

1 **The influence of hours worked prior to delivery on maternal and neonatal**
2 **outcomes: a retrospective cohort study**

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35 **Condensation:** The number of hours already worked by obstetricians prior to
36 undertaking unscheduled deliveries significantly influences the risk of adverse
37 outcomes.

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39 **Short Version of Article Title:** Influence of delivery timing on outcomes

40 **Abstract**

41 **Background:** Long continuous periods of working contribute to fatigue, which is an
42 established risk factor for adverse patient outcomes in many clinical specialties. The
43 total number of hours worked by delivering clinicians prior to delivery may therefore
44 be an important predictor of adverse maternal and neonatal outcomes.

45 **Objective:** We aimed to examine how rates of adverse delivery outcomes vary with
46 number of hours worked by the delivering clinician prior to delivery during both day
47 and night shifts.

48 **Study design:** We conducted a retrospective cohort study of 24,506 unscheduled
49 deliveries at an obstetrics center in the United Kingdom between 2008 and 2013. We
50 compared adverse outcomes between day shifts and night shifts using random-effects
51 logistic regression to account for inter-operator variability. Adverse outcomes were
52 estimated blood loss ≥ 1.5 liters, arterial cord pH ≤ 7.1 , failed instrumental delivery,
53 delayed neonatal respiration, severe perineal trauma, and any critical incident.
54 Additive dynamic regression was used to examine the association between hours
55 worked prior to delivery (up to 12 hours) and risk of adverse outcomes. Models
56 controlled for maternal age, maternal body mass index, parity, birth weight, gestation,
57 obstetrician experience, and delivery type.

58 **Results:** We found no difference in the risk of any adverse outcome studied between
59 day *versus* night shifts. Yet risk of estimated blood loss ≥ 1.5 liters and arterial cord
60 pH ≤ 7.1 both varied by 30-40% within 12-hour shifts ($p < 0.05$). The highest risk of
61 adverse outcomes occurred after 9-10 hours from the beginning of the shift for both
62 day and night shifts. The risk of other adverse outcomes did not vary significantly by
63 hours worked, or by day *versus* night shift.

64 **Conclusions:** Number of hours already worked prior to undertaking unscheduled
65 deliveries significantly influences the risk of certain adverse outcomes. Our findings
66 suggest that fatigue may play a role in increasing the risk of adverse delivery
67 outcomes later in shifts, and that obstetric working patterns could be better designed
68 to minimize the risk of adverse delivery outcomes.

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70 **Key words:** maternal outcomes, neonatal outcomes, delivery, working patterns, night
71 work, intra-partum care

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Introduction

Minimizing the risk of adverse outcomes at delivery is simultaneously a central goal and a major challenge for obstetric services. Previous studies have suggested that the timing of delivery influences the risk of adverse perinatal outcomes. In particular, the risk of neonatal death is higher for babies delivered outside of the normal 09.00-17.00 Monday-to-Friday working week¹. Other studies have produced conflicting evidence regarding whether neonatal mortality is higher overnight²⁻⁴ or at weekends^{5,6}. However, neonatal mortality is a rare outcome (4 per 1,000 in the United States and 2.8 per 1,000 in the United Kingdom⁷), which is determined not only by intra-partum care, but heavily influenced by the antenatal course and immediate neonatal management. There is less evidence regarding variation in the risk of other, more common, adverse maternal and neonatal outcomes depending on the timing of delivery^{2,8}. In this study we focus on commonly occurring adverse outcomes that are closely related to intra-partum management and therefore most likely to be influenced by the timing of delivery.

