the outcome accurately measured to minimize bias?** ***- Did they use subjective or objective measurements?***	**Have the authors identified all important confounding factors?** **Have they take account of the confounding factors in the design and/or analysis?**	**Was the following up of subjects complete enough?** **Was the follow-up of subjects long enough?**	**What are the results of this study?** **How precise are the results?**	**Do you believe the results?**	**Can the results be applied to the local population?**	**Do the results of the study fit other available evidence?** **What are the implications of this study for practice?**
Dixon, Fletcher, Tracy, Guilliland, Pairman, Hendry, (2009).	**To assess and compare the two care pathways options for managing the 3rd stage of labour (AM EM) for all normal physiological births in the NZCOM dataset from 2004 to 2008.**	**Yes** **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	**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**	<u>Conclusion</u> Good level of reliability. Validity to women at low risk birthing 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 uint.	This 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

		criteria. 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.					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.	**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) **.**	<u>Generalisability</u> Study sample can be applied to women at low risk of PPH birthing in a MLU.	AM and EM for blood loss greater than 1,000 mL although the trend favours AM. Not statistically significance 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.

CASP (2018c) Cohort Study Checklist	**Did study address a clearly focused issue?**	**Was the cohort recruited in an acceptable way?**	**Was the exposure accurately measured to minimize bias?**	**Was the outcome accurately measured to minimize bias?** ***- Did they use subjective or objective measurements?***	**Have the authors identified all important confounding factors?** **Have they take account of the confounding factors in the design and/or analysis?**	**Was the following up of subjects complete enough?** **Was the follow-up of subjects long enough?**	**What are the results of this study?** **How precise are the results?**	**Do you believe the results?**	**Can the results be applied to the local population?**	**Do the results of the study fit other available evidence?** **What are the implications of this study for practice?**
Dixon, Tracy, Guilliland, Fletcher, Hendry.Pairman . (2013).	Analysed further the data from their 2009 study (Dixon et al., 2009).	**Yes Retrospective** The study analysed data collected from the New Zealand College of Midwives' research database for women giving birth in from 2004 to 2008. During this time period 33,752 women met the study inclusion criteria.	**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** Conclusion Good level of reliability. Validity to women at low risk birthing 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 uint. **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.**

							95% **CI: 0.5–0.6**). -Amongst women in the EM 3.7% had a blood loss of more than 500mL, compared to 6.9% in the AM group.			
CASP (2018c) Cohort Study Checklist	**Did study address a clearly focused issue?**	**Was the cohort recruited in an acceptable way?**	**Was the exposure accurately measured to minimize bias?**	**Was the outcome accurately measured to minimize bias?** ***- Did they use subjective or objective measurements?***	**Have the authors identified all important confounding factors?** **Have they take account of the confounding factors in the design and/or analysis?**	**Was the following up of subjects complete enough?** **Was the follow-up of subjects long enough?**	**What are the results of this study?** **How precise are the results?**	**Do you believe the results?**	**Can the results be applied to the local population?**	**Do the results of the study fit other available evidence?** **What are the implications of this study for practice?**
Fay, Hastis, Bisits, Marsh (2010)	Is 'holistic psychophysiol ogical 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.	**Yes Retrospective** -It collected and analysed data on all women classified as low risk of PPH who gave birth at a freestanding MLU from July 2005 to June 2008 and in a tertiary level maternity unit. In South Wales, Australia The tertiary level maternity unit consisted of an obstetric	Fahy et al. (2010) study reported that there were wide variations in how AM and holistic psychophysiol ogical (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 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.	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	**Yes** Number of women who had EM but then converted to EM not examined.	-Intention-to-treat analysis overall PPH rate 8.6%, blood loss of 500 mL to 1000 mL, and 1.8%, PPH more than 1000 mL. - PPH (500 mL or more) rate of 11.2% (344 of 3075 women) for AM intended 3rd stage management approach at the tertiary level unit compared with PPH rate of 2.8% (10 of	**No power calculation**	**<u>Conclusion</u>** Reduced validity- Number of women included in the study who birthed on freestanding MLU was small (361) compared to women who birthed in the tertiary unit (3075). Also on the MLU the number of women who received AM compared to EM was over six times smaller (48 versus 313); whilst on the tertiary unit the number of women who received EM	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. Fay 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.	unit and an alongside MLUData for the tertiary level maternity unit was collected from January 2006 to June 2008. -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.	mixed management is unknown, as the study was conducted retrospectively and the researchers did not have control over the interventions being investigated.				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 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.**	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 (2018) Cohort Study Checklist	Did study address a clearly focused issue?	Was the cohort recruited in an acceptable way?	Was the exposure accurately measured to minimize bias?	Was the outcome accurately measured to minimize bias? *- Did they use subjective or objective measurements?*	Have the authors identified all important confounding factors? Have they take account of the confounding factors in the design and/or analysis?	Was the following up of subjects complete enough? Was the follow-up of subjects long enough?	What are the results of this study? How precise are the results?	Do you believe the results?	Can the results be applied to the local population?	Do the results of the study fit other available evidence? What are the implications of this study for practice?
Grigg, Tracy, Tracy, Daellenbach, Kensington, Monk, Schmied, (2017)	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. One of the secondary outcomes: blood loss, 3rd stage of labour management, .	Prospective cohort study. 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.	Unable to blind participants. However, practice both AM and EM.	**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.	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.	**Number of women who had EM but then converted to EM not examined.**	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	**No power calculation given**	**<u>Conclusion</u>** 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	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 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. **Grigg study also found this.** The results of this research suggest a trend in a reduction of PPH 500-1000mls with EM compared to AM following a physiological labour,

