The TRANSFER Project Guide

V6.0 14-Mar-2022

ThReatened preterm birth, Assessment of the Need for in utero tranSFER between 22+0-23+6 weeks' gestation.

The TRANSFER project is a fantastic opportunity to establish the numbers of babies in the UK presenting at risk of early delivery between 22+0 and 23+6 weeks and their management.

Contents

Objective

To establish the incidence of women presenting with threatened preterm birth to obstetric units in England, Scotland and Wales and Northern Ireland between 22+0-23+6 weeks' gestation and determine the number requiring transfer to an obstetric unit with co-located neonatal intensive care unit (NICU) (level 3).

Project design

TRANSFER is a multi-centre, prospective service evaluation of current practice. All obstetric units within the UK are invited to participate. There is no change to the patient pathway, as a result of inclusion within TRANSFER. This is an evaluation of practice.

What's involved in taking part in TRANSFER?

- Prospective anonymised data collection
- Capture data on all eligible women at your unit from when your site is set up to take part in TRANSFER and continue until 30-Jun-22, plus follow up until delivery if before 01-Aug-2022 (the window for including follow up data to the project database will close on 31 July 2022).
- Data will be collected using the secure web application REDCap
- Complete two case report forms (CRFs) for each patient (baseline and outcomes)
- Follow up duration is to delivery

As TRANSFER is a service evaluation rather than a trial set up is quick (just register with your trust).

It is anticipated that at larger centres the time commitment for the whole team should not be more than 2 hours per month.

TRANSFER has a rolling registration for new hospital sites

- Sites can still sign up to take part in TRANSFER (see below for details)
- Once you have permission from your Trust start to collect data on all consecutive, eligible patients.
- The online sign up form contains a list of sites that have already signed up to take part in TRANSFER. Each centre has one team, if your hospital is already involved in TRANSFER let us know and we can put you in touch with the Lead at your site. Contact us at transfer-study@contacts.bham.ac.uk
- This project is prospective so if your centre signed up after the launch date just start to record patients from your start date.

Getting started

1. We recommend that within your site you identify a consultant lead clinician and link with several key people. At each site we anticipate:

   - A consultant lead to provide oversight and ensure the audit approvals are in place (point 2 below)
   - A trainee lead to coordinate patient identification and data collection.

   Sign up your team here: www.redcap.link/transferteams

   Teams should be per hospital, rather than per trust. This is to allow us to establish the need for transfer between all hospitals, including those within a trust.

   As team members may work across multiple hospitals, collaborators can be signed up at more than one hospital.

2. Register TRANSFER with your hospital

   This project is not considered Research by the NHS according to the HRA decision tool (http://www.hra-decisiontools.org.uk/research).

   No patient identifiable data is being collected outside the clinical care teams. We are advising teams to register TRANSFER as a service evaluation at their trust using the protocol and registration guide.

The consultant lead is responsible for ensuring the project is appropriately registered. If you have any questions about this please contact us at transfer-study@contacts.bham.ac.uk.

3. TRANSFER WhatsApp

To facilitate communication centres may find it useful to set up WhatsApp groups for your site. This will facilitate important messages being communicated to and within the team in a timely manner.

There is also a TRANSFER Collaborators National WhatsApp group for collaborators to share any tips they have to help other colleagues. You can join via the following URL

https://chat.whatsapp.com/JEUj7TZgZZ6Kwa4qqVhM4Z

4. Start date and the project database

As soon as you have permission from your Trust to start collecting data you can begin to track eligible patients prospectively. Once you approvals in place let us know and we will organise logins to the TRANSFER online database so you can upload your records.

Identification of women

As per the protocol we are aiming to collect data on all women presenting at risk of preterm delivery between 22+0 -23+6 weeks irrespective of whether active care is planned or not.

