

BMJ Open A prospective cohort study of the morbidity associated with operative vaginal deliveries performed by day and at night

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ABSTRACT

Objective: To evaluate maternal and neonatal outcomes associated with operative vaginal deliveries (OVDs) performed by day and at night.

Design: Prospective cohort study.

Setting: Urban maternity unit in Ireland with off-site consultant staff at night.

Population: All nulliparous women requiring an OVD with a term singleton fetus in a cephalic presentation from February to November 2013.

Methods: Delivery outcomes were compared for women who delivered by day (08:00–19:59) or at night (20:00–07:59).

Main outcome measures: The main outcomes included postpartum haemorrhage (PPH), anal sphincter tear and neonatal unit admission. Procedural factors included operator grade, sequential use of instruments and caesarean section.

Results: Of the 597 women who required an OVD, 296 (50%) delivered at night. Choice of instrument, place of delivery, sequential use of instruments and caesarean section did not differ significantly in relation to time of birth. Mid-grade operators performed less OVDs by day than at night, OR 0.60 (95% CI 0.43 to 0.83), and a consultant supervisor was more frequently present by day, OR 2.26 (95% CI 1.05 to 4.83). Shoulder dystocia occurred more commonly by day, OR 2.57 (95% CI 1.05 to 6.28). The incidence of PPH, anal sphincter tears, neonatal unit admission, fetal acidosis and neonatal trauma was similar by day and at night. The mean decision to delivery intervals were 12.0 and 12.6 min, respectively.

Conclusions: There was no evidence of an association between time of OVD and adverse perinatal outcomes despite off-site consultant obstetric support at night.

INTRODUCTION

Operative vaginal delivery (OVD) accounts for more than 10 000 births in Ireland each year and between 12% and 15% of all deliveries in the UK.^{1 2} The goal of a vacuum or

Strengths and limitations of this study

This cohort study included detailed data on all operative vaginal deliveries performed by all grades of operators, reflecting the entire spectrum of obstetric care within a busy maternity unit. The findings are generalisable to similar units in the UK and Ireland and this approach could be replicated in other settings and disciplines. A cluster randomised controlled trial addressing all aspects of emergency obstetric care would be required to determine whether an entirely on-site consultant obstetric workforce is justified.

forceps delivery is to expedite birth in the maternal and/or fetal interest, while simultaneously attempting to minimise delivery-related morbidity.^{3 4} Both instruments have advantages and disadvantages dependent on maternal, fetal, clinician and situational factors.^{3 5–7} In some circumstances, a caesarean section (CS) is the better option, although second stage caesarean is technically difficult and has important implications for subsequent deliveries.^{8–10} The decision when to intervene, where to deliver, which instrument to use, when to abandon the chosen instrument and whether to seek senior support are challenging elements of OVD.⁵ Doctors in training rely primarily on senior obstetricians to support their learning needs in terms of decision-making, and on the acquisition of technical and non-technical skills on the labour ward.^{5 11 12}

Childbirth and its complications do not differentiate between day and night. Yet fatigue, reduced out-of-hours resources and more limited access to senior obstetric support are factors that prevail when performing OVDs at night. Several studies have reported higher levels of morbidity and mortality in relation to operative interventions

performed outside routine working hours.^{13–15} Few studies to date have addressed OVD outcomes in relation to time of birth. The purpose of this study was to evaluate maternal and neonatal outcomes associated with OVDs performed by day and at night. The findings will contribute to the debate on safe obstetric care and workforce planning and have important implications for all surgical specialties where emergency care is required at night.

METHODS

The Coombe Women and Infants University Hospital, Dublin is a consultant-led university teaching hospital with between 8500 and 9000 deliveries annually. The OVD rate in 2012 was 15% (30% in nulliparae) and the CS rate was 27%. Maternal and neonatal care is provided by an interdisciplinary team of midwives, obstetricians, anaesthetists and paediatricians. Routine care on the labour ward is provided by midwives with medical rounds taking place twice daily at 08:00 and 17:00. Obstetricians in training are allocated to the labour ward and receive direct or indirect supervision depending on their level of experience and expertise. Consultant support is readily available between the hours of 08:00 and 20:00 when consultants are usually on-site. Consultants are likely to be off-site between the hours of 20:00 and 08:00 and provide an on-call service to the labour ward. In addition, consultants attend the delivery of private patients (approximately 15% of the overall caseload),¹⁶ and any consultant who is on the premises at the time of an emergency will provide immediate assistance. At night, there are either one or two obstetric trainees resident on-call, depending on experience, and one on-call consultant who is non-resident. Labour ward protocols for OVDs are in accordance with the RCOG Guidelines.³ The on-call consultant is expected to attend for all second stage CSs, all OVDs conducted in an operating theatre (complex procedures usually involving a malposition or mid-cavity station) and whenever the obstetric trainee (or senior midwife) requests support.