					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.		compared to with 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. **slightly higher in MLU**	**500-999 mL unadjusted OR 0.84 (0.57 to 1.24) p=0.005 NS** **Adjusted OR 1.07 (0.70 to 1.61)* p=0.005 NS** blood loss 1000 or over) **unadjusted OR** 1.30 (0.65 to 2.60) **p=0.005 NS** **Adjusted OR** 1.74 (0.85 to 3.59 **p=0.005 NS**	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**, the rates of PPH similar in MLU and obs unit.**	but an increase in blood loss >1000mls with EM compared to AM.
CASP (2018) Cohort Study Checklist	**Did study address a clearly focused issue?**	**Was the cohort recruited in an acceptable way?**	**Was the exposure accurately measured to minimize bias?**	**Was the outcome accurately measured to minimize bias?** ***- Did they use subjective or objective measurements?***	**Have the authors identified all important confounding factors?** **Have they take account of the confounding factors in the design and/or analysis?**	**Was the following up of subjects complete enough?** **Was the follow-up of subjects long enough?**	**What are the results of this study?** **How precise are the results?**	**Do you believe the results?**	**Can the results be applied to the local population?**	**Do the results of the study fit other available evidence?** **What are the implications of this study for practice?**
Kataoka, Masuzawa, Kato, Eto(2018). After study -The Japanese guidelines for midwifery care management were revised in 2009 and 2014 (Japanese Midwives Association, 2014). Now if	**Yes-**The study compared the maternal and neonatal outcomes of low-risk women who gave birth in MLUs and hospitals in Japan**. Included** blood loss during the 3rd	Prospective cohort study. Tokyo, Japan. 9,588 women who were defined as at low risk of obstetric complications (including PPH) who had a spontaneous vaginal birth at	Unable to blind participants. However, practice both AM and EM.	**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.	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	Outcomes were analysed according to actual place of birth and used logistic regression analysis to compare outcomes at the birth centres with hospital outcomes, adjusting for	Number of women who had a PPH over 500 mL, or over 1000 mL, was higher in the MLU where the women received EM compared to the hospital obstetric units, where women received AM	**No 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	Reliability Important confounding factors not identified Analysis conduced Based on place of birth not risk factor for PPH. i.e. regarding AM and EM and PPH. Birth weight of baby parity. maternal BMI.unsure how	Finding same as 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 Same as RCT and Cochrane reviews who