The key to a successful project is identification of all women at risk of delivery between 22+0 – 23+6 weeks' gestation irrespective of whether active care is planned. We therefore suggest that within each clinical team local pathways are developed to facilitate the identification of women. This will include identifying all women delivering less than 24 weeks, all women undergoing an in utero transfer less than 24 weeks (sending and receiving) and all women admitted to the delivery suite or antenatal ward with signs and or symptoms of preterm labour under 24 weeks who do not go on to subsequently deliver within this hospital episode.

The regional leads and project leads will be happy to facilitate suggested mechanisms to achieve this with individual site advice depending up on the records systems used.

Local support via the TRANSFER regional leads

TRANSFER has a network of regional leads who are able to offer support locally –

- to help troubleshoot and overcome barriers to set up
- explain the project and rationale
- help with identifying patient pathways so all eligible patients are captured.

Please contact your regional leads if you need support with any of the above

Region	Name	Contact details
East Midlands	Penny McParland	penelope.mcparland@uhl-tr.nhs.uk
East of England	Rachel Wooldridge	racheljane.wooldridge@nhs.net
London	Manju Chandiramani & Ellie Watson	manju.Chandiramani1@gstt.nhs.uk helena.watson@nhs.net
North East	Alexandra Patience	alexandra.Patience@nhs.net
North West	Ghazia Saleemi & Angharad Care	angharad.Care@liverpool.ac.uk ghazia.saleemi@mft.nhs.uk
Northern Ireland	Jessica Gomersall & Natalie Thompson	jess.gomersall@belfasttrust.hscni.net natalie.thompson@belfasttrust.hscni.net
Scotland	Jessica Thompson & Sarah Stock	jessica.thompson@ed.ac.uk sarah.stock@ed.ac.uk
South East	Sarah Rizeq	sarah.rizeq@nhs.net
South West	Jane Currie & Latha Vinayakarao	jane.currie@uhbw.nhs.uk latha.vinayakarao@poole.nhs.uk
Wales	Amy Robb & Maryanne Bray & Philip Banfield	amy.robb@wales.nhs.uk maryanne.Bray@wales.nhs.uk philip.banfield@wales.nhs.uk
West Midlands	Nicole Pilarski	nicole.pilarski@nhs.net
Yorkshire and the Humber	Elizabeth Bonney	elizabeth.bonney@nhs.net

The TRANSFER database in REDCap - https://bistc.redcap.bham.ac.uk

If you requested a REDCap login (via www.redcap.link/transferteams) these will be provided when you have notified the TRANSFER office that approvals are in place at your hospital. Logins are personal to each collaborator and must not be shared.

The project has been designed for data to be uploaded directly to REDCap but we can also provide you with a paper data collection tool.

Patient identification Link Sheet

A REDCap Record ID number is automatically generated once a patient record is created in the TRANSFER database.

Please keep a link sheet with a patient identifier against the REDCap ID. Maintain this linkage in strict confidence at your sites. This data must not be submitted to the TRANSFER project office or be sent outside the participating site. We will provide centres with a template link sheet for use.

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Project period

The patient inclusion window for TRANSFER opened on 17-May-21. From the time your centre is set up to take part in TRANSFER, data on all eligible women (pregnant women ≥16 years old admitted to an obstetric unit with threatened preterm birth between 22+0-23+6 weeks' gestation), should be recorded.

All women will be followed up until delivery if before 01-Aug-2022 (the window for including follow up data to the project database will close on 31 July 2022), therefore the follow-up period will be a maximum of 20 weeks from inclusion in TRANSFER.

Key dates	Milestone
17-May-2021	Patient identification window opens. Sites that joined after the TRANSFER launch date should record eligible patients prospectively from the date they joined the TRANSFER project.
30-Jun-2022	Participant identification ends.
Follow-up period: Until delivery if before 01-Aug-2022 (the window for including follow up data to the project database will close on 31 July 2022)	

We have not registered the study/got approval yet - can we record eligible patients?

TRANSFER is a prospective project. However if your Trust allows it you can start to track eligible patients from your start date and record their data on paper at your site. Once you have registered the project and have permission from your centre to upload anonymised data to the project database you can add these patients.

