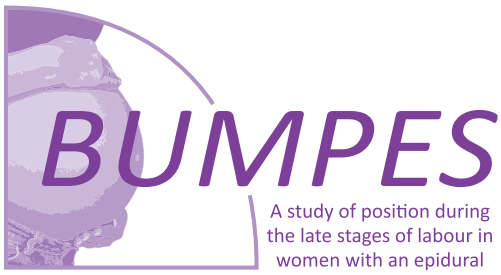
Hospital Code



Woman's study number:

Woman and Infant data collection booklet

Please complete in black ballpoint pen

Eligibility criteria

- 16 years of age or older
- ≥37 weeks' gestation
- Nulliparous (no previous delivery ≥24+0 weeks' gestation)
- Singleton cephalic presentation
- Intend spontaneous vaginal birth
- In second stage of labour, confirmed by vaginal examination (VE)
- With a low dose epidural, sited in the first stage of labour, providing effective pain relief
- Able to understand written and spoken English

Addressograph

or

Woman's name:

Woman's address:

Woman's Hospital ID number:

Woman's NHS number *(if known)*

Part 1

Data to be collected at time of occurrence.

Section 1: Eligibility checklist

Please complete this section before logging on to the BUMPES website to obtain the study number.

1.1 What is the woman's date of birth? D D / M M / Y Y

1.2 What is the expected date of delivery (EDD)? D D / M M / Y Y

1.3 Hospital number: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

1.4 Is the woman nulliparous (no previous delivery greater than or equal to 24+0 weeks' gestation)? Yes ☐ No ☐

1.5 Is this a singleton cephalic presentation? Yes ☐ No ☐

1.6 Is spontaneous vaginal birth intended? Yes ☐ No ☐

1.7 Is the woman in the second stage of labour, confirmed by VE? Yes ☐ No ☐

1.8 Is a low dose epidural, sited in the first stage of labour, providing effective pain relief? Yes ☐ No ☐

1.9 Is the woman able to understand written and spoken English? Yes ☐ No ☐

If all the criteria are fulfilled, the woman in your care is eligible to participate in the BUMPES study.

Please ensure that the consent form for participation in the study has been signed prior to randomisation. The original consent form should be sent back to the coordinating centre. A copy of the consent form should be given to the woman, a copy should be filed in the study site file and a copy should be filed in the woman's notes.

1.10 Has the woman given written consent for participation in BUMPES? Yes ☐ No ☐

Name of person completing this section of the form:

Name: *(Print)* _____ **Signature:** _____

Section 2: Randomisation

After completion of section 1, log on to the BUMPES randomisation website via the internet: https://rct.npeu.ox.ac.uk/bumpes and follow the instructions on the screen.

The randomisation system will provide you with a unique study number and group allocation for the woman in your care. Please enter these below.

2.1 Study number: ☐☐☐☐☐

2.2 Group allocation: *(Please tick only one)* Upright ☐ **OR** Lying down ☐

2.3 Date and time of randomisation: D D / M M / Y Y h h : m m (24hr)

Please go to section 4.1 and record the woman's position prior to study entry.

Then support and encourage the woman to assume the allocated position. Once the woman's position is established, record the start time in the row marked '0'.

Section 3: Pain and Pain Relief at Study Entry

3.1 How painful was the woman's last contraction at its peak?

Using the "Visual Analogue Scale" slide rule in your recruitment pack, ask the woman in your care to rate how painful her last contraction was at its peak. Explain to her that "0" represents "No pain at all" and "100" represents "The worst pain imaginable".

VAS recording: (0-100) ☐☐☐

3.2 Can the woman perform a "Straight leg raise" with one leg? Yes ☐ No ☐

3.3 Was the epidural pain relief maintained with PCEA/infusion up until study entry? Yes ☐ No ☐

If Yes, please record the pump reading at study entry: ☐☐☐ ml

Please note: you will need to make a note of the pump reading post birth (in section 5) prior to turning the pump off or disposing of the infusion bag.

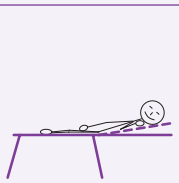
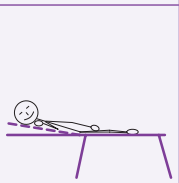
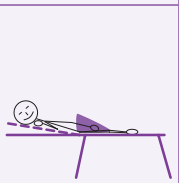
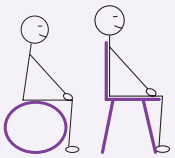
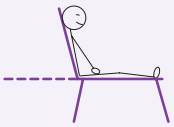
Section 4: Maternal position recordings after study entry

This section records the actual position that a woman adopts after study entry. It provides the study with information which cannot be retrieved at a later time. Therefore, it is important that it is filled in as accurately as possible during labour.

