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ORIGINAL RESEARCH

Severe adverse maternal and neonatal outcomes according to the planned birth setting being midwife-led birth centers or obstetric-led units

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Abstract

Introduction: The establishment of midwife-led birth centers (MLBCs) is still being debated. The study aimed to compare severe adverse outcomes and mode of birth in low-risk women according to their birth planned in MLBCs or in obstetric-led units (OUs) in France.

Material and Methods: We used nationwide databases to select low-risk women at the start of care in labor in MLBCs ($n=1294$) and in OUs ($n=5985$). Using multilevel logistic regression, we compared severe adverse maternal and neonatal morbidity as a composite outcome and as individual outcomes. These include severe postpartum hemorrhage (≥ 1000 mL of blood loss), obstetrical anal sphincter injury, maternal admission to an intensive care unit, maternal death, a 5-minute Apgar score < 7 , neonatal resuscitation at birth, neonatal admission to an intensive care unit, and stillbirth or neonatal death. We also studied the mode of birth and the role of prophylactic administration of oxytocin at birth in the association between birth settings and severe postpartum hemorrhage.

Results: Severe adverse maternal and neonatal outcome indicated a slightly higher rate in women in MLBCs compared to OUs according to unadjusted analyses (4.6% in MLBCs vs. 3.4% in OUs; cOR 1.36; 95%CI [1.01–1.83]), but the difference was not significant between birth settings after adjustment (aOR 1.37 [0.92–2.05]). Severe neonatal morbidity alone was not different (1.7% vs. 1.6%; aOR 1.17 [0.55–2.47]). However, severe maternal morbidity was significantly higher in MLBCs than in OUs (3.0% vs. 1.9%; aOR 1.61 [1.09–2.39]), mainly explained by higher risks of severe postpartum hemorrhage (2.4 vs. 1.1%; aOR 2.37 [1.29–4.36]), with 2 out of 5 in MLBCs partly explained by the low use of prophylactic oxytocin. Cesarean

Abbreviations: aOR, adjusted odds ratio; AUDIPOG, Association des Utilisateurs de Dossiers informatisés en Pédiatrie, Obstétrique et Gynécologie; BMI, body mass index; CI, confidence interval; cOR, crude odds ratio; MDN, maison de naissance (MLBC in French); MLBC, midwifery-led birth center; NICE, National Institute for Health and Care Excellence; OR, odds ratio; OU, obstetric-led unit; PPH, postpartum haemorrhage.

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and operative vaginal births were significantly decreased in women with a birth planned in MLBCs.

Conclusions: In France, 3 to 4% of low-risk women experienced a severe adverse maternal or neonatal outcome regardless of the planned birth setting. Results were favorable for MLBCs in terms of mode of birth but not for severe postpartum hemorrhage, which could be partly addressed by revising practices of prophylactic administration of oxytocin.

KEYWORDS

adverse neonatal outcome, low-risk women, midwifery unit, midwifery-led birth center, postpartum hemorrhage, spontaneous birth

1 | INTRODUCTION

Midwife-led birth centers (MLBCs) are dedicated to low-risk women with straightforward pregnancies and physiological labors.^{1,2} In many high-income countries, although most births occur in hospital units, MLBCs are integrated into the perinatal health care system and concern 1.8% of births in Australia³ and up to 15% in England.⁴ Maternal and neonatal outcomes in MLBCs have been assessed in several comparative studies. Regardless of the study design, they demonstrate favorable outcomes for care provided in MLBCs compared to obstetric-led units (OUs), with a lower risk of interventions such as labor augmentation with oxytocin, episiotomy, cesarean, or operative deliveries.^{3,5-9} Regarding neonatal morbidity, most studies showed no statistically significant differences in Apgar scores and neonatal death rates.^{3,5,6} However, reaching a definitive conclusion about maternal morbidity remains challenging because the selection of outcomes in studies, particularly in a low-risk population, can be criticized. While most studies did not show any difference in maternal intensive care unit admission rates between MLBCs and OUs,^{3,5-7} the criteria for assessing severe postpartum hemorrhage (PPH) vary widely between studies, ranging from severe to very severe.^{3,5,10} Except in Scarf et al.,⁵ severe PPH is not defined using clinically recognized international criteria, and the frequency of prophylactic administration of oxytocin is never reported. In this context, the establishment of MLBCs remains controversial in some countries, and is often hindered.¹¹

In France, MLBCs are a recent development, with the first facilities opening in 2016 as part of a 5-year pilot program.^{12,13} There are eight MLBCs, all legally modeled as alongside MLBCs (located inside or adjacent to an obstetric-led unit with direct access for rapid transfer in case of emergency), each facilitating approximately 600 births annually, out of a total of 750 000 national births. In this experimental context, a descriptive analysis of all women with a birth planned in a MLBC during 2018 and 2019 was conducted (Chantry AA et al. *Intrapartum and delivery care and outcomes in midwife-led birth centers in France: a nationwide descriptive study and an analysis of risk factors for maternal and neonatal transfers. Unpublished data*). The results were reassuring and aligned with those reported in international studies: low intervention rates, such as less than 2% episiotomies, and low to very low rates of perinatal complications (0.5% obstetric anal sphincter injury, 1.7%