Previous studies have considered adverse outcomes in relation to the day of the week and time of day at which delivery occurred¹⁻³. However, we hypothesize that total number of hours worked by delivering clinicians prior to delivery may be a more important predictor of adverse outcomes than day of the week or time of day. Long continuous periods of working contribute to fatigue, which is an established risk factor for adverse patient outcomes in many clinical specialties, however adverse outcomes have not previously been explored in relation to number of hours worked. Fatigue is associated with numerous factors that contribute to poor outcomes, including decline in technical skills^{9,10}, slower reaction times¹¹ and riskier decision-

making^{12, 13}, Delivery can be a high-risk situation requiring identification of potential complications and decisive action. Identifying times of increased risk with respect to working patterns is important to optimizing quality and safety in obstetric services worldwide¹⁴. The major advantage of this approach is that in contrast to day and time of non-elective delivery, working patterns are modifiable, predictable, and under the control of individuals and institutions. As previous work has suggested that increased rates of adverse outcomes may occur during night compared to day shifts [caughey], it is possible that the effect of continuous hours worked prior to delivery is systematically different between day and night shifts. Particularly if provider fatigue is a major contributing factor to the risk of adverse outcome, then the effect of continuous hours worked may be magnified in night compared to day shifts.

We aim to determine: (i) whether common adverse maternal and neonatal outcomes occur more frequently during night shifts; and (ii) how risk of adverse outcomes varies with number of hours worked prior to delivery, either during the day or overnight.

Materials and Methods

29,112 women underwent delivery of a singleton, live-born infant of >24 completed weeks of gestation in a UK tertiary obstetrics center between January 2008-October 2013. We excluded 4,611 women who gave birth by elective cesarean section. All other deliveries (24,506) were included in the sample, regardless of final mode of delivery. The working pattern for obstetricians within the study center follows 12-hour shifts from 08.00-20.00 (day shift) and 20.00-08.00 (night shift). This pattern remained constant throughout the study period. Midwives work the same 12-hour

shifts as do the obstetricians in the study center. Handover periods occurred during the first 30 minutes of each shift.

The midwife assigned to the parturient recorded data regarding the pregnancy, delivery and neonate in an electronic maternity database as soon as possible after birth. This database is routinely maintained as part of hospital records and was not created specifically for study purposes. The database is regularly validated by a rolling program of audits where the original case notes are checked against the information recorded in the database. No patient-identifiable data were accessed during this research, which was performed as a provision-of-service study approved by the obstetrics center. Individual medical records were not accessed at any stage, and our institutions determined that Institutional Review Board approval was not required.

Available maternal, neonatal, and delivery characteristics included maternal age, maternal BMI (measured at first-trimester booking), parity, maternal ethnicity, and birth-weight (measured to the nearest gram). Gestational age (measured by crown-rump length at first-trimester ultrasound) was recorded to the nearest week. Mode of delivery was classified as cesarean section, forceps, ventouse, or spontaneous vaginal delivery (including vaginal deliveries that occurred both cephalic and breech). Inductions of labor were included in the analytic sample, as the timing of delivery (during the day *versus* night shift) was not chosen by the woman or her caregivers. The mode of onset of labor was recorded as induction of labor ‘yes’, ‘no’ or ‘not applicable’ (for women not in established labor when emergent delivery occurred).

The year of delivery and day of the week on which delivery occurred were also available.

The type of healthcare professional delivering the baby was classified as follows: midwives, obstetricians with ≤ 5 years obstetric training, or obstetricians with >5 years obstetric training. In the study center most spontaneous vaginal deliveries are performed by midwives, in line with usual practice across the UK. Instrumental deliveries and cesarean sections are performed only by obstetricians. A small number of spontaneous vaginal deliveries was also performed by obstetricians, but these were mainly high-risk cases, for example pre-term or breech presentation. In the study center, an obstetric team consisting of 3 doctors is available for every 12-hour shift. The team comprises: a junior doctor with ≤ 2 years of obstetric experience, an obstetrician-in-training with $\geq 3 - \leq 5$ years of obstetric experience, and a senior obstetrician with >5 years of obstetric experience. Our cohort has the advantage that none of the clinicians provided obstetric care to any patients outside of the time recorded in the study. These clinicians were present solely for the purpose of attending women in labour and undertaking deliveries as required. Elective caesarean sections and any other scheduled obstetric procedures were undertaken by a separate, dedicated team. Inductions of labour are commenced on a scheduled day (including weekends) but at various times throughout the day and night as the workload allows.