women at risk of a PPH, midwives can use uterotonics 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.	stage of labour or shortly after birth. Women who birthed on MLU received EM whilst the women who birthed in the hospital obstetric units received AM	19 MLU and 2 hospital obstetric units. Data was collected from maternity computerised records for women who birthed at MLU from 2001 to 2006; for women who birthed at one of hospital's obstetric unit from 2004 to 2006; and for women who birthed at the other hospital's obstetric unit over a 12 month period from 2008 to 2009.			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.	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 to1.64, *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 Validity: presence of confounders, **Overestimated risk of PPH with EM-in MLU unable to convert to AM if excessive blood loss.**	analyses women at low risk of PPH 2000, 2010, 2011, 2015, 2019 increased PPH (≥1000ml) with However, **Kataoka, found that this difference was statistically significant.** **<u>Generalisability</u>** **AM reduced risk PPH. However, risk of EM and PPH in MLU should not be overestimated due to change in guideline since study.**

CASP (2018c) Cohort Study Checklist	**Did study address a clearly focused issue?**	**Was the cohort recruited in an acceptable way?**	**Was the exposure accurately measured to minimize bias?**	**Was the outcome accurately measured to minimize bias?** ***- Did they use subjective or objective measurements?***	**Have the authors identified all important confounding factors?** **Have they take account of the confounding factors in the design and/or analysis?**	**Was the following up of subjects complete enough?** **Was the follow-up of subjects long enough?**	**What are the results of this study?** **How precise are the results?**	**Do you believe the results?**	**Can the results be applied to the local population?**	**Do the results of the study fit other available evidence?** **What are the implications of this study for practice?**
Laws, Xu,, Welsh., Tracy, Sullivan (2014).	To examine maternal morbidity related to birth center care (MLU) for women in New South Wales. Maternal. Outcomes examined in the study included PPH (defined as blood loss more than 500 mL). Conducted in New South Wales, Australia,	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.	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	**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.	**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.	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.	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]), CI **[95% CI 0.74–0.85**	<u>Conclusion</u> Reliability Does not examine AM versus EM and PPH. It examined Intended place of birth and PPH and intended place if birth and 3rd stage of labour Mange. (AM or EM). <u>Generalisability:</u> 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.**	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.

CASP (2018c) Cohort Study Checklist	Did study address a clearly focused issue?	Was the cohort recruited in an acceptable way?	Was the exposure accurately measured to minimize bias?	Was the outcome accurately measured to minimize bias? *- Did they use subjective or objective measurements?*	Have the authors identified all important confounding factors? Have they take account of the confounding factors in the design and/or analysis?	Was the following up of subjects complete enough? Was the follow-up of subjects long enough?	What are the results of this study? How precise are the results?	Do you believe the results?	Can the results be applied to the local population?	Do the results of the study fit other available evidence? What are the implications of this study for practice?
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	Prospective cohort study. New South Wales, Australia Participants had low risk, singleton pregnancies and were at less than 28_{+0} weeks gestation at the time of booking. Inclusion and exclusion criteria defined	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. 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.**				Analysis of data was by intention-to-treat with outcomes attributed to planned place of birth at the time of booking. PPH 500-999 MLU 9.7% compared with 15.4% at obs unit. P=0.031 Stat sign !000 MLU 3.6 compared with 4.4 at obs unit P=0.168 not stat sign 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.**	<u>Generalisability:</u> 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.**	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.

