

Appendix A. Validation of the denominator

We took a random sample of 100 women from our cohort of women without one of the eight predefined major risk factors in the obstetrician-led care group in order to gain insight in how often these women actually had risk factors that were not registered in the PRN database. The rationale for this is that for the obstetrician-led care group, registration of risk factors is not mandatory in the PRN database, in contrast to the midwife-led care group (reason for referral). Similarly we took a random sample of 100 women from our cohort of women without any indication for obstetrician-led care, according to the Dutch obstetrics indication list, in order to determine whether we were able to reliably retrieve this information from the PRN database.¹ In all samples, case notes were assessed by a primary care and secondary care professional from our research team. We then modified the denominator for the percentage of misclassifications for our primary outcome of intrapartum and neonatal mortality within 28 days of birth, and presented our primary outcome for both the unmodified and the modified denominator.

Results

The validity check for women without major risk factors showed that 13/98 (13%, 95% CI 7-20%) of women in obstetrician-led care had a major risk factor that was not recorded in PRN. In this select 'low risk' obstetrician-led care group there were also 12/98 (12%, 95% CI 6-19%) women who were transferred during labour and would therefore be in the primary midwife-led care group according to our definition. The high discrepancy in level of care at onset of birth was an important new finding, as a previously performed validity check by our group in our overall cohort (including high risk patients) showed only 1.8% (95% CI 0-5) misclassification in level of care at onset of birth. The low risk subgroup in the obstetrician-led care group is probably at higher risk for misclassification due to a higher risk of being referred from midwife- to obstetrician led care (high risk women already had a pre-labour indication for obstetrician-led care). We incorporated this finding in our validation analysis. Modification of the denominator based on these two validity check findings generated incidences of 0.62‰ (30/48,035) and 0.25‰ (2/7,918) and did not significantly alter our results (OR 2.5; 95% CI 0.6-10.4), nor when we used the minimum or maximum value of the 95% CI of the modified denominator (OR between 2.0 and 3.0; Table A.1).

Table A.1 Relative risk of intrapartum and postpartum (<28 days) mortality for onset of labour in midwife-led versus obstetrician-led care for the unmodified and modified denominator

Outcome	Midwife-led care	Obstetrician-led care	p-value	Crude odds ratio (95% CI)
A. Unmodified denominator				
Intrapartum and neonatal mortality	30/46,764 (0.64‰)	2/10,632 (0.19‰)		3.41 (0.82-14.28)
B. Modified denominator				
Intrapartum and neonatal mortality	30/48,035 (0.62‰)	2/7,918 (0.25‰)		2.47 (0.59-10.35)

*Modification based on mean values of validity check for misclassification of 'line of care at start labor' (12%) and underreporting of risk factors (13%) in PRN database.

Using the lower and upper limits of the 95% CI of the validity check did not significantly alter our findings (min OR 2.0 with 95% CI of 0.5-8.4 and max OR 3.0 with 95% CI of 0.7-12)

Our group first intended to also use a second definition of low risk, which included women without any medical indication (including those not directly related to perinatal mortality, e.g. previous preterm birth) for obstetrician-led care. A validity check within this group showed an underreporting of medical indications in 35/95 (37%,95% CI 27%-47%; 5 missing records) of test files, which limited the validity of conducting analyses using this group and we decided to further remove this patient subgroup from our analyses.

*LVR is an acronym for the Dutch “Landelijke verloskundige registratie” which translates as “National obstetrics registration

Reference

1. Eskes M, Waelput AJ, Erwich JJ, Brouwers HA, Ravelli AC, Achterberg PW, et al. Term perinatal mortality audit in the Netherlands 2010-2012: a population-based cohort study. *BMJ open*. 2014;4(10):e005652.