Key Message

In this study, 3%–4% of low-risk women experienced at least one severe adverse maternal or neonatal outcome. Midwife-led birth centers had favorable results for mode of birth but not for postpartum hemorrhage compared to obstetric-led units.

neonatal resuscitation). However, the descriptive nature of the study and the absence of a control group prevented the authors from drawing conclusions regarding the safety of MLBCs.

The French National Perinatal Surveys (*Enquête Nationale Périnatale - ENP*) conducted in 2016 provide a reliable control group to address the question of the safety of MLBCs.¹⁴ These surveys are regular population-based cross-sectional studies that include all births (live births and stillbirths) in all maternity units in France over a 1-week period. The data are available and sufficiently accurate to select low-risk women. They enable the assessment of relevant clinical outcomes, particularly maternal outcomes such as postpartum hemorrhage, using several indicators.

The main objectives of our analysis were to assess severe adverse maternal and neonatal outcomes and mode of birth in low-risk women with a birth planned at the start of care in labor in an MLBC compared to an OU. Another objective was to explore the role of prophylactic administration of oxytocin as an intermediate factor in the association between planned birth setting and severe PPH.

2 | MATERIAL AND METHODS

2.1 | Study design

We conducted an analysis comparing severe adverse maternal and neonatal outcomes in low-risk women according to their planned birth setting in France: MLBCs or OUs, using two nationwide population-based surveys.

2.2 | Data sources

Data came from two distinct databases.

- The electronic AUDIPOG database, which includes medical charts of all women with a birth planned in any MLBC in France regardless of the final birth setting (MLBC or OU in case of transfer).¹⁵ We used data from January 1, 2018 to December 31, 2019.
- The 2016 French National Perinatal Survey, which includes data from medical charts of women with a birth planned in all OUs during a 1-week period in March 2016.¹⁴ This nationwide population-based cross-sectional study included all live births and stillbirths from 22 weeks' gestation or with a birthweight exceeding 500g.

The exhaustiveness of both databases was assessed by cross-referencing with administrative birth certificates and the French national hospital discharge database.

2.3 | Study population

We excluded from these datasets women who were not considered low-risk as per the National Institute for Health and Care Excellence (NICE) guidelines for the identification of healthy women with

low-risk pregnancies.¹⁶ We used NICE guidelines instead of French guidelines for risk assessment during pregnancy to more closely align with international standards. Specifically, the study included women with singleton cephalic pregnancies who delivered after 37 weeks of amenorrhea following spontaneous labor, had no pre-pregnancy medical conditions, no history of complications in previous pregnancies, and no complications in the current pregnancy, as defined by UK guidelines and detailed in the supplementary files (Appendix S1).

In the dataset of women with a birth planned in a MLBC, this excluded a few women at the beginning of pregnancy (15/1725: 10 women with a body mass index (BMI) > 35 kg/m², 1 with a previous stillbirth, and 4 with chronic disease) and 375 women during pregnancy (375/1710) (Figure 1). In the dataset of women with a planned birth in an OU, this excluded 2804 women at the beginning of pregnancy (2804/13240) and 4238 women during pregnancy (4238/10436). Lastly, we excluded women who gave birth outside a MLBC or an OU and in overseas French territories without MLBCs because women's profiles and care organizations are very different from those on the mainland.

2.4 | Outcomes

Outcomes were consensually defined in agreement with members of the MDN Research group, which included researchers and

