

#### CONFIDENTIAL WHEN COMPLETED

# **Baseline and Birth Form**

To be completed by the local site team, entered onto the electronic system, and paper copy to be kept securely at site.

#### Part 1: Background Information on Mother

1.1 Ethnic Origin taken from green pregnancy notes ('*if mixed, tick more than one box'*):

British European (e.g. England, Wales)
East European (e.g. Poland, Romania)
Irish European (e.g. N. Ireland, Eire)
North European (e.g. Sweden, Denmark)
South European (e.g. Greece, Spain)
West European (e.g. France, Germany)
North African (e.g. Egypt, Sudan)
East African (e.g. Ethiopia, Kenya)
Central African (e.g. Cameroon, Congo)
South African – Black (e.g. Botswana, S. Africa)
South African – Euro (e.g. Botswana, S. Africa)
West African (e.g Gambia, Ghana)

Middle Eastern (e.g . Iraq, Turkey)
Indian
Pakistani
Bangladeshi
Chinese
Other Far East (e.g. Japan, Korea)
South East Asia (e.g. Thailand, Phillippines)
Caribbean (e.g. Barbados, Jamaica)
Declined
Other
'If other, please specify'

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1.2 Indications for induction:	Post-term pregnancy (37 weeks or over)	Yes No
	Diabetes mellitus/gestational diabetes	Yes No
	Gestational hypertension	Yes No
	Pre-eclampsia	Yes No
	Maternal renal disease	Yes No
	Maternal hepatic disease	Yes No
	Rhesus isoimmunisation/increasing antibody titre	Yes No
	Intrauterine growth restriction/oligohydramnios	Yes No
	Elected by mother	Yes No
	Other maternal disease	Yes No
	'If other, please specify'	
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1.3 Expected date of delivery (based on USS	)		MMM	Y Y Y Y
1.4 Number of previous miscarriages (<24 w	veeks)			
1.5 Number of previous terminations of pre	gnancies (<24 weeks	s)		
1.6 Previous deliveries >24 weeks	Yes No			
'If yes, what was the mode of delivery' :	Unassisted vaginal	Yes	No	'If yes, please give number'
	Instrumental vagina	Yes	No	'If yes, please give number'
	Elective caesarean	Yes	No	'If yes, please give number'
	Emergency caesare	ean Yes	No	'If yes, please give number'
1.7 Presence of risk factor for GBS (accordin	g to local protocol)	Yes	No	
1.8 Weight at booking antenatal visit (kg)				
1.9 Height (cm)				
1.10 BMI (kg/ m <sup>2</sup> )				

Part 2: Induction of Labour (to be completed after randomisation):								
2.1 Bishop score on initiation of cervical ripening i.e. 1 <sup>st</sup> VE since randomisation (see score system below)								
Please tick the relevant boxes below:								
Score		0		1		2		3
Dilation (cm):	<1		1-2		3-4		<u>&gt;</u> 5	
Length of cervix (cm):	>4		2-4		1-2		<1	
Station relative to ischial spines (cm):	-3		-2		-1, 0		+1, +2	
Consistency:	Firm		Medium		Soft			
Position of cervix:	Posterior		Mid		Anterior			
Time and date of Bishop score HH MM DD MMM YYYY recorded (24 hour clock)								
2.2 What treatment allocation was the woman randomised to (tick one)? Dilapan-S Propess								

Dilapan-S OR	Propess O	R	Intervention not given
f NO intervention was given OR the alloc	cated intervention was NO	T given, wha	t was the reason:
Bishop score 6 or over (please record sco	ore in appendix Yes	No	
Spontaneous labour	Yes	No	
Caesarean due to maternal deterioration	Yes	No	
Caesarean due to fetal deterioration	Yes	No	
Declined induction of labour	Yes	No	
Received Foley catheter	Yes	No	
Received other form of pessary	Yes	No	
nability to fit allocated intervention	Yes	No	
ailure of cervical ripening	Yes	No	
Nithdrawal of consent	Yes	No	
Other Yes No	'If other, please specify'		
Number of rods inserted (if Dilapan-S)	Ľ	OT number (i	if Dilapan-S)
Fime and date inserted (24 hour clock)			
Fime and date removed (24 hour clock)			
Nas the intervention removed due to co	mplications (if yes, record	complicatior	n in question 2.8) Yes No
Did the intervention fall out?			Yes No
If yes, please record details of insertion o	f new intervention in next	series'	
If yes, what was the time/date interventi 24 hour clock)	ion fell out H H M		