Delay in neonatal respiration was recorded where spontaneous respiration was not achieved within 1 minute of delivery. Umbilical arterial pH was measured from cord blood taken immediately after delivery, where the delivering professional determined that this was required (9,143 cases, 37.3%). This included all cases of operative

delivery and any case where there was concern regarding fetal wellbeing. Correlation between arterial and venous pH was checked to confirm accuracy of the measurements. Arterial pH was categorized as ≤ 7.1 or > 7.1 ¹⁵. Failed instrumental delivery was recorded where an operator applied an instrument, but eventually delivered the baby by any other method (249/4,042 cases, 6%). A critical-incident form was generated at delivery in the case of any obstetric or neonatal emergency, including neonatal resuscitation, shoulder dystocia, maternal visceral injury, or any other event generating an obstetric emergency call. The generation of a critical incident form was used to compile a composite outcome of rare and serious morbidity, which captures rare instances of neonatal death. No peripartum maternal deaths occurred in the center during the study period. Maternal blood loss was estimated immediately after delivery, using suction blood collection and weighing of swabs and other pads. Blood loss was categorized as < 1.5 liters or ≥ 1.5 liters. Severe maternal perineal trauma was defined as any disruption to the anal sphincter complex.

We compared the characteristics of deliveries occurring during the day *versus* night using binary logistic regression. We defined two cohorts: 1) all the deliveries that met our inclusion criteria during the study period (n=24,506); and 2) subset of these where delivery was performed by an obstetrician (n=7,680). We hypothesized that, if the chance of an adverse outcome were significantly influenced by operator fatigue, then this would be more apparent in the obstetrician-only cohort, because complex operative procedures are more likely to have been performed. However, decision-making and management during labor is an important mediator of adverse outcomes regardless of whether surgery is required, and thus we also present outcomes for the full dataset including spontaneous vaginal deliveries. The results from this

comparison of delivery characteristics were used to determine covariates included in the models examining the risk of adverse delivery outcomes.

We compared adverse maternal and fetal outcomes during day and night shifts, both for all deliveries and for deliveries conducted by obstetricians only, using binary logistic regression. To control for variation in baseline complication rates between individual obstetricians, and to account for multiple deliveries by the same operator, we also compared adverse outcomes during day and night shifts using mixed-effects logistic regression models including a random effect for each individual obstetrician. Data from all obstetricians who delivered >100 babies during the study time period were included in this model (n=3,203 deliveries by 28 operators).

Finally, we examined the risk of each adverse outcome dependent on the number of hours worked prior to delivery—*i.e.* the time in full hours between the start of each shift and the time of delivery—using a generalized additive model in which all events were considered equivalent. This model incorporated a nonlinear term for hours worked prior to delivery on the risk of an adverse outcome, estimated using cubic splines. This model allows us to avoid making any prior assumptions about the nature of the relationship between hours worked and the risk of adverse outcomes, thus allowing the model to best fit the data. Statistical significance of the nonlinear effect of hours worked was assessed using a likelihood-ratio test. We fit a model for all deliveries as well as two separate models for deliveries taking place during night shifts and during day shifts.

Findings were considered statistically significant at an alpha level of 0.05. Power calculations were performed by Monte Carlo simulation. All analyses were conducted using the R statistical software package version 2.14.1¹⁶.

Results

Women who delivered overnight were more likely to be delivered by an obstetrician (with ≤ 5 years experience $p < 0.01$; with > 5 years experience $p < 0.05$) and less likely to have labored prior to delivery ($p < 0.05$) (Table 1). Deliveries overnight were also less likely for women of higher parity (parity 1 $p < 0.05$; parity ≥ 2 $p < 0.01$), to involve induction of labor ($p < 0.05$), or to involve the use of obstetric instruments (ventouse $p < 0.01$; forceps $p < 0.05$). Deliveries overnight were also associated with slightly lower gestational age ($p < 0.05$). While statistically significant, this difference represents a very small difference in actual gestational age, which is unlikely to be clinically meaningful. For women who required delivery by an obstetrician, deliveries overnight were more likely to be performed not in active labor ($p < 0.01$) (Table 1). Women delivered by obstetricians at night were less likely to be of higher parity ($p < 0.05$) or to be delivered by obstetricians with > 5 years experience ($p < 0.05$).