Cohort

All women who required an OVD were eligible for inclusion in the study if they were nulliparous (no previous delivery ≥ 24 weeks of gestation), with a live singleton pregnancy and a cephalic presentation at term (gestation of ≥ 37 weeks). A team of research midwives and obstetricians identified participants from daily labour ward records and the electronic maternity database. The recruitment period took place from 1 February 2013 to 19 November 2013. We recorded detailed data on each mother and baby up until the time of hospital discharge. The study was non-interventional and required no direct patient contact, and no request for follow-up information. Under these circumstances, we were not required

to seek individual written patient consent and were able to include all eligible women in the study.

Explanatory variables

Handwritten contemporaneous patient records and computerised obstetric and neonatal databases were consulted to complete individual case report forms for each participant. In addition, a detailed OVD proforma completed by the operator immediately following the delivery was assessed for procedural details and immediate delivery outcomes. Maternal and infant characteristics, labour and postnatal details and the outcome measures detailed below were entered in the data set by a research fellow, including morbidities up until the first hospital discharge.

Outcome measures

The primary outcome measures of interest were maternal and neonatal morbidities following OVDs occurring during the day (08:00–19:59) and at night (20:00–07:59). Maternal outcomes included postpartum haemorrhage (estimated blood loss >500 mL), third or fourth degree perineal tear (anal sphincter injury), shoulder dystocia and prolonged length of stay (>3 days). Neonatal outcomes included traumatic injury (excluding instrument marks and minor bruising), Apgar scores (subclassified as Apgar score of ≤ 3 at 1 min or <7 at 5 min), paired cord blood results (subclassified as arterial pH of <7.00) and neonatal intensive care unit (NICU) admission. Procedural factors included grade of operator, sequential use of instruments, more than three pulls with an instrument (s) and CS after abandoned or failed OVD. Obstetricians at the grade of senior house officer or junior registrar were classified as ‘junior operators’ and typically had between 1 and 3 years’ experience in obstetrics. Obstetricians at the grade of year 1–3 registrar were classified as ‘mid-grade’ operators and had between 3 and 6 years’ obstetric experience. Senior operators included trainees at the grade of registrar year 4 or above, and typically had between 6 and 10 years’ experience. Consultant operators varied, with between 10 and 30 years’ experience, some of whom had fixed daytime sessions on the labour ward. In all cases, where women were transferred to the operating theatre in the second stage of labour, an assessment was made to decide whether to attempt an OVD or to proceed to immediate CS.

Statistical analysis

The purpose of the cohort study was to gain insights on OVD from an entire population of affected women. A binary variable was created for time of OVD performed during the day (08:00–19:59) and at night (20:00–07:59). We used descriptive statistics for the maternal, neonatal, labour and delivery details to characterise the cohort in relation to the two time periods. Results were reported as ORs and 95% CIs. Multivariable logistic regression analyses were performed to address potential confounding

factors. Factors were chosen for the regression analyses primarily based on statistically significant differences between the two groups for baseline clinical and procedural variables. We also included choice of primary instrument as it is likely to have an important bearing on delivery outcomes. We estimated that we would have adequate statistical power to detect important differences in postpartum haemorrhage, third and fourth degree tears and neonatal unit admission.⁶ A sample size of 600 deliveries could detect an OR of 2.25 with 80% power and 5% significance level assuming a complication rate of 5% in the lower risk group. Data analysis was performed with the statistical package SPSS (V.20.0).