2.4 <u>Series 2: Intervention used</u> (Please tick one treatment and complete the corresponding information. Please use a new series for each insertion. There is more space to complete further series, if required, at the back of this form).					
Dilapan-S OR	Propess 🦳	OF	ł	Intervention no	ot given
If NO intervention was given OR the	e allocated interventio	on was NOT	given, what	was the reason:	
Bishop score 6 or over (please reco	rd score in appendix	Yes	No		
Spontaneous labour		Yes	No		
Caesarean due to maternal deterior	ration	Yes	No		
Caesarean due to fetal deterioration	n	Yes	No		
Declined induction of labour		Yes	No		
Received Foley catheter		Yes	No		
Received other form of pessary		Yes	No		
Inability to fit allocated intervention	ı	Yes	No		
Failure of cervical ripening		Yes	No		
Withdrawal of consent		Yes	No		
Other Yes No	ʻlf other, please	specify'			
If intervention was given, what was	the reason for the ne	w series?			
Slow/failure to ripen					
Maternal request					
Previous intervention fell-out		ſ			
Other	ʻlf other, please	specify'			
Number of rods inserted (if Dilapan	-S)	LO	T number (if	f Dilapan-S)	
Time and date inserted (24 hour clo	ock) HH	MM	DD		ŶŶŶŶŶ
Time and date removed (24 hour cl	ock) HH	MM	DD		ŶŶŶŶ
Was the intervention removed due	to complications (if y	es record co	omplication	in question 2.8)	Yes No
Did the intervention fall out?					Yes No
'If yes, please record details of inser	tion of new interventi	on in next s	eries'		
'If yes, what was the time/date inter (24 hour clock)	rvention fell out H	H M	MD	D M M M	γγγγ

2.5 <u>Series 3: Interver</u> (Please tick one treat There is more space	ment and complete	•	-			for each insertion.
Dilapan-S	OR	Propess	О	R	Intervention n	ot given
If NO intervention u	uss given OD the all	acted interventi		Taiwan what	twosthe reason	
If NO intervention w	-				t was the reason	
Bishop score 6 or ov	er (please record so	core in appendix	Yes	No		
Spontaneous labour			Yes	No		
Caesarean due to m	aternal deterioratio	on	Yes	No		
Caesarean due to fe	tal deterioration		Yes	No		
Declined induction of	of labour		Yes	No		
Received Foley cath	eter		Yes	No		
Received other form	n of pessary		Yes	No		
Inability to fit alloca	ted intervention		Yes	No		
Failure of cervical ri	pening		Yes	No		
Withdrawal of conse	ent		Yes	No		
Other Yes	No	ʻlf other, please	e specify'			
If intervention was g	given, what was the	reason for the n	ew series?			
Slow/failure to riper	n 🗌					
Maternal request						
Previous interventio	n fell-out					
Other		'If other, please	e specify'			
Number of rods inse	erted (if Dilapan-S)			OT number (ii	f Dilapan-S)	
Time and date inser	ted (24 hour clock)	НН		DD	MMM	γγγγ
Time and date remo	wed (24 hour clock)	НН	MM	DD	MMM	γγγγ
Was the interventio	n removed due to c	omplications (if y	ves record o	complication	in question 2.8)	Yes No
Did the intervention	fall out?					Yes No
ʻlf yes, please record	details of insertion	of new intervent	ion in next	series'		
ʻIf yes, what was the (24 hour clock)	time/date interver	tion fell out H	H M	MD		

