GUIDANCE SHEET 7B:
Continuing Care Sites

Introduction

The infant being transferred to your hospital is enrolled on the SurfON Study. SurfON is a multicentre, open-label, randomised controlled trial evaluating the use of early surfactant therapy in late preterm and early term infants with respiratory distress. Further information can be obtained by visiting the study website - https://www.npeu.ox.ac.uk/surfon.

Infants are randomised to either:

Early Surfactant Therapy OR **Expectant Management**

The allocated study arm for the infant will be indicated on the outside of this Transfer Pack. Please continue the same allocated study arm until the infant is discharged home.

This form provides guidance on the forms contained within your Transfer Pack and when and how to complete them. Please follow this guidance **until an infant is discharged home.**

Once the infant is discharged home (or transferred or died), please immediately inform the recruiting site (contact details can be found at the back of the Participant Information Leaflet (PIL)).

Please note that for the majority of case report forms, except where otherwise detailed, the Recruiting Site will continue to have responsibility for entering the information online on the study database. When sending scanned paper forms to the Recruiting Site, these should be emailed from your nhs.net account to the Recruiting Site's nhs.net account. It is important to remember that **only nhs.net to nhs.net emails are end-to-end encrypted**. **Please check the email addresses thoroughly before sending any data**.

The Transfer Pack

The contents of the Transfer Pack are:

- Photocopy of existing Respiratory Support Log and additional blank copies
- Mother's Discharge Questionnaire *if consent has been provided*
- SurfON PIL (will contain recruiting site research team contact information)
- SurfON Serious Adverse Event (SAE) Report Form
- SurfON Incident and Deviation Form
- SurfON Surfactant Form
- SurfON Transfer Form
- SurfON Withdrawal Form
- SurfON sticker (for use on infant's medical notes) & SurfON cot card
- 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

GUIDANCE SHEET 7B

Completion of Respiratory Support Log

The Respiratory Support Log reports the primary outcome for the study and must be completed correctly for all babies. If, after reading this Guidance Sheet and **Guidance Sheet 5: Case Report Forms**, you have any questions about how to complete the log, please contact the SurfON Study Team.

The Respiratory Support Log **must be completed for every day that the infant is on respiratory support, including oxygen only**. The completion of the log will continue until the infant records a **full 24 hour period** of **'Breathing in air'**. After this, the log can be stopped but **must be re-started** if there is any subsequent episode where **further respiratory support is required**. **This process should be adhered to until the infant is discharged home (or transferred or died).**

- A photocopy of the current log from the Recruiting Site is included in your Transfer Pack
- Detailed guidance on how to complete the Respiratory Support Log is provided in **Guidance Sheet 5: Case Report Forms** (included in your transfer pack). Please complete the log when respiratory support is being received, as per the guidance detailed
- The person completing each 4 hour entry should print their name in the right hand column. However, the final sign-off of each sheet at the bottom on the Respiratory Support Log will be completed by a **delegated individual** at the **Recruiting Site**
- **A copy of the paper log should be kept by the cot side for completion by clinical staff**
- An additional blank copy is also included in the Transfer Pack, should you need it

Once complete, the Recruiting Site is responsible for entering the data on the OpenClinica database. A scanned copy of the Respiratory Support Log should be emailed from your nhs.net account to the Recruiting Site's nhs.net account, following the guidance on emailing detailed in the Introduction.

The original paper log should be filed in the infant's medical notes.

Additional Respiratory Intervention

In **either treatment group**, surfactant may be given if the attending clinician deems this necessary. Where additional respiratory intervention and surfactant administration is provided, this should be documented in the **Surfactant Form**, provided in the Transfer Pack. Please see **Guidance Sheet 5: Case Report Forms** for further information on completing the Surfactant Form.

If completed, please send a scanned copy of the form to the Recruiting Site using nhs.net to nhs.net email and following the email guidance detailed in the Introduction.

Completion of Mother's Discharge Questionnaire

The Mother's Discharge Questionnaire is completed by the mother when the infant is due to be discharged home. It will be indicated on the front of your Transfer Pack if the mother has consented to complete the questionnaire and, where applicable a copy will be enclosed in your Transfer Pack.