Appendix B

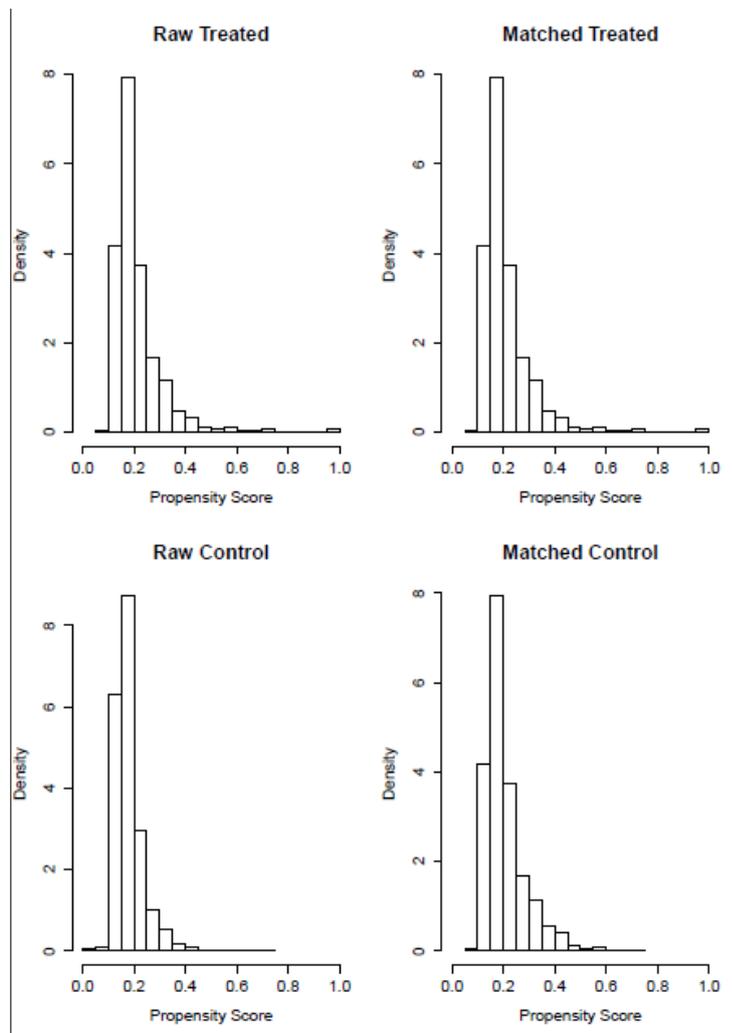


Figure B.1

Plot propensity scores before and after matching for the treated (obstetrician-led care) and control (midwife-led care) groups.

Appendix C

Table C.1 Timing and most relevant clinical condition for all perinatal deaths in pregnancies without major risk factors (in parentheses the additional perinatal deaths from pregnancies **with** major risk factors for the midwife-led care group).

Most relevant clinical condition	Midwife-led Care				Obstetrician-led care	Total
	Died at home	Died in hospital after referral in suspected poor condition*	Died in hospital after referral in suspected acceptable condition*	Mortality (probably) not directly related to birth	Good perinatal condition upon arrival at Hospital	Total
Asphyxia of unknown cause	4 ^[a]	8 ^[b,c] (+2) ^[d]	4		1	17 (+2)
Meconium aspiration syndrome		1 ^[e]				1
Asphyxia nuchal cord		1				1
Perinatal infection		1	2 (+3) ^[f]	2	1	6 (+3)
Cord prolapse		2 (+1) ^[g]				2 (+1)
Placental abruption		1				1
Uterine rupture			1			1
Velamentous cord insertion bleeding		1 (+1) ^[h]				1 (+1)
Sinus transversus thrombosis				1		1
Postpartum death of unknown cause, after initially good neonatal condition				1		1
Total	4	15 (+4)	7 (+3)	4	2	32 (+7)

* referral either pre- or postnatal

[a] including one unsupervised homebirth

[b] in 2 cases the fetal condition was considered good at the moment of referral but poor at the moment of arrival in secondary care

[c] 1 suspected velamentous cord insertion bleeding

[d] 2 additional deaths in pregnancies with major risk factors (PROM, Hypertension)

[e] unsupervised homebirth, initially good condition, several hours later hypothermia and acute cardiac arrest, obduction: asphyxia, meconium aspiration syndrome with persisting pulmonary hypertension.

[f] 3 additional deaths in pregnancies with major risk factors (PROM, unexpected breech, postdate pregnancy)

[g] 1 additional death in a pregnancy with a major risk factor (unexpected breech)

[h] 1 additional perinatal death, bleeding of placenta praevia (risk factor vaginal bleeding 2nd half of pregnancy)

Appendix D

Table D.1-D.3: Sensitivity analyses

1. Including women in the midwife-led care group with one or more of the pre-identified risk factors. Odds ratio of intrapartum and postpartum (<28 days) mortality for onset of labour in midwife- versus obstetrician-led care.

Outcome	Midwife-led care N=53,123	Obstetrician-led care N=10,632	Odds ratio (95% CI)
Intrapartum and neonatal mortality	37 (0.70‰)	2 (0.19‰)	3.71 (0.89-15.37)

* 7 additional deaths: prolonged rupture of membranes (n=2), unexpected breech (n=2), hypertensive disorder (n=1), vaginal bleeding (n=1) and postdate pregnancy (n=1).

2. Excluding cases that were not registered in the PRN or lacking information from primary care. We present the odds ratio of intrapartum and postpartum (<28 days) mortality for onset of labour in midwife- versus obstetrician-led care

Outcome	Midwife-led care N=44,691	Obstetrician-led care N=10,632	Odds ratio(95% CI)
Intrapartum and neonatal mortality	24 (0.54‰)	2 (0.19‰)	2.86 (0.67-12.08)

3. Including all deaths in which we were unable to differentiate between antepartum and intrapartum death to explore the unlikely possibility that all of these deaths were intrapartum. Odds ratio of intrapartum and postpartum (<28 days) mortality for onset of labour in primary versus secondary care.

Outcome	Midwife-led care N=46,764	Obstetrician-led care N=10,632	Odds ratio(95% CI)
Intrapartum and neonatal mortality	42 (0.90‰)	4 (0.38‰)	2.39 (0.86-6.66)