2.6 Was analgesia used o	during cervical ripening (including insertion)?	Yes	No		
<i>'If yes, what types were</i> Oral non-steroidal anti-i	used?': nflammatory drugs (excluding paracetamol)	Yes	No		
Paracetamol		Yes	No		
Oral opioid		Yes	No		
Pethidine		Yes	No		
Entonox		Yes	No		
Epidural		Yes	No		
Other Yes No	'If other, please specify'				
If analgesia was used, w (24 hour clock)	hat was the time/date first analgesic was started	HH?	M M M M M	γγ	γγ
2.7 Was the woman suit	able to go home following first insertion of device	e/drug?	Yes	No	
ʻlf yes, did she go hom	ne?'		Yes	No	_
2.8 Complications durin	ng cervical ripening?			Yes	No
'If yes, were they?'	Cervical injury			Yes	No
	Uterine activity or contractions			Yes	No
	Uterine tachysystole (defined as uterine contractions of more than 5 in 10 minu	ites for 20 mi	nutes)	Yes	No
	Uterine hyperstimulation with non reassuring/al (defined as uterine contractions of more than 5 in 10 minuton NICE guidelines)			Yes	No according
	Effect on fetus (CTG) with non-reassuring/abnor	mal fetal h	eart rate	Yes	No
	Nausea			Yes	No
	Vomiting			Yes	No
	Diarrhoea			Yes	No
	Fever			Yes 🗌	No
	Hypotension			Yes	No
	Maternal tachycardia			Yes 🗌	No
	Rupture of membranes			Yes 🗌	No
	Suspected chorioamnionitis			Yes	No
	Other Yes No 'If other, please	specify'			

Part 3: Labour Events							
3.1 Bishop score	on completio	on of cervical ri	pening pro	cess (see scoring	system be	low)	
Please tick the re	levant boxes	below <u>for last</u>	VE:				
Score		0		1		2	3
Dilation (cm):	<1		1-2		3-4		<u>&gt;</u> 5
Length of cervix (cm):	>4		2-4		1-2		<1
Station relative to ischial spines (cm):	-3		-2		-1, 0		+1, +2
Consistency:	Firm		Medium		Soft		
Position of cervix:	Posterior		Mid		Anterior		
Time and date of Bish recorded (24 hour clo	-	НН				MYY	YY
3.2 Was another	intervention	used to induce	labour?		Ye	s No	
ʻIf No, time/date	labour starte	ed' (24 hour clo	ck) [H]	H M M	DD		γγγγ
ʻlf yes, what inter	'If yes, what intervention was used?' 1) Amniotomy undertaken for induction Yes No						
Time/Date of a	mniotomy (2	24 hour clock)	H	H M M	DD		ΥΥΥΥ
		2) Requi	red oxytoc	in for induction	Ye	es No	
Time/Date of o	xytocin start	ed (24 hour clo	ck) H		DD		ΥΥΥΥ
Time/Date of o	xytocin com	pleted (24 hour	clock)		DD		YYYY
		3) Other	Yes	No 'If o	other, pleas	e specify'	
Time/Date of 'c	other' interve	ention (24 hour	clock) [H		DD		ΥΥΥΥ
3.3 Did the labou	r require au	gmentation?			Ye	s No	
'If yes, what method was used?' 1) Amniotony undertaken for augmentation Yes No							
Time/Date of a	mniotomy (2	24 hour clock)	H	H	DD		γγγγ
2) Required oxytocin for augmentation Yes No							
Time/Date of o	oxytocin start	ed (24 hour clo	ck)		DD		ΥΥΥΥ
Time/Date of o	xytocin com	pleted (24 hour	clock)		DD		ΥΥΥΥ
		3) Other Yo	es 📃 N	Io <i>'If othe</i>	er, please sp	ecify'	
Time/Date of '	other' interv	ention (24 hour	clock				γγγγ
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3.4 Was analgesia used during	labour?				Yes	No
'lf yes, what types were us		Oral non-steroi (excluding para	dal anti-inflammatory dru cetamol)	ugs	Yes	No
		Paracetamol	Paracetamol			No
		Oral opioid	Yes	No		
		Systemic opioic	Yes	No		
		Epidural/spinal	Yes	No		
		Remifentanil PO	Yes	No		
		Entonox			Yes	No
		General anaest	hesia		Yes	No
Other Yes No 'If other, please specify'				ify'		
3.5 Ultimate mode of delivery	(please tio	ck one) Unassis	ted vaginal			
		Caesare	ean			
		Instrum	nental Ventouse			
		Instrum	nental Forceps			
If the delivery was instrume	ntal, wha	t was the indica	ation for this?			
Suspicious CTG Yes	No		Poor maternal effort	Yes	No	
Pathological CTG Yes	No		Abnormal FBS ( <u>&lt;</u> 7.20)	Yes	No	
Delay in 2 <sup>nd</sup> stage Yes	No		Significant STAN event	Yes	No	
Hyperstimulation** Yes	No		Other	Yes	No	
			'If other, please specify'			
** Hyperstimulation is defined as more		erine contractions i	n 10 mins, for a period of 20 m	nins or more, a	and resulting in a	non-