When the mother has completed the Discharge Questionnaire, please check that:

- The infant's study number has been inserted
- The date of completion has been filled in
- In the case of multiples, the mother has to complete a Questionnaire for each infant with the correct study number indicated

Once complete, a clear scanned copy should be emailed to the SurfON Study Team at ouh-tr.surfon@nhs.net from an nhs.net or trust email address and the original filed in the infant's medical records. A copy should also be emailed to the Recruiting Site for their records.

Additional Case Report Forms

In addition to the forms detailed above, in your Transfer Pack, you will also find a **Serious Adverse Event Form**, **Incident Reporting Form**, **Withdrawals Form** and **Transfer Form**.

Serious Adverse Events Form

The safety reporting window for this trial for each participant will be from randomisation to discharge home. SAEs must be reported as soon as possible and within 24 hours of the site becoming aware of the event. Please refer to **Guidance Sheet 6: Safety & Incident Reporting** for detailed guidance on what constitutes an SAE and how to report them to the SurfON Study Team. Please note that, in particular, the following events require expedited reporting:

- Death
- Transfer to another hospital related to early respiratory management
  - for escalation of care
  - for neonatal intensive care because of lack of intensive care cot capacity in the NICU or LNU of birth

  (Please note that transfers for a lower level of care (SCU) or for reasons unrelated to respiratory management do not need to be reported as an SAE.)
- Serious complication of ETT intubation, such as hypoxia resulting in encephalopathy
- Severe pulmonary haemorrhage
- Severe intracranial haemorrhage

SAEs can be reported by any member of staff. Causality assessment is required for SAEs: **Guidance Sheet 6: Safety & Incident Reporting** states that individuals must be delegated to

complete causality, however, for Continuing Care Sites, this can be completed by a medically qualified Investigator. Do not delay reporting the SAE whilst waiting for a causality assessment. The SAE may be sent to the SurfON Study Team initially without the causality assessment. An updated form must be sent when the causality is complete.

Incident Reporting Form

Deviations from Protocol, trial specific procedures, or Good Clinical Practice (GCP) must be reported to the SurfON Study Team, using the Incident and Deviation form. A scanned copy should be sent to ouh-tr.surfon@nhs.net from an nhs.net email address

For guidance on how to report incidents please refer to **Guidance Sheet 6: Safety & Incident Reporting.**

Withdrawals Form

Please complete this form only if an infant is withdrawn from the trial.

As per GCP guidance, the parent does not need to specify reasons for withdrawal. Where appropriate, the parent/s should be asked:

1. If they are happy for data to continue to be collected from the infant's and mother's clinical notes.
2. If data can be collected from national databases such as NHS Digital at one year of age (corrected for prematurity), this would require no direct involvement from the parent.
3. If they would like to receive results at the end of the study.

They should also be made aware that data collected up until the point of withdrawal cannot be withdrawn.

Please email a copy of the scanned form to the Recruiting Site using nhs.net to nhs.net email and following the email guidance detailed in the Introduction. File the original in the infant's medical records.

For further information on how to report withdrawals, see **Guidance Sheet 8: Withdrawals**.

Transfer Form

This form is completed for infants who are transferred to another hospital. This does not apply to any internal transfer that could occur, for example, transfer from NNU to surgical ward.

If the transfer of the infant has occurred due to escalation of care or because lack of intensive care capacity, then you should report this as a Serious Adverse Event (SAE).

If an infant is due to be transferred please immediately notify the Recruiting Site (contact details can be found on the back of the PIL). Once a transfer has occurred please complete the paper Transfer Form and email a scanned copy to the Recruiting Site using nhs.net to nhs.net email and following the email guidance detailed in the Introduction.

If you have any queries please contact the SurfON Study Team on:

SurfON Study Team Contact details

Any queries should be directed to the SurfON Study Team during office hours (i.e between 0900 – 17.00, Monday to Friday) on 01865 289 437 / 738 or email surfon@npeu.ox.ac.uk

Out of hours:

If you require any assistance with the trial out of office hours or have an emergency, please call 0800 138 5451.

GUIDANCE SHEET 7B