	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 if birth and 3rd stage of labour Mange. (AM or EM).**		

Appendix 6- Structure Literature Review Two database search table

References	Database	Included	Reason Excluded
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	PubMed		Did not explore midwives experiences, regarding the third stage of labour.
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.	**Medline CINAHL EMABSE BNI PubMed**	**YES**	**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).**
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	CINAHAL EMBASE PsycINFO BNI PubMed		Did not explore midwives experiences, regarding the third stage of labour.
4.Davis D.; Herbison P.; Wilson D.; Baddock S.; Pairman S.; Hunter M.; Benn C.; Anderson J.; Dixon L. . (2011). Comparing active and physiological management of third stage of labour in a cohort of low risk women in the care of midwives in New Zealand. Journal of Paediatrics and Child Health; Apr 2011; vol. 47 ; p. 19	EMBASE		Did not explore midwives experiences, regarding the third stage of labour.

5.De Groot, A N; van Roosmalen, J; van Dongen, P. (1996). Survey of the management of third stage of labour in The Netherlands.(1996). European journal of obstetrics, gynecology, and reproductive biology; May 1996; vol. 66 (no. 1); p. 39-40.	Medline		STUDY EXAMINES The standard practice during the third stage of labour of Dutch midwives and obstetricians was elucidated by a questionnaire mailed to all Dutch midwives and obstetricians. **Midwives 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.
6.Dencker, Anna; Smith, Valerie; McCann, Colette; Begley, Cecily. (2017). BMC Pregnancy & Childbirth; Mar 2017; vol. 17 ; p. 1-8. Midwife-led maternity care in Ireland - a retrospective cohort study.	CINAHL		Did not explore midwives experiences, regarding the third stage of labour.
7.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 & Birth; Dec 2010; vol. 23 (no. 4); p. 146-152.	CINAHL PubMed EMBASE		Did not explore midwives experiences, regarding the third stage of labour.
8.Farrar, Diane; Tuffnell, Derek; Airey, Rebecca; Duley, Lelia. (2010). Care during the third stage of labour: a postal survey of UK midwives and obstetricians. BMC pregnancy and childbirth; May 2010; vol. 10 ; p. 23	Medline		Examines current UK practice during the third stage of labour. A postal survey ofv2230 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 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.

9.Feeley C. (2018). What evidence informs midwifery clinical practice when women make birthing decisions that are outside of guidelines?-An empirical study of UK midwives working in the NHS. BMJ Evidence-Based Medicine; Jun 2018; vol. 23	EMBASE		Did not explore midwives experiences, regarding the third stage of labour.
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	PubMed CINAL		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.
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.	BNI		Did not explore midwives experiences, regarding the third stage of labour. Also a low income country-
12..Harding JE; Elbourne DR; Prendiville WJ (1989).Views of mothers and midwives participating in the Bristol randomized, controlled trial of active management of the third stage of labor. Birth (Berkeley, Calif.); Mar 1989; vol. 16 (no. 1); p. 1-6	**PubMed**	**YES***	
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	**Medline CINAHL EMBASE PubMed**	**YES***	**Explored Swedish midwives' experiences of management of third stage of labour.**

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.	Medline HMIC		**Did not explore factors that midwives feel influence their practice during the third stage of labour.**
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	**Medline**	**Yes**	**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.**
16.Prick B.W.; Steegers E.A.P.; Duvekot J.J.; Vos A.A.; Hop W.C.J.; Bremer H.A.. (2013). The current state of active third stage management to prevent postpartum hemorrhage: A cross-sectional study. Acta Obstetricia et Gynecologica Scandinavica; Nov 2013; vol. 92 (no. 11); p. 1277-1283	EMBASE		**Did not explore midwives experiences, regarding the third stage of labour.**
17.Schack, Stina Mannheimer; Elyas, Amna; Brew, Gladys; Pettersson, Karen Odberg (2014). Experiencing challenges when implementing Active Management of Third Stage of Labor (AMTSL): a qualitative study with midwives in Accra, Ghana. BMC Pregnancy and Childbirth; Jun 2014; vol. 14 (no. 193); p. 10	BNI PubMed		**Low income country.**
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 & Women's Health; Jul 2018; vol. 63 (no. 4); p. 446-454.	CINAHL EMBASE BNI PubMed		The purpose of this study was to describe variables that influence US midwives' and physicians' management of the third stage of labor. Methods The extent of influence was defined in terms of always to never altering management. Discussion: This study identifies variables reported as influencing clinical decision making during the third stage of labour. Did not explore midwives experiences, regarding the third stage of labour.