After adjusting for delivery characteristics, we found no significant differences in the rates of adverse outcomes occurring among all deliveries during day *versus* night shifts, (Table 2). We also found no significant differences between rates of adverse outcomes between day *versus* night shifts for deliveries performed by obstetricians only (Table 2).

Accounting for inter-operator variability, we found no significant differences in the rates of adverse outcomes at deliveries performed by the same obstetricians during their day shifts *versus* their night shifts (Table 3). We observed a tendency towards more babies being born with an arterial pH ≤ 7.1 during night shifts, but this finding was not statistically significant ($p=0.09$) (Table 3).

While we found no associations between risk of adverse outcomes *between* day and night shifts, we did observe significant associations *within* day and night shifts. The risk of estimated maternal blood loss ≥ 1.5 liters varied significantly over the course of all 12-hour shifts ($p<0.05$) (Figure 1A). The estimated difference in the magnitude of risk between the time of lowest risk (after 3-4 hours worked since the beginning of the shift) and the time of highest risk (after 9-10 hours worked since the beginning of the shift) was approximately 30%. Similarly, the risk of umbilical arterial pH ≤ 7.1 varied by approximately 45% during the course of 12-hour shifts ($p<0.05$) (Figure 1B). For arterial pH ≤ 7.1 , the time of lowest risk was at the start of the shift (after 0-1 hours worked) and the time of highest risk was again after 9-10 hours worked since the beginning of the shift. None of the other outcomes studied showed any significant difference in risk magnitude during the course of 12-hour shifts (data not shown).

Comparing the patterns of risk during the course of day shifts and night shifts separately, we observed that for estimated blood loss ≥ 1.5 liters, there was a tendency towards a significant difference in risk across the course of 12-hour day shifts ($p=0.07$) (Figure 2A). During night shifts, there was no significant difference in the risk of estimated blood loss ≥ 1.5 liters dependent on hours worked (Figure 2B). For arterial pH ≤ 7.1 , we found no significant difference in risk dependent on hours

worked during day shifts (Figure 2C), but there was a significantly increased risk with increasing hours worked during night shifts ($p < 0.01$) (Figure 2D). For all models, regardless of the significance of the trend, the highest risk of adverse outcomes was between 8-10 hours worked since the beginning of the shift. None of the other adverse outcomes studied showed any difference in risk of adverse outcomes dependent on number of hours worked for either day or night shifts.

Comment

We observed no significant differences in the risk of adverse maternal and neonatal outcomes for deliveries taking place during day shifts *versus* night shifts. However, the number of hours worked since the beginning of the shift by obstetricians and midwives prior to delivery does influence the risk of adverse outcomes. In particular, the risks of heavy maternal blood loss and fetal acidosis are increased. The highest risk for these outcomes occurs after 8-10 hours into a 12-hour shift. This is a novel finding, as the risk of adverse outcomes has not previously been studied with respect to shift-patterns within an obstetric cohort.

An interesting feature of the relationship between hours worked and risk of adverse outcomes is the risk profile within the initial and final hours of shifts. While the overall pattern demonstrates increased risk of both heavy maternal blood loss and fetal acidosis across shifts, in both cases there is a fall in risk within the final 2 hours of the shift. While we are unable to provide a definitive causal explanation of this trend from the data available, we hypothesize that this decline may be related to a process of deferment, whereby an increasingly fatigued team may chose not to undertake further very high risk cases unless time is of the essence. Conversely, for

the outcome of maternal blood loss ≥ 1.5 liters, the risk is elevated in the first 2 hours of the shift (relative to the time of minimum risk, although not to the average risk across the whole 12 hours). This increased risk may result from deferred high-risk cases, or may be related to the process of hand-over. Previous studies of adverse outcomes in a variety of hospital settings have identified hand-overs as times of increased risk¹⁷ when errors are liable to be introduced into care. While the variations in the rates of other outcomes studied with respect to hours worked did not reach the defined thresholds for statistical significance, the data showed similar trends. It is possible that the outcomes that did vary significantly with hours worked (heavier blood loss and lower fetal pH) were the most likely to be influenced by operator fatigue.

