

It is essential that the movement and allocation of TOAST medication packs are carried out and recorded in an accurate and timely fashion by site staff to ensure that TOAST medication is available at site for participants. The Pack Management System on the TOAST Randomisation website will be used to control stock levels, and can be accessed by the TOAST Study team at NPEU, and delegated hospital staff in the Neonatal Unit and Pharmacy.

Pack Management

Logged in as: **Site 1 (City 1)**

Esomeprazole: 0 packs available
Omeprazole: 0 packs available
The following 12 packs are in transit to your site: 6 Esomeprazole, 6 Omeprazole

Menu

Please select one of the following options:

- 1. Login packs at pharmacy (12)**
- 2. Login packs at NNU**
- 3. Pack summary**
- 4. Log out**

Receiving TOAST Medication deliveries at Pharmacy

The TOAST Study team at NPEU will allocate TOAST medication packs to participating sites when stock levels are low. Packs will then be sent from the distributor to the hospital pharmacy. Packs will show as “in transit” on the Pack Management System until received at site.

To log that a delivery of TOAST medication packs has arrived at Pharmacy, a delegated Pharmacy staff member will need to login to the TOAST Randomisation website using their individual username and password to access the Pack Management System: www.rct.npeu.ox.ac.uk/toast

- Select ‘Login packs at pharmacy’
- Select the pack ID(s) that have arrived from the list and mark them as ‘Available for use’, ‘Damaged’, ‘Missing’ or ‘Quarantine’.
- You will need to select ‘Yes’ to confirm your selection.

If ‘Available for use’ is selected, the Pack Management System will immediately assign the logged in packs for transfer to the Neonatal Unit (NNU):

Esomeprazole: 0 packs available (6 in Pharmacy assigned to NNU)
Omeprazole: 0 packs available (6 in Pharmacy assigned to NNU)

Menu

Please select one of the following options:

- 1. Login packs at pharmacy**
- 2. Login packs at NNU (12)**
- 3. Pack summary**

Transferring Packs to Neonatal Unit for storage

Randomised infants should receive their first daily dose of TOAST medication as soon as possible, and following randomisation within 3 days of OA/TOF surgery. It is therefore preferable for the stock of TOAST medication packs to be stored in Neonatal Unit (NNU) rather than pharmacy, to prevent accessibility restrictions outside of pharmacy working hours.

On the NNU, stock of the enteral TOAST medication should be stored below 25°C, and intravenous TOAST medication should be stored below 30°C. No formal monitoring of storage temperatures is required. Once a bottle of enteral TOAST medication has been reconstituted, it should be stored in a fridge (2-8°C) for a maximum of 28 days before disposal.

Once packs have been physically collected from Pharmacy, they can be electronically transferred from Pharmacy to NNU on the Pack Management System by a delegated NNU staff member, using their individual username and password to login. Packs that are showing as 'In Pharmacy assigned to NNU' can be electronically transferred to NNU by clicking "Login packs at NNU" and selecting the pack ID(s) from the list. The number of packs in each location can be viewed in the Pack Management System by clicking 'Pack Summary'.

Esomeprazole: 6 packs available (6 in NNU)
 Omeprazole: 6 packs available (6 in NNU)

Pack status summary

Pack type	In transit	Available	Pharmacy	Pharmacy--NNU	NNU
IV (esomeprazole)	0	6			6
Enteral (omeprazole)	0	6			6

Randomisation and Daily Dosing Log

The TOAST randomisation website will generate a Study ID number for the participant, and allocate two TOAST medication packs – one enteral and one IV - each identified with its own Pack ID.

Ensure that you write the participant's Study ID number on the label of each medication pack/bottle/vial for identification purposes.

You should also write the pack IDs on the participant's Daily Dosing Log.

If the participant does not require IV TOAST medication (i.e. is not nil-by-mouth), and is ready to take the enteral TOAST medication, the IV TOAST medication pack allocated at randomisation will need to be destroyed. Return the IV medication pack to pharmacy, where a delegated Pharmacist can login to the Pack Management System with their individual username and password, and enter the destruction details.

Study no	Pack ID	Vials				Date of destruction	Comments
		Total	Used	Not used	Destroyed		
1017	A1000	7	<input type="text" value="0"/>	<input type="text" value="7"/>	<input type="text" value="7"/>	28/11/2025	<input type="text"/> <input type="button" value="Save"/>

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Allocating new packs

After initial randomisation, which will allocate one pack each of IV and enteral medication, further packs can be allocated using the randomisation website as required.

- Log into the randomisation website www.rct.npeu.ox.ac.uk/toast using your assigned login details.
- Select 'Allocate another pack'
- Select the participant's study ID. Select the type of pack needed (IV or enteral) from the dropdown box, the participant's current pack ID of that type, and enter the date the medication will be started. Once complete, click 'confirm'.
- Review your request (such as double-checking the study ID and DOB), then click 'Allocate'.
- The randomisation website will then allocate a pack ID, list the estimated date that the pack will run out (based on the start date you entered), and state the expiry date for the medication. From here you can 'print' for the infant's medical records, and to collect the allocated pack from your NNU stock.
- Each enteral pack contains 6 bottles which each contain enough medication for 28 days.
- To allocate packs for more than one participant, you will need to repeat this process.

Please note that once a TOAST participant has switched to enteral TOAST medication, they should not return to using intravenous TOAST medication. If a pause in enteral TOAST medication is required for clinical reasons, please contact the TOAST Study team.

Discharge Home

When the participant is discharged:

- Give all unopened bottles of enteral TOAST medication to the parent(s) to take home.
- Dispose of any reconstituted bottles of enteral medication by normal waste routes in the NNU. These do not need to be returned to Pharmacy in the same way as unopened intravenous medication packs.

Partly used, reconstituted bottles of medication should not be sent home with parents.

Record this disposal in the Daily Dosing Log, and confirm with the signature of the staff member carrying out the disposal and a witness.

- Provide parents with a TOAST Accessory Pack – containing measuring cylinders, reminder magnet, marker pen – to help with administering the TOAST medication at home. Remind parent(s) that packs can be stored at room temperature until they are reconstituted, but once a bottle is reconstituted, it must be kept refrigerated (2-8°C) and discarded after 28 days.
- Ensure that parents have been trained on the TOAST app: show them the user guide, support them in registering their account, and explain that they should use the app to report every day whether their baby has had the medication. Once you have done this, access the Contact Details form for the baby on the randomisation website and enter the date that the parent was trained on the app.

Parents cannot log medication records on the app until a training date has been entered on the Contact Details Form.

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Transfers and Readmission

Where an infant is transferred or readmitted to a Continuing Care Site, the Continuing Care Site will continue to administer the TOAST medication, and complete the Daily Dosing Log subject to the relevant approvals being in place.

All transfers to a Continuing Care Site should be reported to the TOAST Study Team in advance (please refer to **TOAST Guidance Sheet 12: Transfers and Continuing Care Sites**).

Any unopened TOAST medication bottles should be transferred with the baby.

Post-discharge, if the baby is readmitted to any other medical facility, parents/carer(s) can continue to administer the TOAST medication themselves, with adherence logged on the TOAST App (where permitted by regulations and individual NHS Trust policies, and considered clinically appropriate by the treating clinician).

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