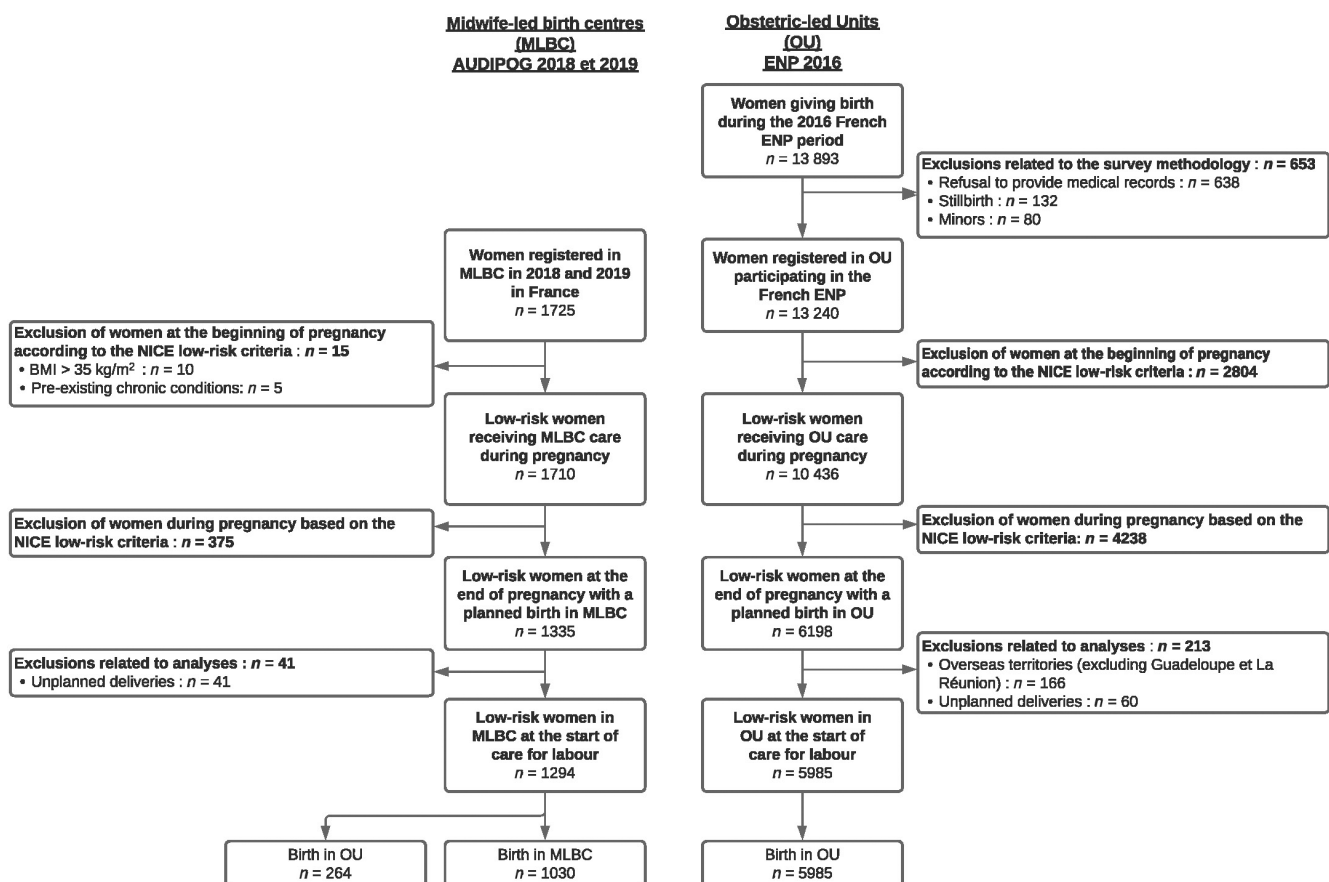


FIGURE 1 Flow Chart.

representatives from obstetricians, midwives, pediatricians, anesthesiologists, midwives from MLBCs, and perinatal services users.

The primary outcome was a composite criterion for severe adverse maternal and neonatal outcomes, including at least one of the following issues: severe PPH (considered as blood loss over 1000 mL +/- red blood cell transfusion +/- secondary procedure); obstetrical anal sphincter injury; maternal admission to an intensive care unit; maternal death; an Apgar score under 7 at 5 min; the need for neonatal resuscitation maneuvers at birth (including intubation, cardiac massage, or adrenalin injection); neonatal admission to an intensive care unit; and stillbirth or neonatal death. This primary composite outcome was then split into two distinct secondary outcomes: (1) severe maternal morbidity composite outcome, including all previously detailed severe maternal complications and (2) severe neonatal morbidity composite outcome, including all previously detailed severe neonatal complications. Lastly, each of the outcomes of the composite was independently analyzed.

The secondary outcome was the mode of birth, assessed in three categories: spontaneous vaginal birth, operative vaginal birth, and cesarean birth.

2.5 | Studied covariates

Maternal characteristics included: age in years (<25; [25–30]; [30–35]; ≥35), BMI in kg/m² (<18.5; [18.5–25]; [25–30]; ≥30), nationality (French, other European countries, African countries, other), educational level (undergraduate and graduate, postgraduate), and living with a partner or not. Obstetric characteristics included parity (primiparous, multiparous), gestational age at birth in weeks of amenorrhea ([37–37+6]; [38–38+6]; [39–39+6]; [40–40+6] and ≥41), and fetal macrosomia defined as a birth weight exceeding 4000 g. The prophylactic administration of oxytocin provided at birth was also studied, as it is recommended in France for all women to prevent PPH and consists in the intravenous or intramuscular administration of 5 or 10 IU of oxytocin within 5 min of delivery.¹⁷

2.6 | Statistical analyses

Analyses respected the planned birth setting at the start of care in labor (MLBCs vs. OUs). Thus, women who initially planned birth at the start of care in a MLBC and transferred to an OU during labor were analyzed in the MLBC group.

