The Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH)

CRF6: C-STICH Baby Outcome

This CRF is to be completed at different time points for neonates born preterm compared with term.

For preterm neonates (born less than 37 weeks), please complete at the estimated date of delivery (as confirmed by first trimester ultrasound) or discharge from hospital whichever occurred sooner.

For term neonates (born after 37 weeks), please complete at 28 days post-delivery or discharge from hospital whichever occurred sooner.

A. Please complete Sections 1 and 3 in all cases.

B. Please follow the instructions in RED for completion of the form.

Section 1. Patient details:

Patient's trial number: ☐☐☐☐

Patient's Date of Birth (MMM-YYYY): M M M - Y Y Y Y

Section 2. Information about the baby:

1. Has the baby been discharged from hospital care?

Yes ☐ *(Please go to question 1a)*

No ☐ *(Please go to question 2)*

1a. Was the baby alive when it was discharged from hospital Care?

Yes ☐ Date of discharge: D D - M M M - Y Y Y Y

No ☐ Date of death: D D - M M M - Y Y Y Y

2. Did the baby require any advanced resuscitation at birth? Yes ☐ No ☐

2a. If advanced resuscitation at birth was required, please state what this was:

	Yes	No		Yes	No
Endotracheal intubation	☐	☐	Chest compressions	☐	☐
Resuscitation drugs	☐	☐			

Section 2. Information about the baby continued:

3. Did the baby require any additional care after delivery? Yes ☐ No ☐

3a. If additional care was required, please record the number of days of additional care at each level:

SCBU/Level 1		NICU/Level 3	
HDU/Level 2		Transitional Care	

4. Were any antibiotics administered to the baby in the 72 hours after birth?

Yes ☐

No ☐ *If NO, please go to question 5.*

4a. If YES, please tick yes or no to indicate which antibiotic(s) the baby was or was not giv-

	Yes	NO
Benzyl penicillin	☐	☐
Aminoglycoside (e.g. gentamicin)	☐	☐
Intravenous cephalosporin	☐	☐
Other (please specify below)	☐	☐

Other antibiotic(s) administered to the baby (please state name here):

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	Yes	NO
4c. Were antibiotic(s) continued for 72 or more hours?	☐	☐

Section 2. Information about the baby continued:

	Yes	NO
4d. Was infection microbiologically confirmed (positive blood or CSF culture)?	☐	☐

4e. If confirmed, please indicate below which organism was, and was not, identified?

Gram-positive bacteria	Yes	No
Staphylococcus aureus		
Group B, β -haemolytic Streptococci		
Other β -haemolytic		
S. pneumoniae		
Enterococci		
Other		

If Other, please state what this is_____

Gram-negative bacteria	Yes	No
Escherichia coli		
Klebsiella spp.		
Proteus spp		
Enterobacter spp.		
Haemophilus influenzae		
Neiserria gonorrhoaea		
Pseudomonas aeruginosa		
Enterococci		
Acinetobacter		
Listeria monocytogenes		
Other		

If Other, please state what this is_____

Section 2. Information about the baby continued:

Other Microorganisms	Yes	No
Candida		
Anaerobic bacteria		
Other		

If Other, please state what this is_____

5. Did the baby receive any additional respiratory support? YES ☐ NO ☐

5a. If 'Yes', please indicate which support was received

Ventilation YES ☐ NO ☐ CPAP YES ☐ NO ☐ Oxygen via nasal prongs YES ☐ NO ☐

5b. What was the total number of days support? ☐

	YES	NO
6. Was the baby born preterm? *If born preterm, answer the remainder of Q6. If no, move to Q7.*	☐	☐
6b. Was the baby dependent on additional oxygen at 36 weeks corrected gestation?	☐	☐
6c. Did the baby have necrotising enterocolitis (Bell's stage 2 or Bell's stage 3)?	☐	☐
6d. Did the baby have retinopathy of prematurity which required laser treatment?	☐	☐
7. Was an cranial ultrasound scan performed?	☐	☐
7a. If 'Yes', are there any severe abnormalities present on the cranial ultrasound scan?	☐	☐

7b. If severe abnormalities were present, please state what these are:

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Section 2. Information about the baby continued:

	YES	NO
8. Does the baby have any disabilities?	☐	☐

8a. If YES, please state what these are:

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	YES	NO
9. Were there any congenital anomalies ?	☐	☐

9a. If YES, please state what these are:

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Section 3. Some information about you:

Your Name: ……

Your Centre: ……..

Today's date: D D - M M M - Y Y Y Y

THANK YOU FOR COMPLETING THIS FORM

Please enter the information from this CRF into the C-STICH online database by logging in at trials.bham.ac.uk/CSTICH

OR return a copy of the completed form to the trials office to be entered on-to the database. Please return to:

C-STICH Trial, FREEPOST RTGS-UKLK-JKHS, Birmingham Clinical Trials Unit, Institute of Applied Health Research, University of Birmingham, B15 2TT

Or by fax to **0121 415 9136**

Or via email to **cstich@trials.bham.ac.uk**