Publication Policy

The TRANSFER Project Lead will co-ordinate dissemination of data from this project. All publications using data from this project to undertake original analyses will be submitted to the Study Management Group for review before release. The success of the project depends on many clinicians. For this reason, credit for the results will not be given to the committees or central organisers, but to all who have collaborated and participated in the project. Acknowledgement will include all collaborators, members of the project committees, the SMG and administrative staff. Authorship at the head of the primary results paper will be cited as a collaborative group to avoid giving undue prominence to any individual. All contributors to the service evaluation will be listed at the end of the report, with their contribution to the study identified.

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Completing the electronic case report forms

The following pages will guide you through data entry for the key data fields, please complete all the fields that appear. If you are new to REDCap there is a separate document (The REDCap User Guide) that covers how to create and view records.

A. CRF 1: Eligibility Criteria

REDCap field	Notes
Please confirm if the patient * must provide value ○ **Presented** at your hospital with threatened preterm birth ○ Was **received** at your hospital after being transferred from another hospital with threatened preterm birth	How did the patient arrive at you hospital, presented to your unit, or received at your unit after transfer from another hospital? The questions you see in the study database will depend on how the patient came to your unit.
Please confirm the site where the patient presented at If the hospital is not listed please select "Other". If there is an error in the name of the hospital let us know by emailing TRANSFER-Study@contacts.bham.ac.uk * must provide value Begin typing the name of your hospital to search	**Only receiving sites will see this question.** Select from the dropdown list, if the hospital is not on the list, select 'Other' at the bottom of the list. This will bring up a free text box for you to entered the hospital name.
Is the patient 16 years old or or over Patient must be 16 or over to be eligible * must provide value ○ Yes ○ No	Confirm patient is 16 years or over. Patients must be 16 years or older to be eligible.
Gestational age at presentation Weeks [dropdown] Days [dropdown]	**Only presenting sites will see this question.** To meet the eligibility criteria the gestational age at presentation should be between 22+0 to 23+6 weeks.

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REDCap field	Notes
Threatened preterm birth Was the patient transferred to your unit because they were deemed to be at risk of threatened preterm birth (between 22+0-23+6 weeks' gestation) by the hospital they initially presented at * must provide value ○ Yes ○ No	**Only receiving centres will see this question.** If the presenting centre has deemed the women eligible for the TRANSFER project the receiving hospital should include the patient – even if they no-longer meet the eligibility criteria by the time they reach your hospital during this episode. This will help to ensure each patient has a full set of data.
Threatened preterm birth In the opinion of the assessing medical team is the woman admitted to an obstetric unit with threatened preterm birth Threatened preterm birth is defined as: Any woman presenting with regular uterine activity but no cervical change and/or ruptured membranes and/or vaginal bleeding who in the opinion of the assessing medical team is in threatened preterm birth * must provide value ● Yes ○ No	**Only presenting centres will see this question.** After this question you will be asked to confirm a series of eligibility questions.
Is the woman presenting with regular uterine activity * must provide value ○ Yes ○ No How frequent are her contractions * must provide value [dropdown] 4 contractions in 10 minutes 3 contractions in 10 minutes 2 contractions in 10 minutes 1 contraction in 10 minutes 1 contraction in 15 minutes 1 contraction in 30 minutes	If the woman is presenting with regular uterine activity you will see an additional question for details of frequency, select from the drop down list.
Evidence of cervical dilation * must provide value ○ Yes ○ No Cervical dilatation at presentation * must provide value [dropdown] Cervical dilatation at transfer If the patient was not transferred, please mark as 'Not applicable' * must provide value [dropdown]	If the patient shows evidence of cervical dilation an additional question will appear asking for a measurement at presentation and at transfer. If the patient did not transfer select 'Not applicable'.