We described maternal and obstetric characteristics using numbers and percentages and compared them between groups using chi-squared or Fisher's exact tests, as appropriate. We assessed associations between primary and secondary outcomes and the planned birth setting at the start of care in labor (MLBCs or OUs) using univariate and multivariate multilevel logistic regression models. A multilevel analysis was chosen to account for the hierarchical structure of the data and to address the lack of

independence among women managed in the same birth setting (MLBCs or OUs). The first level was the women's characteristics and the second level was the birth setting. Factors considered for adjustment included maternal age, prepregnancy BMI, nationality, educational level, family status, and parity. These factors were selected on an a priori hypothesis based on literature and using a directed acyclic graph (Appendix S2). The interaction tested with parity was non-significant. Variables pertaining to labor management or labor complications were not included in the models as they were considered to be intermediate factors in the association between planned birth setting and severe adverse outcomes (Appendix S2).

The proportion of women with missing data for any covariate of the multivariable model ranged from 0 to 7%. The characteristics of women with complete data were similar to those of women with missing data (data not shown). A missing at random hypothesis was plausible, so we used multiple imputation chained equations according to Rubin's rules to generate 10 imputed data sets. Results are presented with the imputed data, and associations are expressed as adjusted odds ratios (aORs) with 95% confidence intervals (CIs).

Based on previous results showing a prophylactic administration of oxytocin of 17% in MLBCs versus 93% in the general French population in OUs,¹⁵ we investigated the contribution of prophylactic administration of oxytocin as an intermediate factor in the association between the planned birth setting and severe PPH using a pathway analysis. Following Buis et al.'s methodology,¹⁸ we decomposed the total effect of the planned birth setting on severe PPH into an indirect effect mediated by prophylactic administration of oxytocin and a direct (or residual) effect not mediated by it. This method of analysis addresses the question: "What would be the risk of severe PPH in MLBCs if women had the same probability of receiving prophylactic oxytocin in MLBCs as in OUs?" Direct and indirect effects of the planned birth setting on severe PPH, mediated by prophylactic administration of oxytocin, were estimated using a logistic regression model with the same covariates as in the main analysis.

Lastly, we performed a sensitivity analysis to control the possible indication bias, i.e., the possibility that the planned birth setting be influenced by some of the women's characteristics, despite all being considered low-risk. We estimated a propensity score including maternal age, BMI, nationality, educational level, family status, and parity. The inverse probability of treatment weighting based on estimated propensity scores was used to obtain a synthetic population in which planned birth setting was independent of measured baseline covariates. Imbalance was checked by calculating standardized mean differences before and after applying the inverse probability of treatment weighting (Appendix S3). The association between planned birth setting and severe adverse maternal and neonatal composite outcome was assessed using Odds Ratios and 95% CIs, without further adjustment. Statistical significance was set at two-tailed $p < 0.05$, and analyses were performed with Stata 15 (Stata Corp., College Station, TX, USA).

3 | RESULTS

We compared 1294 low-risk women with a birth planned at the start of care in labor in MLBCs to 5985 low-risk women with a birth planned at the start of care in labor in OUs (Figure 1). Among the 1294 women in MLBCs at the start of care in labor, 1030 gave birth in MLBCs (79.6%) and 264 were transferred and gave birth in OUs (20.4%). Among the 5985 women in OUs at the start of care in labor, 100% gave birth in OUs. Although women were considered low-risk in both groups, their profiles were different: women in MLBCs were significantly older, more frequently primiparous, and gave birth more often beyond 41 weeks of amenorrhea compared to those in OUs (all $p < 0.001$) (Table 1).

Univariate analyses showed a slightly significant higher rate of severe adverse maternal and neonatal outcomes in women with a birth planned at the start of care in labor in MLBCs compared to OUs (respectively 4.6 and 3.4%; crude OR 1.36; 95% CI [1.01–1.83]). This association was no longer significant between groups in the multilevel multivariate analysis with multiple imputation (aOR 1.37; 95% CI [0.92–2.05]) (Table 2). When independently assessed, severe maternal morbidity was significantly higher in women with a birth planned at the start of care in labor in MLBCs compared to OUs: 3.0 vs. 1.9%; aOR 1.61; 95% CI [1.09–2.39] (Table 2). This was primarily due to severe PPH, followed by lower proportions of obstetrical anal sphincter injuries and maternal intensive care unit admissions. Severe PPH accounted for 80% of the severe maternal morbidity outcome for low-risk women with a birth planned at the start of care in labor in MLBCs, compared to 60% for those in OUs. The odds of severe PPH were higher for low-risk women with birth planned at the start of care in labor in MLBCs compared to OUs (2.4 vs. 1.1%; aOR 2.37; 95% CI [1.29–4.36]). There was no significant association between severe neonatal morbidity and birth planned at the start of care in labor (1.7 vs. 1.6%; aOR 1.17; 95% CI [0.55–2.47]). When independently assessed, all criteria that composed the severe neonatal morbidity composite outcome did not differ between groups.

