

- Trial activities (e.g. administration of the intervention) **can only be carried out** at sites that have the necessary approvals (i.e. site R&D approval). It is therefore important that you notify the SurfON Study Team of any transfer as soon as it is considered
- Please note that infants can be included to participate on SurfON even if you anticipate subsequent transfer after birth. Hospital transfers are not an exclusion criteria for participation
- You can check sites that are participating in the SurfON trial by going to the SurfON website (<https://www.npeu.ox.ac.uk/surfon/sites>). If the site the infant is being transferred to is not listed, then they do not have the necessary authorisations and you **should contact the SurfON Study Team immediately**
- As soon as the transfer of an infant, to a different hospital has been agreed, please complete the Transfer Form in OpenClinica

If a transfer occurs as a result of an escalation of care, or because of a lack of intensive care capacity it must also be reported as a Serious Adverse Event. (SAE). Transfer for a lower level of care or for reasons unrelated to respiratory management does not need to be reported as an SAE. (See Guidance Sheet 6 Safety & Incident Reporting).

Transfer to an approved site

If the transfer is to another **SurfON study approved site** (recruiting/continuing care) you should:

1. Contact the receiving site and inform them that the infant is on the SurfON trial.
2. Make a photocopy of the respiratory support log and provide a copy in the Transfer Pack. The original should be kept at the recruiting centre.
3. Detail on the Transfer Pack which study arm the infant has been randomised to and whether the Mother has consented to complete the Discharge Questionnaire.
4. No IMP is sent with the infant regardless of which treatment arm they are randomised to (Expectant Management or Early Surfactant Therapy).

5. Send the Transfer Pack, with the infant to the receiving unit. The Transfer pack should include:

Documents to be added to envelope by site at time of transfer:

- Recruiting site SurfON Participant Information Leaflet (PIL)
- Photocopy of existing Respiratory Support Log and Other transfer pack contents which are provided in the Site Documents Box:
- Additional blank copies Respiratory Support Log
- SurfON sticker (for use on infant's medical notes) & SurfON cot card
- Mother's Discharge Questionnaire (*if the mother has not provided consent to complete the questionnaire please remove it from the transfer pack*)
- SurfON Incident and Deviation Form
- SurfON Serious Adverse Event (SAE) Report Form
- SurfON Surfactant Form
- SurfON Transfer Form
- SurfON Withdrawal Form
- SurfON Guidance Sheet 7B for Continuing Care Sites
- SurfON Guidance Sheets 5 (Case Report Forms), 6 (Safety Incident Reporting) & 8 (Withdrawals)
- Freepost envelopes for Coordinating Centre

Key points to remember:

- It is important to note that although a Transfer Pack is provided when the infant is transferred, **the Recruiting Site is responsible for collecting all data related to the participant** and entering it on OpenClinica
- Continuing Care Sites will send scanned copies of completed Case Report Forms back to the Recruiting Site using nhs.net email to nhs.net email
- Please note, that where the Continuing Care Site returns a Respiratory Support Log, it will be the responsibility of a delegated individual at the **Recruiting Site** to check and sign off the log
- The Continuing Care Site will notify the Recruiting Site as soon as an infant has discharged, transferred or died
- In the event of multiples, a Transfer Pack should be sent for each infant

- Continuing Care sites must continue to report safety events (e.g. SAEs) until discharge home. If required, incidents must be reported by Continuing Care sites according to the guidance sheets provided

Transfer to an unapproved site

If a transfer is planned to a **site that does not have approval** to act a continuing care site or recruiting site for SurfON study:

- This must not interfere with the planned timing of the infant's transfer
- If the receiving hospital does not have the necessary authorisations, contact the SurfON study team, who will try to gain these urgently

Please complete steps 1-4 as above and transfer the infant just as you would, as if the authorisations were in place. The SurfON study team will liaise with the recruiting site and the receiving hospital to keep them informed as to when data collection can be continued.

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