A key strength of our study is the use of non-parametric dynamic additive models. These models provide a powerful and flexible way to determine the risks of adverse outcomes relative to baseline risk at any point in the shift and avoid making strong assumptions about the form of the risk/time relationship. A further strength is that the outcomes studied here are patient-centered, immediate, issues that frequently influence the cost of the immediate hospital episode, patient satisfaction, and long-term health outcomes of the mother and her infant after delivery. Furthermore, the outcomes are selected to relate as closely as possible to intra-partum management and are carefully controlled for pre-existing factors. Deliveries occurred throughout the day and night as-if-at-random within our analytic cohort⁸, and there was no increase in the number of deliveries occurring later in shifts.

A limitation of our study is that the data are derived from a single large obstetrics center in the UK. Therefore, our result may not be generalizable to other settings. The advantage of data from a single center, however, is that working patterns are clearly defined and remain constant throughout the study period, making detailed analyses with respect to working time possible. Data from national cohorts are prone to heterogeneity in the shift patterns actually worked by obstetric teams in different hospitals and other clinical duties fulfilled outside of the delivery unit hours, making such analyses unfeasible. A further limitation of our study is that our cohort is not sufficiently powered to isolate the outcomes of neonatal and maternal mortality, other than as part of the composite outcome of critical incidents occurring at delivery. The UK maternal mortality rate is currently 1:10,000¹⁸, meaning that over 4.5 million births would be required to detect even a very large effect size – this exceeds the total number of UK births during the study period. Neonatal mortality is a more tractable study question, with a current perinatal mortality rate of 6:1,000 births (although this figure includes antepartum stillbirths, which would not be expected to vary with working patterns in intrapartum care). Neonatal mortality rates have been examined by other studies using national data¹ and were found to be higher outside the 09.00-17.00 working week.

Deliveries occur with equal frequency throughout day and night shifts, 7 days a week within our analytic cohort. Emergencies may happen at any time and it is reassuring that working patterns that employ ‘night float’-type system, do not put women who deliver overnight at higher risk of adverse outcomes than those delivering during the day. Despite some systematic differences between women who deliver overnight and during the day (for example higher risk women are more likely to be induced and to

deliver during the day), the consistent availability of an experienced obstetric team means that the risk remains similar in both periods.

Our finding of increasing risk with hours worked is concerning and suggests that improvements may be possible to minimize risk to mothers and babies. Our results suggest that fatigue may play a role in increasing the risk of adverse delivery outcomes later in shifts. Literature from other disciplines suggests that fatigue is a plausible factor influencing patient outcomes, both in terms of deterioration in technical skills¹⁰ and in impairing decision-making¹². Our results support the idea that limitations on resident's working hours may be of benefit to both doctors and their patients. There are many possible interventions that could potentially reduce the identified risk, for example shorter shift times, enforced rest periods within shifts, or encouragement to consider seeking extra help or deferring complex cases if it is safe to do so during high-risk periods. An important area for further study is to evaluate the potential of such interventions to lower the risk of adverse outcomes and to weigh the advantages and disadvantages of each in practice. Many interventions may not be feasible in diverse practice settings worldwide, but self-awareness of increased risk is nonetheless valuable to any obstetrician contemplating a complex procedure.

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Table 1 Characteristics of the maternal-fetal dyad and the delivery for the full cohort

		All deliveries (n=24,506)		Deliveries by doctors (n=7,680)	
Characteristic		OR (95% CI) (Day v. Night)	p value	OR (95% CI) (Day v. Night)	p value
Gestational age (weeks)		0.98 (0.96-0.99)	0.02*	0.98 (0.96-1.01)	0.25
Birth weight (g)		1.00 (0.99-1.01)	0.06	1.00 (0.99-1.00)	0.18
Maternal age		0.99 (0.98-1.00)	0.10	0.99 (0.99-1.00)	0.16
Maternal BMI		1.00 (0.99-1.01)	0.33	1.00 (0.99-1.01)	0.92
Onset of labour	Spontaneous	Ref			
	Induced	0.82 (0.77–0.87)	<0.01**	0.96 (0.87-1.05)	0.36
	No labour	1.17 (1.01-1.34)	0.04*	1.31 (1.12-1.54)	<0.01**
Obstetrician experience:	Midwife	Ref		N/A	N/A
	≤ 5 years obstetrician	1.40 (1.16-1.68)	<0.01**	Ref	
	> 5 years obstetrician	1.25 (1.02-1.52)	0.03*	0.90 (0.82-0.99)	0.04*
Parity:	0	Ref			
	1	0.94 (0.88-1.00)	0.04*	0.98 (0.89-1.07)	0.65
	≥2	0.88 (0.81-0.94)	<0.01**	0.86 (0.75-0.99)	0.04*
Delivery Type:	SVD	Ref			
	Caesarean section	0.89 (0.74-1.09)	0.26	0.86 (0.71-1.04)	0.13
	Forceps	0.97 (0.79-1.18)	0.04*	0.95 (0.77-1.16)	0.59
	Ventouse	0.95 (0.77-1.17)	<0.01**	0.94 (0.76-1.15)	0.54

