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

CRF5 PART A: C-STICH Pregnancy Outcome.

PLEASE COMPLETE THIS FORM IMMEDIATELY FOLLOWING DELIVERY.

A. PLEASE COMPLETE SECTIONS 1, & 6 IN ALL CASES.

B. IF THE BABY WAS BORN ALIVE, PLEASE ALSO COMPLETE Q3 AND ALL SUBSEQUENT QUESTIONS.

C. IF THE BABY WAS NOT BORN ALIVE, PLEASE ALSO COMPLETE Q2 AND FOLLOW THE CORRESPONDING INSTRUCTIONS AT [1] [2] and [3].

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. Was the baby born alive?

☐ **Yes** *Date of live birth:* D D – M M M – Y Y Y Y *Please go to Q3.*

☐ **No** *Date of delivery:* D D – M M M – Y Y Y Y *Please go to Q2.*

2. Please tick the cause of death?:

☐ Still birth (interuterine death at 24 weeks or more of pregnancy)[1]

☐ Spontaneous Miscarriage (interuterine death within 24 weeks of pregnancy[2]

☐ Missed Miscarriage[2]

☐ Septic Miscarriage[2]

☐ Termination due to fetal anomaly[3]

☐ Termination due to maternal medical condition (but not infection)[3]

☐ Termination due to maternal sepsis[3]

☐ Other factor[3] (Please specify) _____

Management?:

☐ Medically ☐ Surgically ☐ Expectantly ☐ Other

*If 'Other', please specify*_____

[1]Please complete the remainder of this form including Section 3.

[2]Please complete the remainder of this form but do not complete questions 7 and 8 or Section 3.

[3]Please complete the remainder of this form excluding Section 3.

Section 2. Information about the mother continued:

	YES	NO
3. Did the mother develop preterm pre labour rupture of membranes (PPROM)? *If Yes, please answer the remainder of Q3. If No, go to Q4.*	☐	☐
3b. Was the cerclage removed at confirmation of PPROM?	☐	☐
3c. Did the mother receive prophylactic antibiotics following PPROM?	☐	☐

3d. If the mother received prophylactic antibiotics following PPROM please tick to indicate which anti-biotics she received?

PO Erythromycin ☐ **Other** ☐ **If Other, please specify**……

	YES	NO
4. Was the mother admitted to hospital with any episodes of per vaginal bleeding in this pregnancy?	☐	☐
5. Did the mother receive antenatal corticosteroids for foetal maturity during the pregnancy?	☐	☐

5a. If yes, please specify gestation when received: weeks ☐ **days** ☐

	YES	NO
5b. Was the steroid course completed prior to delivery of the baby?	☐	☐
6. Did the mother receive any progesterone treatment during this pregnancy? *If Yes, please answer the remainder of Q6. If No, go to Q7.*	☐	☐

6a. Please specify preparation of progesterone the mother received.	YES	NO
• Cyclogest 200mg PV daily	☐	☐
• Cyclogest 400mg PV daily	☐	☐
• 17 alpha-hydroxyprogesterone 250mg IM weekly	☐	☐
• Other	☐	☐

If 'Other', please specify _____

6b. At what gestation did the mother commence progesterone? weeks ☐ **days** ☐

6c.At what gestation was the progesterone discontinued? weeks ☐ **days** ☐

Section 2. Information about the mother (continued):

7. Was the onset of labour spontaneous or induced? (Please tick one box only):

Spontaneous ☐

Induced due to maternal infection ☐

Induced due to other maternal reason ☐ Please specify …….

Induced due to foetal reason ☐ Please specify …….

8. What was the mode of delivery? (Please tick the relevant box, and answer all corresponding questions):

Normal Vaginal ☐

Operative Vaginal ☐ *Was the operation* Forceps or Ventouse? **Forceps** ☐ **Ventouse** ☐

Caesarean ☐ *Please indicate the category of caesarean below:*

Emergency		**Elective**	
Category i ☐	Category ii ☐	Category iii ☐	Category iv ☐
Immediate threat to life	Maternal or fetal compromise	Planned for medical reasons or requested by the mother	

9. Did the mother have a fever (38°C or above?) during labour?

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

Section 2. Information about the mother (continued):

9a. Did the mother receive any antibiotics during her labour (excluding prophylaxis during the Caesarean section)?

YES ☐ *Please answer the remainder of Q9.* **NO** ☐ **DON'T KNOW** ☐ *If no or don't know, please go to Q10.*

9b. What was the indication for antibiotics (Please tick 'yes' or 'no' to the following)?:

	YES	NO	
Group B strep prophylaxis	☐	☐	
Chorioamnionitis	☐	☐	
Other reason	☐	☐	If 'Other', please specify……

9c. Which antibiotic(s) did the mother receive (please tick Yes or No to all):

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

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

Other antibiotic (please specify here): ……

Section 2. Information about the mother (continued):

	YES	NO
10. Did the mother spend any time pre-delivery in HDU ?	☐	☐
10a. If YES, please indicate the number of days on HDU:	☐	
11. Did the mother spend any time pre-delivery in the ITU ?	☐	☐
11a. If YES, please indicate the number of days on ITU:	☐	
12. Did the mother receive HDU (level 2 care) during her labour?	☐	☐

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. Information about the baby:

13. What was the baby's birth weight? (grams): .....

14. What is the baby's NHS / CHI number? : ☐☐☐☐☐☐☐☐☐☐

15. What is the baby's gender? :

Male	Female	Indeterminate
☐	☐	☐

16. What was the baby's gestational age at birth? ☐☐ Weeks ☐☐ Days

Section 4. Previous Cervical Surgery:

	YES	NO
17. Has the mother had any cervical surgery prior to joining this trial?	☐	☐

17a. If Yes, please indicate which type of surgery this was:

1 x previous LLETZ	☐	Knife Cone Biopsy	☐	
2x previous LLETZ	☐	Other please specify	☐	……

	YES	NO
18. Does the mother have a uterine anomaly?	☐	☐

18a. If Yes, please specify what this is:

……

Section 5. Other Trial Participation:

	YES	NO
19. Did the mother take part in any other trial whilst recruited to C-STICH?	☐	☐

19a. If yes, please indicate which trial/s the mother was enrolled in:

Trial Name	Intervention (if known)

Section 6. 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**