RESULTS

A total cohort of 597 nulliparous women consented for an OVD between February and November 2013. Of these, 9 women (1.5%) proceeded to a spontaneous vaginal delivery and 22 (3.7%) delivered by CS. The cohort was evenly divided between delivery by day (n=301; 50.4%) and at night (n=296; 49.6%). The peak times for OVD were 18:00–20:00 and 23:00–00:00, and the quietest time periods were 03:00–04:00 and 08:00–10:00 (figure 1). Maternal and neonatal characteristics are presented in table 1. Women with pre-eclampsia were less likely to deliver by day than at night, OR 0.29 (95% CI 0.09 to 0.91) and low birthweight babies (<2.5 kg) were more likely to deliver by day, OR 5.58 (95% CI 1.23 to 25.38). The maternal and neonatal characteristics of the cohort were otherwise similar in relation to time of birth. Labour characteristics and indication for OVD were similar except for induction of labour where women delivered more frequently at night (43% vs 56%; OR 0.59 (95% CI 0.43 to 0.81) for daytime delivery; table 2).

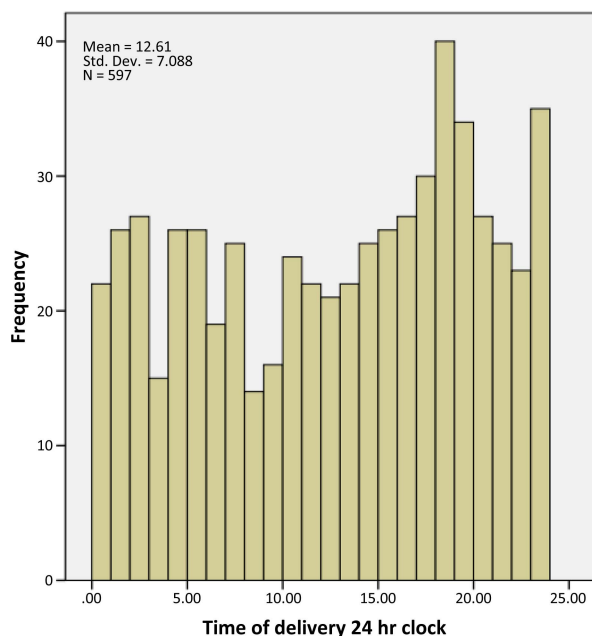


Figure 1 Operative vaginal deliveries performed throughout the 24-hour time period.

The primary instrument of choice for all OVDs was the Kiwi disposable vacuum (64.8%) followed by non-rotational forceps (26.5%) (table 3). More than half the deliveries were mid-station at each time period and similar proportions required rotation for a malposition. The grade of operator varied by time of birth with a higher proportion of OVDs performed by mid-grade operators at night (37.9% vs 50.4%; OR 0.60 (95% CI 0.43 to 0.83) for daytime delivery). A second operator was more likely to be involved during the day, OR 2.84 (95% CI 1.24 to 6.48), as was a supervising consultant, OR 2.26 (1.05 to 4.85). There were no significant differences between the incidence of sequential use of instruments, CS after assessment for OVD, or CS after a failed attempt at OVD. The mean time taken to complete the delivery was similar by day and at night (decision to delivery intervals 12.0 and 12.6 min, respectively).

The maternal and neonatal morbidity outcomes are presented in table 4. The incidence of shoulder dystocia was higher by day than at night, adjusted OR 2.57 (1.05 to 6.28), but there were no other significant differences in maternal complications. One woman who delivered by day required a bladder repair for an injury at CS. The incidence of low Apgar scores, fetal acidosis, neonatal trauma and NICU admission was not significantly different by day and at night. There were no perinatal deaths and the incidence of severe adverse perinatal outcomes was low. Four babies (three by day and one at night) were treated for hypoxic ischaemic encephalopathy and in all cases the cerebral function analysis monitor was normal and brain cooling was not required. Two babies (both by day) had an intracranial haemorrhage diagnosed on ultrasound scan, but in each case a follow-up MRI was normal. Three babies (one by day and two at night) had a brachial plexus injury at the time of hospital discharge and five babies (four by day and one at night) were admitted to the special care baby unit for more than 7 days.

DISCUSSION

Main findings

This cohort study provides detailed information on obstetric practice and morbidity outcomes for OVDs performed by day and at night in a teaching hospital setting. Half of all OVDs and second stage CSs occurred outside routine working hours when consultants are likely to be at home. Although a greater proportion of OVDs were performed by mid-grade operators at night with less direct consultant supervision, this did not result in worse outcomes for mothers and babies. Despite reduced staffing at night, mean decision-to-delivery intervals of between 12 and 13 min were achievable.