Concerning the mode of birth, compared with women in OUs, women with a birth planned at the start of care in labor in MLBCs were more likely to have a spontaneous vaginal birth (89.3 vs. 81.1%; aOR 3.19; 95% CI [2.20–4.61]) and were less likely to have a cesarean birth (2.6 vs. 5.7; aOR 0.41; 95% CI [0.27–0.62]) or an operative birth (6.6 vs. 13.2%; aOR 0.34; 95% CI [0.23–0.52]).

Results showed that prophylactic oxytocin was administered after birth to 28% of women with a birth planned at the start of care in labor in MLBCs, compared to 88% in the OU group. Path analysis indicated that the estimated percentage of indirect effect was 39% (95% CI [5%–82%]), meaning that 39% of the total risk of severe PPH associated with planned birth in a MLBC was mediated by prophylactic administration of oxytocin (Table 3). Analysis of the indirect effect showed that when prophylactic administration of oxytocin is considered as a mediator factor (i.e., if women in MLBCs received prophylactic administration of oxytocin at the same rate as in OUs), the relationship between planned birth in MLBCs and severe PPH was no longer significant (aOR 1.34; 95% CI [0.97–1.85]).

Lastly, results of the sensitivity analysis using the propensity score were similar to those in the main analysis for all the outcomes (Appendix S4).

4 | DISCUSSION

In France, severe adverse maternal and neonatal outcomes were observed in 3 to 4% of low-risk women, with no significant difference between MLBCs and OUs after adjustments for confounders. There was no difference in severe neonatal morbidity between the groups. However, for women, we showed an increased risk of severe PPH when birth was planned at the start of care in labor in a MLBC compared to an OU. Path analyses demonstrated that 2 out of 5 severe PPH in MLBCs could be explained by the low frequency of prophylactic administration of oxytocin in these centers. Low-risk women with a birth planned at the start of care in labor in an MLBC were more likely to have a spontaneous birth and less likely to have a cesarean birth or an operative birth than low-risk women with a birth planned in an OU.

Our analysis of the nationwide population-based control group provides valuable insights into the incidence of severe adverse maternal and neonatal outcomes within the specific population of low-risk women in France. The data can be considered representative of midwifery and obstetric practices in MLBCs and OUs in France since both databases were national in scope, encompassing all births that occurred in all centers across the country during the specified timeframes (8 MLBCs and 501 maternity units). Data exhaustiveness was cross-referenced with administrative birth certificates and the French national hospital discharge database. The quality of data was also ensured. In MLBCs, all studied maternal and neonatal outcomes were verified in medical files and birth registries. In OUs, data was prospectively collected within the maternity units by trained midwives employed specifically for data collection.¹⁴ Data transparency was maintained by providing results for both the composite outcome and the individual outcomes. For our comparison, outcomes were defined in collaboration with clinicians and users of perinatal services within the framework of collaborative research. A precise and rigorous selection of low-risk women in each group was performed by applying the NICE criteria to each database. Analyses of outcomes were based on the planned place of birth at the start of care in labor, mimicking the conditions of an 'intention-to-treat' analysis, and thus limiting interpretation biases. This analytical strategy ensures rigorous, unbiased, and transparent comparisons between groups. Multilevel multivariate analyses did not completely eliminate residual confounding bias, particularly given the variations in women's characteristics based on birth setting, but propensity score analyses also have limitations due to imperfect matching between groups (Appendix S3). However, in this specific study where a randomized controlled trial is not feasible, our analyses using sophisticated statistical methods may constitute the most appropriate approach to analyze the available data and produce reasonably interpretable results. Lastly, with the path analysis, we specifically examined the

TABLE 1 Description of maternal and obstetrical characteristics according to the planned birth setting at the start of care in labor: Midwife-led birth centers or Obstetric-led units.