4.1 Please record maternal position every quarter of an hour after entry to the study.

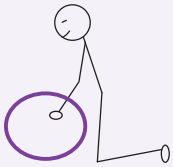
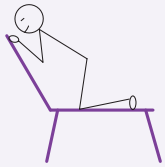
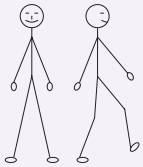
At the end of each time interval, please note down the position that the woman in your care has adopted for the majority of the previous 15 minutes, by ticking the relevant box in the position chart. The images above the matrix act as a guide to chart completion.

Group allocation *(as recorded on page 3)*: Upright ☐ **OR** Lying down ☐

		Predominant maternal position in last 15 minutes						
		Lying (elevation of head of bed up to a maximum of 30°)				Sitting		
		Left lateral	Right lateral	Tilted with a wedge		Out of bed	In bed	
				Wedge on left side	Wedge on right side			
Study time (min)	Actual time (24h)							
Position prior to study entry		☐	☐	☐	☐	☐	☐	
0	:							
15	:	☐	☐	☐	☐	☐	☐	
30	:	☐	☐	☐	☐	☐	☐	
45	:	☐	☐	☐	☐	☐	☐	
60	:	☐	☐	☐	☐	☐	☐	
75	:	☐	☐	☐	☐	☐	☐	
90	:	☐	☐	☐	☐	☐	☐	
105	:	☐	☐	☐	☐	☐	☐	
120	:	☐	☐	☐	☐	☐	☐	
135	:	☐	☐	☐	☐	☐	☐	
150	:	☐	☐	☐	☐	☐	☐	
165	:	☐	☐	☐	☐	☐	☐	
180	:	☐	☐	☐	☐	☐	☐	
195	:	☐	☐	☐	☐	☐	☐	
210	:	☐	☐	☐	☐	☐	☐	
225	:	☐	☐	☐	☐	☐	☐	
240	:	☐	☐	☐	☐	☐	☐	
255	:	☐	☐	☐	☐	☐	☐	
270	:	☐	☐	☐	☐	☐	☐	
285	:	☐	☐	☐	☐	☐	☐	
300	:	☐	☐	☐	☐	☐	☐	

4.1 Maternal position at time of birth Upright ☐ Lying down ☐ Lithotomy ☐ Other ☐

If Other, please describe _____

Predominant maternal position in last 15 minutes					If the woman changes from her allocated position to a non-allocated position, please record the reason
	Supported kneeling		Standing/ walking	Other including lithotomy	
	Out of bed	In bed		*Please briefly describe*	
					
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Section 5: Pain and Pain Relief after Study Entry

5.1 Was PCEA/infusion used after study entry? Yes ☐ No ☐

If Yes, please record the concentration of the epidural solution given and record the PCEA pump reading at time of delivery:

Bupivacaine 0 . ☐☐☐ %

Fentanyl ☐☐ µg/ml

Pump reading ☐☐☐ ml

5.2 How painful was the birth of the woman's baby?

Using the "Visual Analogue Scale" slide rule in your BUMPES recruitment pack, ask the woman in your care to rate how painful the birth of her baby was. Explain to her that "0" represents "No pain at all" and "100" represents "The worst pain imaginable".

VAS recording: (0-100) ☐☐☐

Section 6: Maternal labour and birth questionnaire

Please ask the woman to complete the questionnaire entitled 'Your labour and birth experience' as soon as practicable while she is in the delivery suite.

Please confirm that the questionnaire was given to the woman by ticking this box: ☐

Name and signature of person who completed Part 1:

Name: *(Print)* _____ **Signature:** _____

What to do now:-

Please either complete Part 2 of this form or put it in the midwives recruitment envelope and place in the designated area for the research midwife to complete.