Strengths and limitations of the study

The findings of this cohort study reflect the maternal, fetal and surgical outcomes of OVDs performed during a 10-month period in a high-volume women and infants

Table 1 Maternal and neonatal characteristics in relation to time of operative vaginal delivery

	Daytime 08:00–19:59 n=301 (%)	Night-time 20:00–07:59 n=296 (%)	OR (95% CI)
Maternal			
Maternal age >35 years	33 (11.0)	32 (10.8)	1.02 (0.61 to 1.70)
BMI† ≥30.0	25 (8.3)	26 (8.8)	0.94 (0.53 to 1.67)
Caucasian	274 (91.0)	270 (91.2)	0.98 (0.56 to 1.72)
Diabetes (type 1/2 or gestational)	15 (5.0)	12 (4.1)	1.24 (0.57 to 2.70)
Pre-eclampsia	4 (1.3)	13 (4.4)	0.29 (0.09 to 0.91)†
Cigarette smoker	17 (5.6)	14 (4.7)	1.21 (0.58 to 2.49)
Alcohol in pregnancy	4 (1.3)	2 (0.7)	1.98 (0.36 to 10.89)
Illicit drug use	3 (1.0)	1 (0.3)	2.97 (0.31 to 28.7)
Private patient	45 (15.0)	46 (15.5)	0.96 (0.61 to 1.49)
Neonatal			
Gender male	155 (51.5)	157 (53.0)	0.94 (0.68 to 1.30)
Head circumference ≥37.0 cm	30 (10.0)	32 (10.8)	0.91 (0.54 to 1.55)
Birth weight ≥4.0 kg	47 (15.6)	42 (14.2)	1.12 (0.71 to 1.76)
Birth weight <2.5 kg	11 (3.7)	2 (0.7)	5.58 (1.23 to 25.38)*

*p<0.05.

†BMI, body mass index measured as booking weight divided by the square of height (kg/m²).

hospital. The morbidity outcomes compare favourably with centres in the UK.^{15 17 18} Recruitment methods were robust and multiple sources of ascertainment ensured that no OVDs were missed. Medical records and case report forms were cross-checked with computerised records which minimised missing data and allowed validation for accuracy. It would have been possible to

include a much larger cohort using routinely collected data and a retrospective study design, but detailed information on intrapartum care would have been unavailable.¹⁹ Restricting recruitment to nulliparous women resulted in a smaller cohort, but eliminated confounding factors associated with previous deliveries. Labour can be a lengthy process, particularly for induced

Table 2 Labour characteristics in relation to time of operative vaginal delivery

	Daytime 08:00–19:59 n=301 (%)	Night-time 20:00–07:59 n=296 (%)	OR (95% CI)
Induction of labour	130 (43.2)	167 (56.4)	0.59 (0.43 to 0.81)*
First stage of labour >12 h	20 (6.6)	21 (7.1)	0.93 (0.49 to 1.76)
Second stage of labour >2 h†	164 (54.5)	141 (47.6)	1.32 (0.95 to 1.82)
Oxytocin in first stage of labour	194 (64.5)	193 (65.2)	0.97 (0.69 to 1.35)
Oxytocin in second stage of labour	225 (74.8)	219 (74.0)	1.04 (0.72 to 1.50)
Meconium stained liquor	49 (16.3)	40 (13.5)	1.30 (0.86 to 1.95)
Pathological CTG (first stage)	17 (5.6)	16 (5.4)	1.05 (0.52 to 2.11)
Pathological CTG (second stage)	120 (39.9)	114 (38.5)	1.06 (0.76 to 1.47)
Fetal blood sample (FBS) performed	79 (26.2)	95 (32.1)	0.75 (0.53 to 1.07)
Low pH <7.20 on FBS	5 (1.7)	4 (1.4)	1.23 (0.33 to 4.64)
Regional analgesia (spinal/epidural)	263 (87.4)	264 (89.2)	0.84 (0.51 to 1.38)
Local analgesia (pudendal/perineal)	12 (4.0)	15 (5.1)	0.78 (0.36 to 1.69)
Fetal malposition (OP or OT)‡	36 (12.0)	38 (12.8)	0.92 (0.57 to 1.50)
Mid-cavity station (0/+1 cm)	204 (67.8)	205 (69.3)	0.93 (0.66 to 1.32)
Caput succedaneum >+1§	67 (22.3)	84 (28.4)	0.72 (0.50 to 1.05)
Moulding >+1¶	9 (3.0)	9 (3.0)	0.98 (0.39 to 2.51)

*p<0.05.