REDCap field	Notes
Confirmed ruptured membranes * must provide value ○ Yes ○ No | Weeks Days **Gestational age at ruptured membranes** [▾] [▾]	If there were confirmed ruptured membranes an additional question will appear for the gestational age at ruptured membranes.
Significant vaginal bleeding * must provide value ○ Yes ○ No	Confirm if there was significant vignal bleeding.
Was there another reason the woman was admitted to obstetric unit with threatened preterm birth * must provide value ○ Yes ○ No **Please specify reason the woman was admitted to obstetric unit with threatened preterm birth** * must provide value [_____]	Threatened preterm birth is defined as: Any woman presenting with regular uterine activity but no cervical change and/or ruptured membranes and/or vaginal bleeding who in the opinion of the assessing medical team is in threatened preterm birth. However, if there was another reason/s that the patient was admitted to your unit with threatened preterm birth you can add the details here.
You will be asked to input data on **biomarkers**. TRANSFER is only collecting routine data. If the test has been done please input the data. If any of these tests are not carried out by your centre as part of routine care you will be able to select "Not carried out".	
Fetal fibronectin test result * must provide value ● Under 500 ○ 500+ ○ Not carried out **Fetal fibronectin (phosphorylated IGFBP-1) test result** * must provide value [_____]	If the fetal fibronectin result was over 500 another question will appear and you will be asked input the value.
Actim Partus test result * must provide value ○ Positive ○ Negative ○ Not carried out	You will be asked for the result of the Actim Partus test result, or if this was not done click "Not carried out"
PartoSure test result ○ Positive ○ Negative ○ Not carried out	You will be asked for the result of the PartoSure test result, or if this was not done click "Not carried out"

REDCap field	Notes
QUiPP App **Was the QUiPP app used to predict spontaneous preterm birth** ● Yes * must provide value ○ No **Probability of spontaneous delivery within one week (as reported by the QUiPP app)** * must provide value	If the QUiPP App was used you will asked to input the result.
Estimated fetal weight **Was an estimated fetal weight preformed by ultra sound at presentation within the decision making period of this episode** ● Yes * must provide value ○ No	You will be asked if a estimated fetal weight was performed by ultrasound at presentation within the decision making period of this episode.

B. CRF 2 Patient Pathway and Outcomes

| REDCap field	Notes
Care pathway **Was the decision for an active or expectant care pathway** If you are intending the possibility of active care the baby is on an active care pathway ● Active care pathway * must provide value ○ Expectant care pathway **Did active care pathway happen** ○ Yes * must provide value ○ No	**Active care pathway** – you will be asked for the decision for an active or expectant pathway. If the decision was for an active pathway you will be asked whether this happened
Weeks Days **Gestational age when patient received at your site** [▾] [▾]	**Receiving centres** – you will be asked to input the gestational age when the woman was received at your unit.

REDCap field	Notes
Transfer Information Did the patient require transfer to a unit with co-located NICU (level 3) (H) ○ Yes (💬) ○ No * must provide value	**Presenting centres** – you will be asked to input data to confirm if the patient required transfer, and if they did additional questions will appear to find out if a transfer was achieved. *If transfer was achieved*: • which hospital the woman was transferred to • month the transfer happened • gestational age at transfer *If the woman was not transferred* you will be asked to select a reason from a drop down list.

Outcome information
If the patient presented at your centre and was transferred to another hospital the outcome questions will not appear in the eCRF, you will be taken directly to the question about length of hospital stay instead.

REDCap field	Notes
Pregnancy Outcome Delivery at your unit during this episode (H) ○ Yes (💬) ○ No * must provide value	Did the patient deliver at your hospital during this episode?
If "No" confirm where the patient delivered (H) ○ Home (💬) ● Another hospital presentation * must provide value If delivery was during another hospital presentation, which hospital did this occur in (H) ○ New hospital presentation at your unit (💬) ○ Hospital presentation at different site If "No" confirm where the patient delivered ○ Home (H) ● Born before arrival at your site (💬) ○ Another hospital presentation * must provide value Was the baby born alive (H) ○ Yes (💬) ○ No * must provide value Gestation at delivery or Gestation at fetal demise — Weeks [ ] Days [ ]	If the patient did not deliver at your hospital you will be asked if the patient delivered at home, or during another hospital presentation (at your hospital or at another unit). Receiving centres will see an additional option for where the patient delivered – "Born before arrival at your site" and will be asked to input data on the outcome and gestational age.

