Guidance Sheet 12a: Preparing a Transfer

AZTEC
Azithromycin Therapy for Chronic Lung Disease
CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
Centre for Trials Research
Canolfan Ymchwil Treialon

General guidance

- Trial activities (e.g. data collection or 36 week oxygen reduction test) **can only be carried out** at hospitals that have the necessary authorisations (i.e. Organisation Confirmation of Capacity & Capability). It is therefore important that you notify the Centre for Trials Research (CTR) of any transfer as soon as it is considered.
- You are asked on the **Trial Entry CRF** to list all hospitals that the baby may be transferred to so that the CTR can anticipate transfers and obtain authorisations in advance.
- You can check hospitals that are participating (and those that are not) in the AZTEC trial by reviewing the AZTEC website (https://www.aztec-trial.uk) and selecting the '**Participating sites**' link, or by speaking to the AZTEC team at the CTR.
- If the hospital the baby is being transferred to is not listed there or is listed as 'NHS Permission NOT granted' then they do not have the necessary authorisations and you should **contact the CTR immediately**.

As well as alerting the CTR of transfers, the smooth completion of the trial Protocol across different hospitals is dependent upon adhering to the following procedure. Any transfer for less than 24 hours e.g. for surgery **is not** classed as a transfer. The responsibility for data collection remains with the recruiting site and a separate Transfer form for the brief stay does not need to be completed; instead the brief transfer can be incorporated into the one **Baby Outcomes form**.

Procedure

- If the transfer is to another **AZTEC approved recruiting site during the intervention period** you should ensure:
  - That the receiving hospital is aware that the baby is in the AZTEC trial.
  - That a **Transfer CRF** is completed covering the period that the baby has been an inpatient in your hospital.
  - That the **AZTEC Transfer cover sheet** is completed and is emailed to the receiving recruiting centre along with a copy of the **baby's consent form**.
  - That the Daily log CRF is completed as much as possible and data is entered to the eCRF.
  - That the infant's treatment pack is sealed using the supplied IMP Transfer label.
  - Record the transfer of the IMP on the **Treatment pack tracking log**

- Make Pharmacy aware that the IMP pack has been transferred to the receiving hospital with the baby. Pharmacy should update the accountability log accordingly.
- The CTR will make arrangements for the receiving site to access the baby's eCRF for ongoing data collection

- If the transfer is to an **AZTEC approved continuing care site** you should ensure:
  - That the receiving hospital is aware that the baby is in the AZTEC trial.
  - That IMP is **Not** transferred with the baby
  - If the baby is transferred before 21 days after the start of the intervention, then ensure the **Daily log CRF** is completed as much as possible and data is entered to the eCRF.
  - If the baby is transferred **prior to reaching 36 weeks PMA**, that a **Transfer eCRF** is completed covering the period that the baby has been an inpatient in your hospital.
  - If the baby is transferred **after reaching 36 weeks PMA**, that a **Baby outcomes post 36 weeks eCRF** is completed covering the period that the baby has been an inpatient in your hospital.
  - That the Adverse Reaction eCRF is up to date
- Please complete the information on the **Transfer cover sheet**
  - Complete the baby's details and the local PI and research nurse at the recruiting site
  - Confirm that the required tasks have been completed
  - Document who prepared the transfer pack, the date, and their telephone number
  - Record the date of when the 36-week oxygen reduction test would be due

- Email the **transfer cover sheet** to the continuing care site, and include a **copy of the baby's consent form**

- The research team at the recruiting site should liaise with the continuing care site to ensure a smooth transfer of AZTEC babies.
- **Successful completion of the trial protocol** relies on a completed 36-week oxygen reduction test and the associated data collection.
- It is the responsibility of the research team at the continuing care site to ensure that any further CRFs are completed. All AZTEC approved continuing care sites have been provided with electronic copies of the relevant CRFs and guidance sheets to facilitate completion of the data collection

- This should be via the trial eCRF wherever practical, or via return of a scanned paper CRF by email to AZTEC@Cardiff.ac.uk. The CTR will complete the data entry on receipt of paper CRFs from continuing care sites (**unless you are informed otherwise**).

- Please ensure regular correspondence between the recruiting and continuing care sites so we can work together to complete the data collection for AZTEC babies.

- If the transfer is planned to a **site which does not yet have approval** for the AZTEC trial: This must not interfere with the planned timing of the baby's transfer.
  - If the receiving hospital does not have the necessary authorisations the CTR will try to gain these urgently. Please complete **steps as above** and transfer the baby just as you would if the authorisations were in place.
  - The CTR will liaise with the receiving hospital and keep them informed as to when they may continue data collection.