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

CRF5 Part B: C-STICH Maternal Outcome.

PLEASE COMPLETE THIS FORM AT 7 DAYS POST NATAL.

PLEASE FOLLOW THE INSTRUCTIONS IN RED FOR COMPLETING THIS 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 Mother:

1. Did the mother develop a fever (38°C or above?) whist an inpatient postnatally?

YES (≥ 38°C)	NO (≤ 37.9°C)	If 'Yes', please record highest temperature °C
☐	☐	

2. Did the mother receive any antibiotics whilst an inpatient postnatally?

YES ☐ **NO** ☐

If yes, please answer the remainder of Q2, otherwise proceed to Q3.

2a. What was the indication for antibiotics (Please tick all that apply)?:

	YES	NO
• Prophylaxis following MROP/ Perineal tear.	☐	☐
• Endometritis.	☐	☐
• Urinary Tract Infection.	☐	☐
• Other.	☐	☐

If other, please specify:

……

Section 2. Information about the mother continued:

2b. Which antibiotic(s) did the mother receive (please tick yes or no to the following)?

β-lactam antibiotics:	**YES**	**NO**
Intravenous benzyl penicillin		
Intravenous co-amoxiclav		
Intravenous cephalosporin		
Oral cephalosporin		
Oral co-amoxiclav		

Other antibiotics	**YES**	**NO**
Intravenous gentamicin		
Intravenous clindamycin		
Intravenous metronidazole		
Oral nitrofurantoin		
Oral metronidazole		
Other (*Please specify below*)		

If other antibiotic (please specify here): ……

Section 2. Information about the mother continued:

*Defined as infection plus any 2 systemic manifestations of infection from the following: Fever ≥ 38°C or hypothermia <36°C, tachycardia (HR>90), tachypnoea (respiratory rate >20).

	YES	NO
3. Did the mother develop any sepsis within the pregnancy or within 7 days postnatal*?	☐	☐

If the mother developed sepsis, please answer the remainder of Q3. If No, go to Q4.

3a. When was the onset of sepsis? (please tick one box only):

During Pregnancy? ☐ **If during pregnancy, what was the gestation of sepsis?** **Weeks** ☐ **Days** ☐	**Postnatal?** ☐ **If postnatal, please specify the number of days postnatal from delivery?** **Days** ☐

3b. What was the primary site of infection? (Please tick one box only)

	YES
• **Urinary Tract**	☐
• **Chorioamnionitis**	☐
• **Endometritis**	☐
• **Wound infection**	☐
• **Other**	☐

If Other, please specify……

	YES	NO
3c. Was the infection confirmed on culture?	☐	☐

3d. If Yes, which organism was identified on culture? (Please tick Yes or No to all)

	YES	NO
• **E.coli**	☐	☐
• **Group B streptococci**	☐	☐
• **Group A streptococci**	☐	☐
• **Other**	☐	☐

If Other, please specify ……..

Section 2. Information about the mother (continued):

3e. Which antibiotic(s) was the mother given to treat the sepsis (Please tick Yes or No to all)?

β-lactam antibiotics:	**YES**	**NO**
Intravenous benzyl penicillin		
Intravenous cephalosporin		
Intravenous co-amoxiclav		
Oral cephalosporin		
Oral co-amoxiclav		

Other antibiotics	**YES**	**NO**
Intravenous gentamicin		
Intravenous clindamycin		
Intravenous metronidazole		
Other (*Please specify below*)		

If other antibiotic (please specify here): ……

	YES	**NO**
4. Did the mother spend any time post delivery in the HDU?		

If YES, How many days? ☐

	YES	**NO**
5h. Did the mother spend any time post delivery in the ITU?		

If YES, How many days? ☐

IF THE MOTHER HAS SUFFERED A SERIOUS ADVERSE EVENT PLEASE COMPLETE CRF7 SERIOUS ADVERSE EVENT REPORTING FORM AND FAX IT TO THE C-STICH TRIALS OFFICE

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**