†Included the passive and active phases of the second stage of labour.

‡Occipito-posterior (OP) or occipito-transverse (OT).

§Caput succedaneum refers to the oedematous swelling formed on the presenting part of the fetal scalp during labour and is measured in centimetres.

¶Moulding refers to the change in shape of the fetal head as it adapts to the pelvic canal. It is classified as none when the fetal skull bones are normally separated, + when the bones touch, ++ when the bones overlap but separate easily with digital pressure and +++ when the bones overlap but are not separable with digital pressure.

Table 3 Procedural factors in relation to time of operative vaginal delivery

	Daytime 08:00–19:59 n=301 (%)	Night-time 20:00–07:59 n=296 (%)	OR (95% CI)
Vacuum—primary instrument	195 (64.8)	213 (72.0)	0.72 (0.51 to 1.01)
Forceps—primary instrument	95 (31.6)	79 (26.7)	1.27 (0.89 to 1.81)
Sequential use of instruments	28 (9.3)	38 (12.8)	0.70 (0.42 to 1.17)
More than 3 pulls with instrument (s)	21 (7.0)	13 (4.4)	1.63 (0.80 to 3.33)
Junior operator (SHO/junior registrar)	69 (22.9)	52 (17.6)	1.40 (0.93 to 2.09)
Mid-grade operator (registrar year 1–3)	114 (37.9)	149 (50.4)	0.60 (0.43 to 0.83)*
Senior operator (registrar year 4–5+)	48 (15.9)	35 (11.8)	1.42 (0.89 to 2.26)
Consultant operator	70 (23.3)	60 (20.3)	1.19 (0.81 to 1.76)
Second operator involved	22 (7.3)	8 (2.7)	2.84 (1.24 to 6.48)*
Consultant supervisor present	22 (7.3)	10 (3.4)	2.26 (1.05 to 4.85)*
Consultant called after complication	5 (1.7)	3 (1.0)	1.65 (0.39 to 7.00)
Transfer to theatre	26 (8.6)	37 (12.5)	0.66 (0.39 to 1.12)
Caesarean section assessed for OVD	12 (4.0)	10 (3.3)	1.19 (0.51 to 2.79)
Caesarean section after failed instrumental	2 (0.7)	6 (2.0)	0.32 (0.07 to 1.62)
Caesarean no attempt at instrumental	10 (3.3)	4 (1.3)	2.51 (0.78 to 8.09)
Mean DDI in minutes (SD)†	12.0 (8.1)	12.6 (8.7)	−0.6 (−0.3 to 1.1)

*p<0.05.

†DDI—the time between the decision to intervene to the delivery of the infant; difference in means.

DDI, decision to delivery interval; OVD, operative vaginal delivery; SHO, senior house officer.

nulliparous women, and women requiring an OVD may have received care across the two time periods of day and night. For the purpose of the analyses, we defined cases by time of birth, which is the most objective measure. The study was powered to address the commonly occurring maternal and neonatal complications, but the sample size was insufficient to address rare outcomes such as neonatal seizures and perinatal death. OVD is one of several emergency obstetric procedures that have implications for workforce planning on labour wards, and further work addressing emergency CS and

the management of obstetric emergencies would be required to reflect the full spectrum of obstetric care by day and at night.

Interpretation

We found no significant associations between time of OVD and maternal and neonatal morbidities. This is consistent with two previous studies.^{20 21} The US Maternal-Fetal Medicine Units Network Cesarean Registry found no association between change of shift for physicians and maternal or neonatal morbidity

Table 4 Maternal and neonatal outcomes in relation to time of operative vaginal delivery