reassuring or abnormal fetal heart rate.

3.6 If delivery by caesarean, tick one category only:	Caesarean category I (immediate threat to life of woman or fetus)
	Caesarean category II (maternal or fetal compromise which is not immediately life threatening)
	Caesarean category III (no maternal or fetal compromise but needs early delivery)

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3.7 If delivery by caesarean tick all indications that apply:

Fetal hypoxia/distress	Yes		No				
Abnormal/non-reassuring CTG	Yes		No				
Abnormal FBS ( <u>&lt;</u> 7.20)	Yes		No				
Significant STAN event	Yes		No				
Uterine hyperstimulation/tachy	systole Yes		No				
Failure of induction	Yes		No				
Failed instrumental birth	Yes		No				
Unsuitable for instrumental	Yes		No				
Failure to progress	Yes		No				
If failure to progress, was this:	a) failure to di	late		Yes	No		
	b) fetal malpo	sition		Yes	No		
	c) poor materi	nal eff	ort	Yes	No		
	d) delay 1st st	age		Yes	No		
	e) delay 2nd st	tage		Yes	No		
Induction refused by mother	Yes		No				
Caesarean requested by mother	Yes (		No				
Other	Yes		No				
'If other, please specify'							
3.8 If <b>delivery by caesarean</b> what	at was the deci	sion to	birth ir	nterval (mi	nutes)		
3.9 Complications during/imme	diately after la	abour	(please re	port uterine	dehisce	nce as an SA	E)
Uterine hyperstimulation						Yes	No
Perineal injury						Yes	No
If perineal injury please	specify tear gr	ade:	Ι				
			II				
			Ш				
			IV				
			Epis	iotomy			

Manual removal of placenta	Yes No
Primary post-partum haemorrhage (loss <a>500 ml blood from genital tract)</a>	Yes No
Cervical injury	Yes No
Other Yes No 'If other, please specify'	
3.10 Where did delivery take place? Home Birth centre	Hospital maternity unit
Other <i>'If other, please spo</i>	ecify'
Part 4: Information on birth and baby (– please use 24 hour clock for times)	
4.1 Birth weight (grams)	
4.2 Was the baby born alive? Yes No Time/date delivery	(24 hour clock) H H M M
4.3 Please record APGAR Score at:	
1 Min 5 Mins 10 Mins	
Please tick if the score was not recorded at 1 minute	
Please tick if the score was not recorded at 5 minutes	
Please tick if the score was not recorded at 10 minutes	
4.4 Was meconium staining noted? Yes No	
4.5 Were cord blood gases collected? Yes No 'If no, go to	o question 4.6'
If any core blood gases were collected, what were the results?	
Arterial pH or tick if not recorded Base deficit(mmol/I)/Base ex	xcess(mmol/l )
or tick if not recorded base deficit/base excess	
Venous pH or tick if not recorded Base deficit (mmol/l)/Base e	excess(mmol/l)
or tick if not recorded base deficit/base excess	
Lactatemmol/l or tick if not recorded	
4.6 Where did the baby go after birth? Transferred to postnatal w	ard
Discharged home from lab	our ward
Admitted to intensive care	
Admitted to high dependent	ncy unit
Admitted to special/transit	ional care