19.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 & Women's Health; Jan 2017; vol. 62 (no. 1); p. 58-67.	CINAHL EMBASE BNI PubMed		The purpose of this study was to determine routine practice patterns for managing the third stage of labour in the United States. Explored midwives practice regarding components regarding active management of the third stage of labour. Did not explore factors that midwives feel influence their practice during the third stage of labour.
20.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 & Women's Health; Mar 2015; vol. 60 (no. 2); p. 187-198.	**CINAHL EMBASE PsycINFO BNI PubMed**	**YES**	**This study obtained preliminary data for the development of a national study of interventions used by US birth attendants during the third stage of labor, work that will ultimately lead to a study examining links between activities and outcomes The specific aims were to identify provider-reported assessments and interventions used during the third stage of labor and to examine which management steps or interventions providers believe should always be used during the third stage of labor.**
21.Schorn M.N.; Dietrich M.S.; Donaghey B.; Minnick A.F.. (2016). A national study of the active management of the third stage of labor standards: Adherence and variations among US midwives and physicians. Journal of Midwifery and Women's Health; 2016; vol. 61 (no. 5); p. 662	EMBASE		Conference Abstract for Schorn et al (2015) study
22.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	Medline CINAHL		STUDY investigate current knowledge and practice regarding AMTSL in midwifery practices and obstetric departments in the Netherlands. Reason why excluded: Did not explore views regarding third stage management of labour or factors that midwives feel influence their practice during the third stage of labour.

23.Tan WM; Klein MC; Saxell L; Shirkoohy SE; Asrat G (2008).How do physicians and midwives manage the third stage of labour? Birth: Issues in Perinatal Care; Sep 2008; vol. 35 (no. 3); p. 220-229.	CINAHL BNI PsycINFO PubMed		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 labour; 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.
24.Tenaw, Zelalem; Yohannes, Zemenu; Amano, Abdela. (2017). Obstetric care providers' knowledge, practice and associated factors towards active management of third stage of labor in Sidama Zone, South Ethiopia. BMC Pregnancy & Childbirth; Sep 2017; vol. 17 ; p. 1-7.	CINAHL	NO	LOW INCOME COUNNTRY
25.Smit M.; van Roosmalen J.; Slootweg Y.; van Stralen G.; Wolterbeek R.; van Dillen J. . (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 To investigate current knowledge and practice regarding AMTSL in midwifery practices and obstetric departments in the Netherlands postal questionnaire. Setting: in August and September 2011 a questionnaire was sent to all midwifery practices and all obstetric departments in the Netherlands.	EMBASE BNI PubMed		Did not explore midwives views regarding third stage management approaches or factors that midwives feel influence their practice during the third stage of labour.

Words used “midwives”, “midwife”, third stage of labour” “study”

Inclusion criteria	Exclusion criteria
Midwife/midwives experience of third stage approaches of labour	Any other outcome examined
Midwives practising in high income countries	Midwives practising in low income countries
Factors midwives/midwife feel influence their practice during the third stage of labour	