	Midwife-led birth centers <i>n</i> = 1294 <i>n</i> (%) $\mu \pm \text{et}$ [min-max]	Obstetric-led units <i>n</i> = 5985 <i>n</i> (%) $\mu \pm \text{et}$ [min-max]	Total <i>n</i> = 7279 <i>n</i> (%) $\mu \pm \text{et}$ [min-max]	<i>p</i> -value
<i>Maternal characteristics</i>				
Maternal age (years)	32.4 \pm 4.3 [18-45]	29.7 \pm 5.0 [18-46]	30.2 \pm 5.0 [18-46]	
<25	42 (3.2)	886 (14.8)	928 (12.7)	<0.001
[25-30]	283 (21.9)	2063 (34.5)	2346 (32.2)	
[30-35]	567 (43.8)	2001 (33.4)	2568 (35.3)	
≥ 35	392 (30.3)	1031 (17.2)	1423 (19.5)	
NA	10 (0.8)	4 (0.1)	14 (0.2)	
Body Mass Index (kg/m ²)	21.8 \pm 3.2 [14.5-34.9]	22.8 \pm 3.7 [14.2-34.9]	22.6 \pm 3.7 [14.2-34.9]	
<18.5	114 (8.8)	458 (7.7)	572 (7.9)	<0.001
[18.5-25]	954 (73.7)	3785 (63.2)	4739 (65.1)	
[25-30]	119 (9.2)	986 (16.5)	1105 (15.2)	
≥ 30	36 (2.8)	331 (5.5)	367 (5.0)	
NA	71 (5.5)	425 (7.1)	496 (6.8)	
Nationality				
French	1163 (89.9)	4894 (81.8)	6057 (83.2)	<0.001
European	40 (3.1)	217 (3.6)	257 (3.5)	
African	3 (0.2)	411 (6.9)	414 (5.7)	
Other	31 (2.4)	102 (1.7)	133 (1.8)	
NA	57 (4.4)	361 (6.0)	418 (5.7)	
Educational level				
\leq high school degree	119 (9.2)	2328 (38.9)	2447 (33.6)	<0.001
> high school degree	1084 (83.8)	3260 (54.5)	4344 (59.7)	
NA	91 (7.0)	397 (6.6)	488 (6.7)	
Family status				
Partnered	1235 (95.4)	5333 (89.1)	6568 (90.2)	0.012
Single mother	45 (3.5)	292 (4.9)	337 (4.6)	
NA	14 (1.1)	360 (6.0)	374 (5.1)	
<i>Obstetrics characteristics</i>				
Parity				
Primiparous	684 (52.9)	2740 (45.8)	3424 (47.0)	<0.001
Multiparous	603 (46.6)	3245 (54.2)	3848 (52.9)	
2nd	427 (33.0)	2136 (35.7)	2563 (35.2)	
3rd	133 (10.3)	772 (12.9)	905 (12.4)	
≥ 4 th	43 (3.3)	337 (5.6)	380 (5.2)	
NA	7 (0.5)	0 (0.0)	7 (0.1)	
Term at delivery (WoA)				
[37-37+6]	36 (2.8)	321 (5.4)	357 (4.9)	<0.001
[38-38+6]	118 (9.1)	800 (13.4)	918 (12.6)	
[39-39+6]	345 (26.7)	1807 (30.2)	2152 (29.6)	
[40-40+6]	499 (38.6)	2093 (35.0)	2592 (35.6)	
≥ 41	290 (22.4)	962 (16.1)	1252 (17.2)	
NA	6 (0.5)	2 (0.0)	8 (0.1)	
Macrosomia (g)				
≥ 4000	78 (6.0)	355 (5.9)	433 (5.9)	0.530
NA	76 (5.9)	2 (0.0)	79 (1.1)	

Abbreviation: WoA, weeks of amenorrhea.

TABLE 2 Association between planned birth setting at the start of care in labor and severe adverse maternal and neonatal outcomes, univariate and multivariate analyses.

	Midwife-led birth centers	Obstetric-led units	p-value	Univariate analysis		Multivariate analysis ^a	
	n = 1294 n (%)	n = 5985 n (%)		crude OR [CI 95%]	adjusted OR [CI 95%]		
Composite primary outcome							
Severe adverse maternal and neonatal outcome	59 (4.6)	203 (3.4)	0.042	1.36	[1.01–1.83]	1.37	[0.92–2.05]
Outcomes included in the primary outcome							
Severe maternal morbidity	39 (3.0)	113 (1.9)	0.011	1.61	[1.12–2.34]	1.61	[1.09–2.39]
Severe PPH ^b	31 (2.4)	68 (1.1)	0.001	2.14	[1.39–3.28]	2.37	[1.29–4.36]
OASIS	9 (0.7)	43 (0.7)	0.878	0.95	[0.46–1.94]	-	-
ICU admission	0 (0)	8 (0.1)	-	-	-	-	-
Maternal death	0 (0)	0 (0)	-	-	-	-	-
Severe neonatal morbidity	22 (1.7)	94 (1.6)	0.530	1.16	[0.73–1.86]	1.17	[0.55–2.47]
Resuscitation maneuvers at birth	17 (1.3)	43 (0.7)	0.034	1.84	[1.05–3.24]	4.43	[0.95–20.78]
Apgar score <7 at 5 min	5 (0.4)	36 (0.6)	0.414	0.69	[0.27–1.76]	-	-
NICU admission	4 (0.3)	20 (0.3)	0.887	0.92	[0.32–2.71]	-	-
Stillbirth or neonatal death	1 (0.1)	1 (0.0)	0.233	-	-	-	-
Secondary outcome							
Cesarean birth	33 (2.6)	340 (5.7)	<0.001	0.44	[0.31–0.63]	0.41	[0.27–0.62]
Operative vaginal birth	85 (6.6)	791 (13.2)	<0.001	0.47	[0.37–0.59]	0.34	[0.23–0.52]
Spontaneous vaginal birth	1156 (89.3)	4853 (81.1)	<0.001	2.28	[1.87–2.79]	3.19	[2.20–4.61]

Abbreviations: ICU, Intensive care unit; NICU, Neonatal Intensive care unit; OASIS, Obstetric anal sphincter injury.