	Daytime 08:00–19:59 n=301 (%)	Night-time 20:00–07:59 n=296 (%)	OR (95% CI)	Adjusted OR† (95% CI)
Maternal				
Postpartum haemorrhage (>500 mL)	57 (18.9)	55 (18.6)	1.02 (0.68 to 1.54)	1.15 (0.75 to 1.78)
3rd/4th degree perineal tear	24 (8.0)	19 (6.4)	1.26 (0.68 to 2.36)	1.34 (0.70 to 2.55)
Shoulder dystocia	17 (5.6)	8 (2.7)	2.16 (0.92 to 5.07)	2.57 (1.05 to 6.28)*
Pyrexia/antibiotic treatment	56 (18.6)	54 (18.2)	1.02 (0.68 to 1.55)	1.10 (0.72 to 1.69)
Prolonged length of stay (>3 days)	44 (14.6)	60 (20.3)	0.67 (0.44 to 1.03)	0.67 (0.43 to 1.04)
Hospital readmission	3 (1.0)	5 (1.7)	0.59 (0.14 to 2.47)	0.53 (0.12 to 2.34)
Neonatal				
Apgar score ≤3 at 1 min	5 (1.6)	2 (0.7)	2.48 (0.48 to 12.90)	2.20 (0.42 to 11.67)
Apgar score <7 at 5 min	2 (0.7)	0 (0.0)	—	—
Arterial pH <7.00	4 (1.2)	4 (1.2)	0.98 (0.24 to 3.97)	1.13 (0.27 to 4.67)
Neonatal trauma‡	17 (5.6)	18 (6.1)	0.92 (0.47 to 1.83)	0.89 (0.44 to 1.78)
Neonatal unit admission	35 (11.6)	37 (12.5)	0.92 (0.56 to 1.51)	0.91 (0.55 to 1.51)

*Statistically significant p<0.05.

†Adjusted for induction, pre-eclampsia, birth weight, operator grade, instrument used.

‡Excluding bruising and skin abrasions, including facial nerve palsy, Erb's palsy, fractures, retinal haemorrhage, cerebral injury and cephalhaematoma.

following an unscheduled CS.²⁰ Another US study found no difference in timing of birth and resident duty-hour restrictions on outcomes for small preterm infants.²¹ However, a recent retrospective cohort study in the Netherlands found that evening (18:00–22:59) and night-time (23:00–07:59) deliveries requiring obstetric interventions or labour augmentation were associated with increased perinatal morbidity and mortality.¹³ Another retrospective study evaluating neonatal morbidity in an unselected population found increased rates of emergency CS and NICU admission during the hours of 23:00 and 03:00.¹⁴ Varying study designs, obstetric environments and limited ability to control for confounding factors may have contributed to the conflicting findings. We found a higher rate of shoulder dystocia during the day, which was unexpected but may reflect our policy of prioritising inductions of labour for pregnancies with suspected macrosomia and diabetes early in the day.

Operator inexperience has been linked to excessive number of pulls at OVD, use of multiple instruments and CS for failed OVD, all of which increase the risk of trauma to the mother and neonate.^{8 22–25} It was perhaps surprising that there was no evidence of excess morbidity at night, even though a greater proportion of deliveries were performed by mid-grade operators with access to a consultant but in most cases no direct supervision. It was also notable that the mean decision-to-delivery intervals were under 15 min in both time periods.²⁶ Our findings suggest that consultant support was available when necessary and that the travel time associated with attendance from home did not compromise patient care. Fewer OVDs were completed by mid-grade operators during the day, which was directly related to a higher proportion of daytime deliveries performed by junior operators. From a training perspective, it is essential that obstetricians have opportunities for both direct and indirect supervision in order to develop clinical decision-making skills and this appears to happen for mid-grade operators more often at night.

The overall complement of staff available at night is another important consideration. The obstetric staffing for a unit of this size falls below the recommended levels described by the RCOG.²⁷ This is probably the case for many units in the UK and Ireland. While appropriate staffing, both quality and quantity, underpins the safety of any clinical service, it is important that there is an evidence base informing workforce planning and resource allocation. An additional benefit of this study was that it demonstrated when peak activity occurs and staff could be deployed accordingly. Nonetheless, OVDs occurred frequently throughout the day and at night. The current drive to implement consultant-provided care for all patients has important resource implications for disciplines providing a 24 h/7 day service. A cluster randomised controlled trial would be the ideal approach to determine whether an entirely on-site consultant obstetric workforce, as recommended by the RCOG, is the way forward. It would also be interesting to replicate this

study in other settings and in other disciplines where emergency care is provided by day and at night.

CONCLUSIONS

There are many valid reasons why consultant obstetricians should be equally available on the labour ward by day and at night. For now, with a predominantly off-site consultant staff at night in most units in the UK and Ireland, women and health service providers can at least be reassured that care is not compromised in terms of maternal and fetal outcomes at OVD.

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Competing interests None.

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