C-STICH2: Emergency Cervical Cerclage to Prevent Miscarriage and Preterm Birth

Minimal Dataset Form

Please complete this form for all women who were screened for C-STICH2, but did not consent to the RCT or observational study.

Section 1 - Patient Details

Patient Trial Number: ☐☐☐☐

Patient partial DOB: *Months, Years* M M M Y Y Y Y

Section 2 - Patient Demographics

BMI at booking ___ ___ . ___ kg/m^2

Did the mother smoke at booking? ◯ No ◯ Yes

Estimated date of delivery: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Section 3 - Patient Ethnicity

Ethnicity

◯ British European ◯ Irish European ◯ East European ◯ North European ◯ South European ◯ West European
◯ North African ◯ Sub-Saharan African ◯ Middle Eastern ◯ Indian ◯ Pakistani ◯ Bangladeshi ◯ Chinese
◯ Other Far-Eastern ◯ South East Asian ◯ Caribbean ◯ Other ◯ Information Not Available

Section 4 - Pregnancy Details

Cervical dilatation at time assessed for eligibility ◯ <=3cm ◯ >=4cm ◯ Fully dilated (minimal cervix seen/felt)

Section 5 - Care received

Cerclage

Was there an attempt to place an ECC? ◯ No ◯ Yes

If **yes**, date attempted: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Was the attempt to place the ECC successful? ◯ No ◯ Yes

If **yes**, please continue to Section 6. If **no**, please indicate why the ECC was unsuccesful (answer all):

Cervical Bleeding	◯ No	◯ Yes
Infection	◯ No	◯ Yes
Unable to replace membranes	◯ No	◯ Yes
Cervix too dilated	◯ No	◯ Yes
Membranes ruptured	◯ No	◯ Yes
Delivery prior to placement	◯ No	◯ Yes
Other, (specify below):	◯ No	◯ Yes

If **other**, please specify:

Section 6 - Preterm, pre-labour rupture of membranes (PPROM)

Did the mother develop PPROM? *Tick one* ◯ No ◯ Yes

If **yes**, date of PPROM: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Section 7 - Pregnancy Outcome

Gestation at delivery: *Weeks, Days* W W D D

What was the pregnancy outcome?

Stillbirth (intrauterine death ≥ 24 weeks)	◯ No	◯ Yes
Miscarriage (intrauterine death < 24 weeks of pregnancy)	◯ No	◯ Yes
Termination due to fetal anomaly	◯ No	◯ Yes
Termination due to maternal medical condition (but not infection)	◯ No	◯ Yes
Termination due to maternal infection	◯ No	◯ Yes
Live birth	◯ No	◯ Yes
Other please specify	◯ No	◯ Yes

If **other**. please specify:

_____

Section 8 - Labour & Delivery

Did the mother labour? *Tick one* ◯ No ◯ Yes

If **yes**, was the labour induced? ◯ No ◯ Yes

If **yes**, please specify the reason for induction *answer all*

Small for gestational age/IUGR	◯ No	◯ Yes
PPROM	◯ No	◯ Yes
Maternal hypertension/pre eclampsia	◯ No	◯ Yes
Suspected/Confirmed Infection	◯ No	◯ Yes
Other	◯ No	◯ Yes

If **other**. please specify:

_____

What was the final mode of delivery? *tick one* ◯ Normal vaginal ◯ Forceps ◯ Ventouse ◯ Caesarean Section

Section 9 - Baby information

Baby's birth weight: ___ ___ ___ ___ grams

Baby's gender *tick one* ◯ Male ◯ Female ◯ Indeterminate

Did the baby die following delivery prior to discharge home? ◯ No ◯ Yes

If **yes**, please complete the remainder of this section. If **no**, continue to Section 10.

Age at death: *Weeks, Days* W W D D

Cause of death: *as per the death certificate*

_____

_____

Section 10 - Your details

Name: _____ Signature: _____

Today's Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Please enter the information from this CRF into the C-STICH2 online database by logging in at: www.trials.bham.ac.uk/C-STICH2. Please then send a copy to **c-stich2@trials.bham.ac.uk** or to C-stich2 trials office, FREEPOST RTZL–JGLJ–TALA, Birmingham Clinical Trials Unit, Institute of Applied Health Research, University of Birmingham, B15 2TT