^aMultivariate multilevel logistic regression on imputed data. Adjusted for maternal age, BMI, nationality, educational level, family status and parity; Reference: Obstetric-led units.

^bSevere PPH: severe post-partum hemorrhage (1000 mL blood loss +/- red blood cell transfusion +/- secondary procedure).

TABLE 3 Estimation of the contribution of prophylactic administration of oxytocin as an intermediate factor in the relation between planned birth setting at the start of care in labor and severe postpartum hemorrhage by path analysis.

Planned birth setting at the start of care Midwife-led birth centers versus Obstetric units (ref.)	Severe postpartum hemorrhage	
	crudeOR [CI 95%]	adjustedOR ^a [CI 95%]
Total effect	2.09 [1.26–3.49]	2.10 [1.24–3.54]
Indirect effect mediated by prophylactic administration of oxytocin	1.40 [1.07–1.83]	1.34 [0.97–1.85]
Residual effect not mediated by prophylactic administration of oxytocin	1.50 [1.02–2.21]	1.56 [1.03–2.37]
% Indirect effect	45% [11–79]	39% [5–82]

^aAdjusted for maternal age, BMI, nationality, educational level, family status, and parity.

role of prophylactic administration of oxytocin in the association between MLBCs and severe PPH. This analysis added substantial value by identifying opportunities to improve practices. Such information will be useful for clinicians, allowing them to better inform women about the risks associated with their low-risk pregnancy.

This study also presents some limitations. Due to the recent development of MLBCs in France, our analyses were based on a sample of 1294 low-risk women with a birth planned in a MLBC at the start of care in labor over a 2-year period. Therefore, we cannot entirely dismiss the potential lack of statistical power in drawing conclusions regarding non-significant associations in rare adverse outcomes,

such as those concerning newborns. However, the frequencies of severe neonatal morbidity were closely matched (1.6 vs. 1.7%) and aligned with existing literature, suggesting no significant difference in adverse neonatal outcomes according to the birth setting.⁶ We also conducted post hoc power calculations. The association with the severe adverse maternal and neonatal primary outcome, as well as with severe maternal morbidity and severe neonatal morbidity, can be interpreted with a power of approximately 60%. Our calculations suggest that including 3500 women in the MLBC group would be necessary to detect a significant difference with 80% power for severe neonatal morbidity. This analysis would represent

the inclusion of 6 years of activity in all French MLBCs. In contrast, associations between the planned place of birth at the start of care in labor and mode of birth, or PPH found in our analyses, can be interpreted with a power exceeding 95%. Data were collected in 2018 and 2019, and to date, they still constitute the only consolidated database of planned births in MLBCs in France. We selected data from the 2016 French National Perinatal Survey as it represented the most readily accessible nationwide control sample, which was aligned in terms of data collection timing with those of the MLBCs. Obstetric practices and women's profiles did not notably change between 2016 and 2018/2019, providing a useful comparative sample.

The frequency of the severe adverse maternal and neonatal composite outcome is low in absolute terms (3 to 4 per 100 births) but demonstrates that it still exists in a highly selected population. This finding underlines the importance of (i) a rigorous selection of low-risk women, (ii) qualified midwives for childbirth with regular training in PPH management, and (iii) the establishment of a well-defined transfer system from MLBCs to OUs based on clear criteria shared by both teams. While this frequency cannot be directly compared to the literature, where indicators of morbidity in MLBCs are usually reported individually,^{3,5,6} our work provides an overall approach that includes severe adverse maternal and neonatal outcomes. This approach can be relevant for informing women and assisting them in their decision-making processes.