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

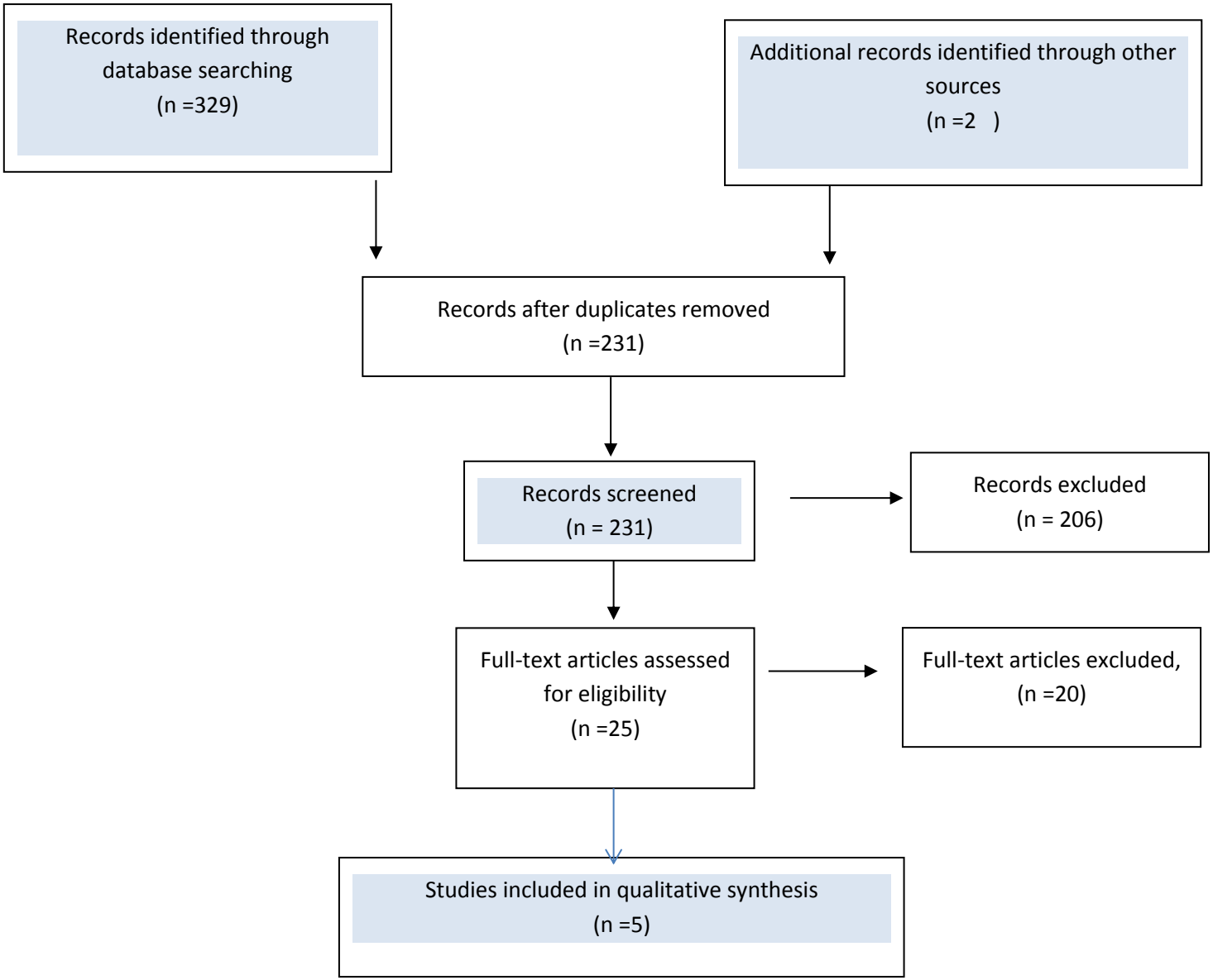
Then inclusion exclusion criteria used.

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



Appendix 8- Structure Literature Review Two Critical appraisal table using CASP (2018d) tool