Part 5: From delivery until discharge
REMEMBER TO COMPLETE SAE FORMS FOR MATERNAL AND NEONATAL SAEs WHERE NECESSARY
5.1 Did the woman experience any complications? Yes No
<i>'If yes, please tick all that apply':</i> clinical diagnosis consistent with vaginal infection Yes No
clinical diagnosis consistent with endometritis Yes No
clinical diagnosis consistent with uterine infection Yes No
secondary post-partum haemorrhage (>500ml) Yes No
other Yes No 'If other, please specify'
5.2 If 'yes' to 5.1, was the woman given antibiotics? Yes No
<i>'If yes, was this by'</i> IV or given orally and how long for (days)?
5.3 Date of discharge of mother from this hospital DDDMMM YYYYY
5.4 Did baby require review by a doctor from the neonatal team (excluding routine baby check)? Yes No
5.5 If 'yes', why was the baby reviewed (please tick)?
Infection Other Other <i>'If other, please specify'</i>
5.6 If review was for INFECTION was the baby given antibiotics?
'If yes, how long for (days)?'
5.7 Was the baby admitted to NNU at this hospital? Yes No
'If yes, what was the reason' Infection Yes No
Meconium aspiration Yes No
Other Yes No 'If other, please specify'
If baby was admitted to NNU, what was the date of admission DD MMM YYYYY
Date of discharge from NNU
5.8 Date of discharge of baby from this hospital
5.9 Was the baby transferred to another hospital? Yes No
Name of person completing form (PRINT) Date form completed Signature

Appendix 1: Additional Bishop Scores (between 1 <sup>st</sup> and last VE)
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Bishop score (see	e scoring syst	em below)						
Please tick the re	levant boxes	below:						
Score Dilation (cm): Length of cervix (cm): Station relative to ischial spines (cm): Consistency: Position of cervix: Time and date o		0 □ □ □ ■ e   (+) (+	1-2 2-4 -2 Medium Mid		3-4 1-2 -1, 0 Soft Anterior		≥5 <1 +1, +2	3   
recorded (24 ho	UT CIOCK)							
Bishop score (see	e scoring syste	em below)						
Please tick the re	elevant boxes	below:						
Score Dilation (cm): Length of cervix (cm): Station relative to ischial spines (cm): Consistency: Position of cervix:	<1 >4 -3 Firm Posterior	0 	1-2 2-4 -2 Medium Mid	1	3-4 1-2 -1, 0 Soft Anterior	2 	<u>≥</u> 5 <1 +1, +2	3   
Time and date or recorded (24 hor	•	e H		MDD			( ) Y	
Bishop score (see scoring system below)								
Score Dilation (cm):	<1	0	1-2	1	3-4	2	<u>&gt;</u> 5	3
Length of cervix (cm):	>4		2-4		1-2		<u>-</u> 5 <1	
Station relative to ischial spines (cm): Consistency:	-3 Firm		-2 Medium		-1, 0 Soft		+1, +2	
Position of cervix:	Posterior		Mid		Anterior			
Time and date recorded (24 h		ore H		MDD	MM	MYYN	(   Y	

Bishop score (see scoring system below)									
Please tick the relevant boxes below:									
Score		0		1		2		3	
Dilation (cm):	<1		1-2		3-4		<u>&gt;</u> 5		
Length of cervix (cm):	>4		2-4		1-2		<1		
Station relative to ischial spines (cm):	-3		-2		-1, 0		+1, +2		
Consistency:	Firm		Medium	ו 🗌	Soft				
Position of cervix:	Posterior		Mid		Anterior				
Time and date of Bishop score recorded (24 hour clock)									

Bishop score (see scoring system below)									
Please tick the re	elevant boxes	s below:							
Score		0		1		2		3	
Dilation (cm):	<1		1-2		3-4		<u>&gt;</u> 5		
Length of cervix (cm):	>4		2-4		1-2		<1		
Station relative to ischial spines (cm):	-3		-2		-1, 0		+1, +2		
Consistency:	Firm		Medium		Soft				
Position of cervix:	Posterior		Mid		Anterior				
Time and date of Bishop score recorded (24 hour clock)HMDMYYY									