and the deliveries performed by doctors comparing each characteristic between

deliveries occurring during day *versus* night shifts. *p<0.05, **p<0.01

Table 2 Risk of adverse outcome for the full cohort and the deliveries performed by doctors comparing each characteristic between deliveries occurring during day *versus* night shifts. Model coefficients are expressed as odds ratios and 95% confidence intervals (CI).

Adverse outcome	All deliveries (n=24,506)		Deliveries by doctors (n=7,680)	
	OR (95% CI) (Day v. Night)	p value	OR (95% CI) (Day v. Night)	p value
EBL \geq 1.5 litres	1.04 (0.85-1.26)	0.72	0.99 (0.76-1.27)	0.91
3 rd /4 th degree tear	1.02 (0.89-1.17)	0.79	1.07 (0.84-1.35)	0.59
Umbilical arterial pH \leq 7.10	1.09 (0.90-1.32)	0.40	1.22 (0.98-1.53)	0.08
Delayed neonatal respiration	1.08 (0.96-1.23)	0.19	1.10 (0.94-1.29)	0.26
Failed instrumental delivery	1.13 (0.85-1.49)	0.41	1.13 (0.85-1.49)	0.41
Critical incident	0.89 (0.77-1.02)	0.10	0.94 (0.77-1.16)	0.58

Table 3 Risk of adverse outcome for deliveries performed by doctors with random effect for delivering individual comparing each characteristic between deliveries occurring during day *versus* night shifts. Model coefficients are expressed as odds ratios and 95% confidence intervals (CI).

Deliveries by doctors (3032 deliveries by 28 individuals)		
Adverse outcome	OR (night v. day) (95% CI)	p value
EBL \geq 1.5 litres	1.18 (0.72-1.94)	0.52
3 rd /4 th degree tear	1.06 (0.71-1.59)	0.77
Umbilical arterial pH \leq 7.10	1.44 (0.95-2.18)	0.09
Delayed neonatal respiration	0.95 (0.71-1.26)	0.69
Failed instrumental delivery	1.13 (0.84-1.53)	0.41
Critical incident	1.28 (0.92-1.77)	0.14

444

445 **Figure Legends**446 **Figure 1:** Risk of adverse outcomes dependent on hours worked prior to delivery (A)447 Estimated maternal blood loss $\geq 1\text{L}$ ($p < 0.05$) (B) Umbilical arterial pH ≤ 7.1 ($p < 0.05$).

448 Dashed line represents the mean risk level for the outcome; risks that are negative

449 with respect to this line are therefore less likely than average, and those that are

450 positive are more likely than average.

451

452 **Figure 2:** Comparison of risk of adverse outcomes dependent on hours worked prior453 to delivery between day and night shift (A) Estimated maternal blood loss $\geq 1\text{L}$ during454 day shift 08.00-20.00 ($p = 0.07$) (B) Estimated maternal blood loss $\geq 1\text{L}$ during night455 shift 20.00-08.00 (C) Umbilical arterial pH ≤ 7.1 during day shift 08.00-20.00 (D)456 Umbilical arterial pH ≤ 7.1 during night shift 20.00-08.00 ($p < 0.01$). Dashed line

457 represents the mean risk level for the outcome; risks that are negative with respect to

458 this line are therefore less likely than average, and those that are positive are more

459 likely than average.

460