Evaluation criteria for qualitative research CASP (2018d) Study	**Was there a clear statement of the aims**	**Is qualitative methodology appropriate**	**Design appropriate to address aim**	**Appropriate recruitment Strategy**	**Appropriate data collection**	**Appropriate consideration of researcher/ participant role?**	**Ethical issues/ Funding ?**	**Sufficient rigour of data analysis?**	**Clear statement of findings?**	**How valuable is the research?**
Begley, C., Guilliland, K., Dixon, L., Reilly, M., Keegan, C. (2012). .	**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.**	**Yes** **Mixture of interviews and focus grous.-** 11 individual interviews and 1 focus-group with 7 participants. **Advances of both methods**.	**Yes**	**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%.	**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 during interview.	**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.** Reflexivity- Yes- acknowledges theoretical standpoint of all authors (in favour, generally EMTSL for low-risk, consenting women) as a possible influencing factor on data collection, analysis and interpretation.	**Yes** Paper states ethical approval gained.	**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. *Confirmability* – Yes-Data analysed by more than one researcher The lead author's analysis was checked by 'peer debriefing'-The other 4 authors analysed 2 transcripts each and compared findings. Draft results were returned to participants to ensure researchers' interpretations resonated with them. Dependability- yes	**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.' Transparent-Yes search process clearly documented.	**Yes** Researcher discusses contribution study makes to existing knowledge or understanding and possible further research. Relevance-yes Explored expert midwives views who working in MLU. Transferability- results transferable to other settings- midwives working in other MLU, but also midwives providing care in other birth settings. Transparent-Yes search process clearly documented. The study is trustworthy Yes - methodological soundness. Trustworthiness of the study's findings. **However, did not explore AM. NZ midwives-continuity of carer. working in hospital Ireland-new concept MLU. Well established in UK? MLU where study conducted?**

Evaluation criteria for qualitative research (CASP, 2018d) **Study**	**Was there a clear statement of the aims**	**Is qualitative methodology appropriate**	**Design appropriate to address aim**	**Appropriate recruitment Strategy**	**Appropriate data collection**	**Appropriate consideration of researcher/ participant role?**	**Ethical issues/ Funding ?**	**Sufficient rigour of data analysis?**	**Clear statement of findings?**	**How valuable is the research?**
Jangsten, Hellstrom and Berg (2010)	**Yes** To explore midwives' experiences of management of the third stage of labour. AM- The Swedish Guidelines (2001) for Care in Normal Birth recommend that all women giving birth vaginally should be given prophylactic intravenous injection of oxytocin as soon as the infant is born, D do not recommend the entire AM.	**Yes**	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) ,**	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 > 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**	**No** 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.**	Ethical approval gained.	*Confirmability*-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. Not clear if more than one person contributed to this process of data analysis or if categories generated were agreed my participants. Not as rigours as Begley	Midwives' reflections on management of the third stage of labour summarised in three categories. Quotes from the interviews illustrate the content in each subcategory. 'Bring the process under control' Protect normality and women's birthing experiences' 'Maintain midwives' autonomy',	**Yes** Researcher discusses contribution study makes to existing knowledge or understanding and possible further research. 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)

Evaluation criteria for qualitative research CASP (2018d) Study	**Was there a clear statement of the aims**	**Is qualitative methodology appropriate**	**Design appropriate to address aim**	**Appropriate recruitment Strategy**	**Appropriate data collection**	**Appropriate consideration of researcher/ participant role?**	**Ethical issues/ Funding ?**	**Sufficient rigour of data analysis?**	**Clear statement of findings?**	**How valuable is the research?**
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**	**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 8 woman–midwife pairs in a large region in New Zealand in late 2009 and 2010. Midwives were the midwife for the woman and had been in practice 2 or more years. Midwife participants were self-selected. The midwife participants then recruited a woman from their caseloads. Women were 18 years or older, this was their first or subsequent pregnancy and they were between 34and 37 weeks gestation. Numbers limited because of time constraints and the large amount of qualitative data collected.	Yes 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	**Yes** Ethical consent gained. Issues considered.	**Yes** Transcripts analysed using thematic analysis Braun and Clarke (2006) 6 stage guide. Analysis process discussed examples of data in the codes given. *Confirmability*-data collection and analysis outlined. Transcripts and themes discussed with the other researchers. 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 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. . The study is trustworthy