Bishop score (see scoring system below)									
Please tick the re	levant boxes	below	/: /:						
Score		0		1		2	3		
Dilation (cm):	<1		1-2		3-4		<u>&gt;</u> 5		
Length of cervix (cm):	>4		2-4		1-2		<1		
Station relative to ischial spines (cm):	-3		-2		-1, 0		+1, +2		
Consistency:	Firm		Medium		Soft				
Position of cervix:	Posterior		Mid		Anterior				
Time and date of recorded (24 hour	•			M		M	γγγγ		

## **Appendix 2: Additional Treatment Series**

## Series 4: Intervention used

(Please tick one treatment an	d complete the correspo	onding information.	. Please use a new serie	s for each insertion)
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Dilapan-S	OR	Propess	C	DR	Intervention n	ot given	
lf NO, intervent	ion was given OR the all	ocated intervent	ion was NG	DT given, wha	at was the reason	:	
Bishop score 6 o	or over (please record so	core in appendix	Yes	No			
Spontaneous la	bour		Yes	No			
Caesarean due	to maternal deterioratio	on	Yes	No			
Caesarean due	to fetal deterioration		Yes	No			
Declined induct	ion of labour		Yes	No			
Received Foley	catheter		Yes	No			
Received other	form of pessary		Yes	No			
Inability to fit a	llocated intervention		Yes	No			
Failure of cervic	al ripening		Yes	No			
Withdrawal of o	consent		Yes	No			
Other Yes	No	ʻlf other, please	e specify'				
If intervention v	was given, what was the	reason for the n	ew series?				
Slow/failure to	ripen						
Maternal reque	st						
Previous interve	ention fell-out						_
Other		ʻlf other, please	e specify'				
Number of rods	s inserted (if Dilapan-S)		L	OT number (i	f Dilapan-S)		
Time and date i	nserted (24 hour clock)	НН					Y
Time and date r	removed (24 hour clock)	НН			МММ	YVV	Y
Was the interve	ention removed due to c	omplications (if y	es record	complication	in question 2.8)	Yes N	10U
Did the interver	ition fall out?					Yes N	10
ʻlf yes, please re	cord details of insertion	of new intervent	ion in next	series'			— <u> </u>
ʻlf yes, what wa (24 hour clock)	s the time/date interven	tion fell out	H				Y Y
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Series 5: Intervention used

Please tick one treatment an	d complete the correspon	ding information. Please use	a new series for each insertion)
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Dilapan-S	OR	Propess	C	R	Intervention not	given
If NO, intervention wa	as given OR the all	ocated intervent	ion was NC	DT given, wha	t was the reason:	
Bishop score 6 or over	r (please record sc	ore in appendix	Yes	No		
Spontaneous labour			Yes	No		
Caesarean due to mat	ternal deterioratio	n	Yes	No		
Caesarean due to feta	l deterioration		Yes	No		
Declined induction of	labour		Yes	No		
Received Foley cathet	er		Yes	No		
Received other form o	of pessary		Yes	No		
Inability to fit allocate	d intervention		Yes	No		
Failure of cervical ripe	ening		Yes	No		
Withdrawal of consen	ıt		Yes	No		
Other Yes N	lo	ʻlf other, please	e specify'			
If intervention was give	ven, what was the	reason for the n	ew series?			
Slow/failure to ripen						
Maternal request						
Previous intervention	fell-out					
Other		ʻlf other, please	e specify'			
Number of rods insert	ted (if Dilapan-S)		) L	OT number (if	f Dilapan-S)	
Time and date inserte	d (24 hour clock)	HH		DD		YYYY
Time and date remove	ed (24 hour clock)	HH		DD		
Was the intervention	removed due to co	omplications (if y	ves record	complication	in question 2.8)	Yes No
Did the intervention fa	all out?					Yes No
ʻlf yes, please record d	letails of insertion	of new intervent	ion in next	series'		
ʻlf yes, what was the t (24 hour clock)	ime/date interven	tion fell out H	H	MD		ΥΥΥΥΥ

#### THANK YOU

Any queries, please contact the SOLVE Study Office (Tel: 0121 415 9112) Room G24, Public Health Building, University of Birmingham, Edgbaston, Birmingham B15 2TT