Part 2

Section 1: Information about the woman at study entry

Maternal characteristics

1.1 Maternal ethnic group:

White – British/Irish	☐	Asian – Indian	☐
White – Other	☐	Asian – Pakistani	☐
Mixed – White and Black Caribbean	☐	Asian – Bangladeshi	☐
Mixed – White and Black African	☐	Asian – Other	☐
Mixed – White and Asian	☐	Black – Caribbean	☐
Mixed – Other	☐	Black – African	☐
Chinese	☐	Black – Other	☐
Any other ethnic category	☐	Not known	☐

1.2 Booking weight: ☐☐☐.☐ kg **OR** ☐☐ stones ☐☐ lbs **OR** tick if not known ☐

1.3 Height: ☐☐☐ cm **OR** ☐ feet ☐☐ inches **OR** tick if not known ☐

1.4 Has the woman undergone FGM? Yes ☐ No ☐

Information on this pregnancy and labour

1.5 Was the onset of labour: Spontaneous ☐ **OR** Induced ☐

1.6 What was the duration of first stage? ☐☐ hours ☐☐ mins

1.7 What was the date and time of VE diagnosing second stage? *(Full cervical dilatation = 10cm)* D D / M M / Y Y h h : m m (24hr)

1.8 Was there any maternal diagnosis of pre-eclampsia? Yes ☐ No ☐

1.9 Was continuous electronic fetal monitoring used prior to study entry? Yes ☐ No ☐

1.10 Was there a diagnosis of delay made prior to study entry? Yes ☐ No ☐

If Yes, which of the following interventions were used?

None ☐

ARM ☐

Syntocinon ☐

Pain relief up until study entry

1.11 Were any systemic opioids given in labour prior to epidural pain relief? Yes ☐ No ☐

If Yes, which drug was given? *(Please tick all that apply)*:

Pethidine ☐
Diamorphine ☐ Remifentanil ☐
Morphine ☐ Other ☐

If Other, please specify _____

1.12 What epidural technique was used? *(Please tick only one)*

Epidural ☐ **OR** Combined Spinal Epidural ☐

1.13 Date and time first dose epidural/spinal pain relief given: D D / M M / Y Y h h : m m (24hr)

Section 2: Events after study entry

Please refer to time of randomisation to ensure that events recorded in this section did occur after study entry.

2.1 Were any epidural drugs administered by "top-up" after study entry? Yes ☐ No ☐

Please do not include top-ups given for instrumental delivery or caesarean section.

If yes, please provide details below:

Time	Local Anaesthetic		Opioid		Volume (ml)
	Drug	% Conc.	Drug	µg/ml	
:					
:					
:					
:					
:					

2.2 Was augmentation (syntocinon) commenced after study entry? Yes ☐ No ☐

2.3 Was fetal blood sampling performed after study entry? Yes ☐ No ☐

2.4 Was a fetal scalp clip applied for the first time after study entry? Yes ☐ No ☐

2.5 Did the woman complain of dizziness after study entry? Yes ☐ No ☐

2.6 Did maternal hypotension occur after study entry?
Systolic blood pressure <100 mm Hg at any time Yes ☐ No ☐

2.7 Were any drugs to increase the woman's blood pressure given after study entry? Yes ☐ No ☐

These are known as vasopressors and include ephedrine, phenylephrine and metaraminol (aramine). They are usually only administered by anaesthetists for severe maternal hypotension.

Section 3: Birth details

3.1 **Date and time pushing commenced:** D D / M M / Y Y h h : m m (24hr)

3.2 **Date and time of birth:** D D / M M / Y Y h h : m m (24hr)

3.3 **Mode of birth:** *(Please tick only one)*

- Spontaneous vaginal birth ☐
- Instrumental vaginal birth
  - Forceps ☐
  - Ventouse ☐
  - **If instrumental birth**, was this in theatre? Yes ☐ No ☐
- Caesarean section ☐
  - **If caesarean section**, give category *(as per RCOG guidelines, see back page of booklet)* 1 ☐ 2 ☐ 3 ☐

3.4 ***Primary*** **indication for assisted (non-spontaneous) birth:** *(Please tick only one)*

- Fetal distress ☐
- Failure to progress ☐
- Breech presentation ☐
- Other ☐
  - **If Other**, please specify _____

3.5 **Was anaesthesia required for instrumental birth or caesarean section?**
This refers to anaesthesia additional to the routine epidural pain relief given in labour Yes ☐ No ☐

If Yes, please record the additional anaesthetic technique used: *(Please tick all that apply)*

- Local infiltration ☐
- Pudendal (cervical) block ☐
- High dose epidural top-up ☐
- Spinal anaesthesia ☐
- General anaesthesia ☐

3.6 **Was active management of third stage required?** Yes ☐ No ☐

3.7 **Was an episiotomy performed?** Yes ☐ No ☐

3.8 **Was any perineal tear evident after birth, including perineal tear with episiotomy?** Yes ☐ No ☐

If Yes, please record using standard classification system recommended by the 2007 NICE Intrapartum guidelines, see back page of booklet.