Evaluation criteria for qualitative research CASP (2018d) Study	**Was there a clear statement of the aims**	**Is qualitative methodology appropriate**	**Design appropriate to address aim**	**Appropriate recruitment Strategy**	**Appropriate data collection**	**Appropriate consideration of researcher/ participant role?**	**Ethical issues/ Funding ?**	**Sufficient rigour of data analysis?**	**Clear statement of findings?**	**How valuable is the research?**
Schorn, M. N.; Minnick, A. Donaghey, B. (2015) . . .	**Yes** To identify certified nurse-midwives', certified professional midwives', obstetricians', and family practice physicians' assessments and interventions used during the 3rd stage of labour. It also aimed to examine which management steps or interventions these practitioners believed should always be used during the 3rd stage of labour.	**Yes**	**Yes** Focus groups using a nominal group technique. **Groups focus-difficult to discuss midwives reviews regarding 3d stage care (sensitive issues) ,**	Purposive sample of 22 participants among 4 groups. **No certified midwives available to include.** Inclusion criteria attendance of at least 1 birth in the last year. Exclusion criteria included birth attendants other than these 4 groups who did not attend formal education program and all providers still in a learner role. 4-10 participants in a provider category volunteered and convenient meeting was arranged. Group size restricted to allow for opportunity for participation by each attendee. **Lack of certified midwives may influence findings.**	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 .	**No** Reflexivity- No Effect of researchers on study not discussed. However 2 researchers involved in data analysis. .	**Yes**	**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. . Transparent-Yes search process clearly documented	**Yes** Midwives and physicians identified factors such as maternal history, pregnancy and the current labour as affecting their management of 3rd stage of labour. The midwives identified that patient preferences would also impact on their management of 3rd stage.	**Yes** Project was 1st step to determine actions that midwifery and physicians providers in US use to manage 3rd stage of labour. obtain preliminary data for nation wide study. Relevance-Although participants conducted births inclusion criteria-only needed to have conduced 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

Study	What was the research question and was a questionnaire appropriate for answering it|?	Was the questionnaire used valid and reliable?	What did the questionnaire look like, and was it appropriate for target population?	Were the instructions clear?	Was the questionnaire adequately piloted?	What was the sample?	How was the questionnaire administered- and was the response rate adequate	How were data analysed?	What were the main results?	What were the key conclusions?
Harding, Elbourne and Prendiville (1989) .	**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	Reliable. Limited validity/ value as many consisted of multiple choice questions, with a short space to add comments.	Yes	Yes	No Not stated	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.	Opportune sample. Women on postnatal wards whilst research on there.	Data collection: Data for the study was collected via administered questionnaire	Both mothers and midwives commented negatively on the length of time EM took. suggestt 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.	Views of mother not taken into account regarding 3td 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

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

Appendix 10: Head of Midwifery approval for Study One

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.

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

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 identied 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 Huddersield'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 have 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.

University of HUDDERSFIELD
Inspiring global professionals

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 sub-ordinates, 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 identiifed 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 Huddersield'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 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?

Appendix 14: University School Research and Ethics Panel (SREP)

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

NHS
Health Research Authority

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

Email: hra.approval@nhs.net

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 insitititonal birth setting**

IRAS 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 detail 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

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

VE ABOU

Chairman: Andrew Haigh Chief Executive: Owen Williams

SO*N*

INVESTORS IN PEOPLE

*LE*D 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 Categporisation 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

NHS
Calderdale and Huddersfield
NHS Foundation Trust

Research & Development Department
Block 1, Basement Corridor
(South Drive Entrance)
Huddersfield Royal Infirmary
Lindley, Huddersfield
West Yorkshire, HD3 3EA
Telephone: 01484 343966
Email: r&d@cht.nhs.uk

08 August 2017

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

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 HRA 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:

Document	Version	Dated
Notification of Non-Substantial/Minor Amendments		31 July 2017
HRA Email Approval		02 August 2017
Protocol (tracked changes)	3	31 July 2017

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 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.

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 identied 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 Huddersield'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, anticipant 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 Emai

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 ceratin midwives who work on the birth centre been approached to ask to participant 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 you're their 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 identied 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 Huddersield'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

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 Thank you for your time Karen Baker

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 taking consent	Date	Signature

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 choice one approach over the other.