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REDCap field	Notes
If "No" confirm where the patient delivered ○ H ● Home ○ Another hospital presentation * must provide value **Was the baby born alive** ○ Yes ● No * must provide value **What was the pregnancy outcome** ○ Stillbirth (intrauterine death ≥ 24 weeks) ○ Miscarriage (intrauterine death < 24 weeks of pregnancy) ○ Termination due to fetal anomaly ○ Termination due to maternal medical condition **(not including infection)** ○ Termination due to maternal infection * must provide value **Gestation at delivery or Gestation at fetal demise** Weeks [ ] Days [ ]	**If delivery was at Home** you will be asked if the baby was born alive. You will be asked to input gestational age at delivery/fetal demise. If the baby was not born alive you will see an additional question with a list of reasons to select from.
Length of antenatal hospital stay at your hospital during this episode Days [ ] Hours [ ]	Please input, to the nearest hour, the length of stay in your hospital for this episode.
Delivery at your unit during this episode ○ Yes ● No * must provide value **If "No" confirm where the patient delivered** ○ Home ● Another hospital presentation * must provide value **If delivery was during another hospital presentation, which hospital did this occur in** ○ New hospital presentation at your unit ● Hospital presentation at different site * must provide value **Name of hospital patient delivered in** If the hospital is not listed please select "Other". If there is an error in the name of the hospital let us know by emailing TRANSFER-Study@contacts.bham.ac.uk [ ] Aberdeen Maternity Hospital Airedale General Hospital Altnagelvin Hospital Antrim Area Hospital * must provide value	**If delivery was at another hospital presentation** you will be asked – • If delivery happened at another hospital, and if so the name of the hospital. • If delivery was at your hospital during another presentation. If this is the case you will be asked to input questions about the pregnancy outcome (live birth, if it was not a live birth the outcome, and gestational age).
Singleton or multiple Pregnancy **Is this a singleton pregnancy** ○ Yes ● No * must provide value **If Multiple, please confirm number of fetuses in this pregnancy** [ ] * must provide value	Confirm if the pregnancy was a singleton. If multiple you will be asked for the number of foetuses in the pregnancy.

C. I do not have all the data needed to complete the form yet, can I still save my record?

Yes. A message will appear listing fields that are missing. If you select "Ignore and leave record" your CRF will be saved until you are ready to open the form again and input the missing data.
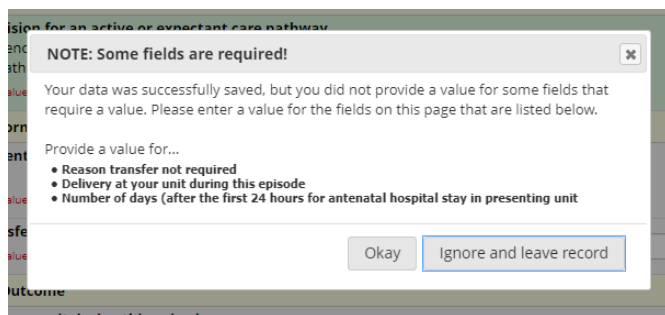
D. Missing data

If there is a field that you will never be able to complete please open up a note in the database to explain why the data is missing. Next to each field you will see a small speech bubble. Clinking on this will bring up the 'Data Resolution Workflow" window.

Complete the comment box to explain why the data is missing.