Women with a birth planned at the start of care in labor in a MLBC were more likely to have a spontaneous vaginal birth and less likely to have an operative vaginal birth or a cesarean birth than women in an OU. These results were consistent with international literature.^{3,5-8} The lower number of interventions in MLBCs compared to OUs could be explained by the philosophy of care employed in MLBCs. This philosophy emphasizes a women-centered care approach, tailored to the physical, psychological, and social needs of women. It promotes a model of autonomy in decision-making and fosters a quiet atmosphere that generates a climate of trust, thereby enhancing physiological responses.^{1,19-24} Indeed, Sandall et al. demonstrated significantly lower risks of operative and cesarean births in midwifery-led continuity models of care compared to standard models of care in a meta-analysis based on 15 randomized clinical trials including 17 674 women.²⁵ Beyond the mode of birth, a midwifery model of care also shows benefits on maternal mental health, which is a major concern for women's health in the postpartum period.²⁶

To examine the role of parity in the association between planned birth setting and the primary outcome, we tested the interaction between these three variables. This analysis showed no significant interaction, thus supporting our decision to consider parity as a covariate in the adjusted analyses instead of stratifying by parity. Beyond this statistical consideration, the test suggested that the association between planned place of birth and the primary outcome did not differ according to parity. This result aligns with findings from the Birthplace study conducted in England, which found that parity had no effect on adverse outcomes for births planned in MLBCs (either alongside or freestanding), unlike those planned at home.⁶

The incidence of severe neonatal morbidity did not differ between MLBCs and OUs, whether we examined the composite outcome or individual categories. Except for the study conducted by Homer et al.,³ these findings align with existing literature and underscore the quality of care provided to fetuses and newborns in MLBCs.^{5,6,8}

Our findings on maternal morbidity showed a significant increase in the risk of severe PPH in women with a birth planned in MLBCs compared to OUs (2.4% vs. 1.1%), a result not documented in existing literature.^{3,5-7,27} However, the definitions of severe PPH used in previous studies lacked homogeneity and described PPH at various levels of severity. Some studies defined PPH with a 500mL threshold of blood loss,⁷ while others use a combination of clinical symptoms and red blood cell transfusion,³ transfer to a higher level of care,¹⁰ or red blood cell transfusion alone.⁶ Some of these criteria can be criticized due to the wide variation in their application across countries, which depends on clinicians' practices and women's characteristics.²⁸⁻³¹ For instance, using red blood cell transfusion alone as a criterion appears to be a poor indicator of severe PPH, especially in a low-risk population where such events are rare.^{32,33} To address this limitation, we used a combined definition (blood loss exceeding a threshold of 1000mL and/or red blood cell transfusion and/or surgical procedure). This approach aligns more closely with the consensual standards set by the World Health Organization, which recommends the visual assessment of bleeding to accurately estimate the severity of hemorrhage.³⁴ Only Scarf et al. used a similar definition in their meta-analysis and reported a severe PPH frequency of 1.3%, with no difference between MLBCs and OUs.⁵ Differences in practices in MLBCs between France and the 10 countries included in this meta-analysis could explain the higher rate of severe PPH found here. Indeed, while the prophylactic administration of oxytocin is recognized as effective in preventing PPH, even among low-risk women, and is recommended by the World Health Organization, its utilization remains low in French MLBCs.^{15,35} Unfortunately, the rate of prophylactic administration of oxytocin was not mentioned in previous studies on MLBCs, preventing us from making comparisons and confirming our hypothesis. Nonetheless, our path analysis suggests that the low rate of prophylactic administration of oxytocin contributes to the risk of severe PPH in MLBCs. This result should raise awareness of its underutilization in MLBCs. Understanding this underutilization using qualitative research tools would provide a complementary perspective to improve practices and achieve the goal of a more systematic prophylactic administration of oxytocin in MLBCs in accordance with guidelines.

5 | CONCLUSION

Severe adverse maternal and neonatal outcomes affect 3-4% of low-risk women. Although neonatal outcomes were reassuring, we cannot exclude a slightly increased maternal risk explained by a higher incidence of severe PPH in MLBCs, partly attributed to a low uptake of prophylactic administration of oxytocin at birth. This highlights areas for improvement in PPH prevention according to World Health

Organization guidelines. We also found a lower risk of cesarean and operative vaginal birth when birth is planned in a MLBC compared to an OU. Our findings could help women enhance their autonomy in choosing their birth setting and encourage policymakers to promote the development of MLBCs in France.

AUTHOR CONTRIBUTIONS

Clara Rollet participated in the project design, performed the statistical analyses, interpreted the results, drafted the manuscript, and edited the final manuscript under the supervision of Anne Alice Chantry and Camille Le Ray. Béatrice Blondel was in charge of the 2016 French National Perinatal Survey and Françoise Vendittelli of the AUDIPOG data base. All authors, including the MDN Research Group, read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ETHICS STATEMENT

AUDIPOG was approved by the French Data Protection Authority (Commission Nationale de l'Informatique et des Libertés, approval no. 95-2623). The 2016 French National Perinatal Survey was approved by the French Data Protection Authority (Commission Nationale de l'Informatique et des Libertés, approval no. 915197), the National Council on Statistical Information on July 3, 2015 (Comité du Label, approval no. 2016X703SA), and the French Institute of Health and Medical Research Ethics Committee on January 14, 2016 (INSERM Ethics Committee approval no. IRB00003888 no. 14-191). Oral consent was obtained from the participants.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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