Severity: Degree: 1 ☐ 2 ☐ 3a ☐ 3b ☐ 3c ☐ 4 ☐

3.9 **Was the perineum sutured?** Yes ☐ No ☐

3.10 **Was any anterior tear evident after birth?** Yes ☐ No ☐

If Yes, was any anterior tear sutured? Yes ☐ No ☐

3.11 **Was manual removal of the placenta performed?** Yes ☐ No ☐

3.12 **Was there a post-partum haemorrhage requiring blood transfusion?**
(Whole blood or packed cells) Yes ☐ No ☐

If Yes, how many units were transfused? ☐☐

3.13 Date and time of maternal discharge from delivery/birth centre: D D / M M / Y Y h h : m m (24hr)

3.14 Maternal destination after leaving delivery/birth centre:

- Home (early discharge) ☐
- Ward ☐
- High Dependency Unit (HDU) ☐
- Intensive Care Unit (ICU) ☐
- Other ☐

If Other, please specify _____

Infant outcomes

3.15 Infant's hospital ID number: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

3.16 Infant's NHS number: *(if known)* ☐☐☐☐☐☐☐☐☐☐

3.17 Apgar score at 5 minutes: ☐☐

3.18 Birth weight: ☐☐☐☐ g

3.19 Umbilical cord pH and base deficit at birth: *(if done)*

If paired samples taken record arterial sample.

pH ☐.☐☐ base deficit ☐☐.☐ mmol/l **OR** tick if not done ☐

3.20 Was meconium stained liquor noted at birth? Yes ☐ No ☐

3.21 Was neonatal resuscitation required at birth? Yes ☐ No ☐

If Yes, please tick all that apply:

- Facial oxygen ☐
- Suction ☐
- Bag and mask ventilation ☐
- Intubation ☐
- Complex resuscitation ☐

3.22 Was skin-to-skin contact achieved in the first hour? Yes ☐ No ☐

3.23 Did the woman initiate breastfeeding within the first hour of birth? Yes ☐ No ☐

3.24 Infant's destination *immediately* after leaving the delivery/birth centre: *(Please tick only one)*

- Home (early discharge) ☐
- Ward ☐
- Transitional care ☐
- Neonatal unit ☐

Section 4: Maternal and Neonatal Discharge and Higher Level of Care Information

4.1 **Date and time of maternal discharge from hospital:** D D / M M / Y Y h h : m m (24hr)

4.2 **Date and time of infant discharge from hospital:** D D / M M / Y Y h h : m m (24hr)

4.3 **Was the woman admitted to a higher level of care (high dependency / intensive care) during her hospital stay?** Yes ☐ No ☐

4.4 **Was the infant admitted to a higher level of care (transitional care / neonatal unit) during their hospital stay?** Yes ☐ No ☐

Name and signature of person who completed Part 2:

Name: *(Print)* _____ **Signature:** _____

What to do now:-

Please put the completed booklet into the midwives recruitment envelope and place in the designated area.

Thank you for completing this form

BUMPES Co-ordinating Centre

Clinical Trials Unit, BUMPES Study, UCL
Gower Street, London, WC1E 6BT

Telephone: 0207 679 0939
Email: bumpes@ucl.ac.uk

www.instituteforwomenshealth.ucl.ac.uk/bumpes

Definitions

EDD: Use the best estimate (dates or ultrasound) based on a 40 week gestation

RCOG Caesarean section classifications

1. Immediate threat to the life of the woman or fetus
2. Maternal or fetal compromise which was not immediately life-threatening
3. No maternal or fetal compromise but needs early delivery
4. Delivery timed to suit woman or staff *(not applicable for BUMPES)*

2007 NICE Intrapartum guidelines on perineal trauma

1. First degree – injury to skin only
2. Second degree – injury to the perineal muscles but not the anal sphincter
3. Third degree – injury to the perineum involving the anal sphincter complex:
    a. Less than 50% of external anal sphincter thickness torn
    b. More than 50% of external anal sphincter thickness torn
    c. Internal anal sphincter torn
4. Fourth degree – injury to the perineum involving the anal sphincter complex (external and internal anal sphincter) and anal epithelium

UCL Clinical Trials Unit

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