E. How to record repeat presentations in REDCap

As TRANSFER aims to establish incidence we want to make sure this is captured in the database in a uniform way. We would be grateful if teams could do the following in REDCap if a women presents again at your hospital and still meets the TRANSFER eligibility criteria -

- Please create a new record for the patient presentation

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- Add a note to the first record in REDCap and any subsequent records for the same patient using the Data resolution workflow (DRW) to indicate the records are for the same patient, make sure to include a note of the relevant REDCap ID and which instance the record is for, e.g. 2nd presentation. This will allow us to track these records for analysis purposes
- Record this note in the first question of the first CRF1, "Please confirm if the patient presented or was received at your site".
- Please complete all the fields on each CRF for each record

Using the data resolution workflow (DRW) in REDCap to indicate multiple records for the same patient:

- Please note that a record must have been saved before you can add a note in the DRW
- Open CRF 1: Eligibility Criteria form and go to the first question "Please confirm if the patient…"
- Click on the yellow speech bubble to open the DRW

- Select "Open Query" in the DRW screen and add a note to indicate this record is for an existing patient in the database, and record the REDCap IDs of any previous presentations, and indicate which instance.

- Click the "Open query" button in the lower right hand side of the DRW box to save your note.

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FAQs

Approvals:

- We don't have approvals yet can we still identify patients? Check your Trust policy, some trusts may let you track and record eligible patients on paper until you have approvals in place. Once you have the green light we'll set you up with REDCap logins to upload your records to the project database.
- Is TRANSFER on the NIHR CRN Portfolio? No TRANSFER is a service evaluation and is not on the Portfolio. However, we ask for a very minimal dataset and encourage trainees to get involved as much as possible.

Identifying patients – experience from other teams:

- Some teams have approvals to receive a weekly report of women within the gestational window, which is then checked manually to spot any eligible women.
- In some centres all the band seven midwives have access to the database. When they are on shift they can then enter the details of eligible woman they see details directly to REDCap.
- Other teams are recording patients weekly, or monthly on paper, before doing an upload to the database (so still recording patients prospectively but uploading them to the central database in batches at set intervals).
- Display the TRANSFER poster in the delivery suite.

Eligibility:

- We have a patient, in the gestational window, with PV bleeding are they eligible? It depends if you think they in threatened preterm birth. If it helps think about it in terms of transfer, if you think that they would need to be transferred then enrol them into the project.
- Are women with threatened miscarriage eligible? Yes, if they are in the gestational window, they should be entered into the TRANSFER database.
- Should women with asymptomatic cervical shortening on ultrasound be included? Not if you don't intend to admit them or recommend them for transfer. If you consider it in terms of whether you think they would need to be transferred, or should be admitted, if the answer to either to those two question is yes, then do capture them on the study database.

> The TRANSFER project aims to be pragmatic and follow what you do in your clinical practice. Please capture women who the clinical team believe are presenting with threatened preterm birth

Recording patients on the database:

- How should twins be recorded in TRANSFER? Twins would be counted as a single record (as in utero), and there is a question in the database where you can indicate if the pregnancy was a singleton or multiple.
- We have transferred a patient to another hospital in the same trust can we include them? Yes, please do record this patient on the TRANSFER database.
- If we don't have any eligible patients should we let the central team know each month that we are still participating? If you have time to drop us a quick email to let us know that you haven't had any eligible patients that would be fantastic (and might stop us bugging you) but don't feel that you have to, we know you are busy and we will check in with you from time to time.
- How to record repeat presentations in REDCap?

TRANSFER webinars available to view

[TRANSFER Jan 2022 webinar](#) (Passcode: x%&.%J3S)

[TRANSFER Nov 2021 webinar](#) (Passcode: K$@N0!mp)

[TRANSFER Sept 2021 webinar](#) (Passcode: e4pwez#7)

[TRANSFER July 2021 webinar](#) (Passcode: A27p*Kjx)

[TRANSFER Launch webinar](#) (Passcode = n@X60#5B)

This guide will be updated regularly, you can find the most current version [here](#)

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