Training Package

What is routine measurement of gastric residual volume?

It is…

- routinely measuring 4-6 hourly to guide enteral feeding
- aspirating whole stomach contents

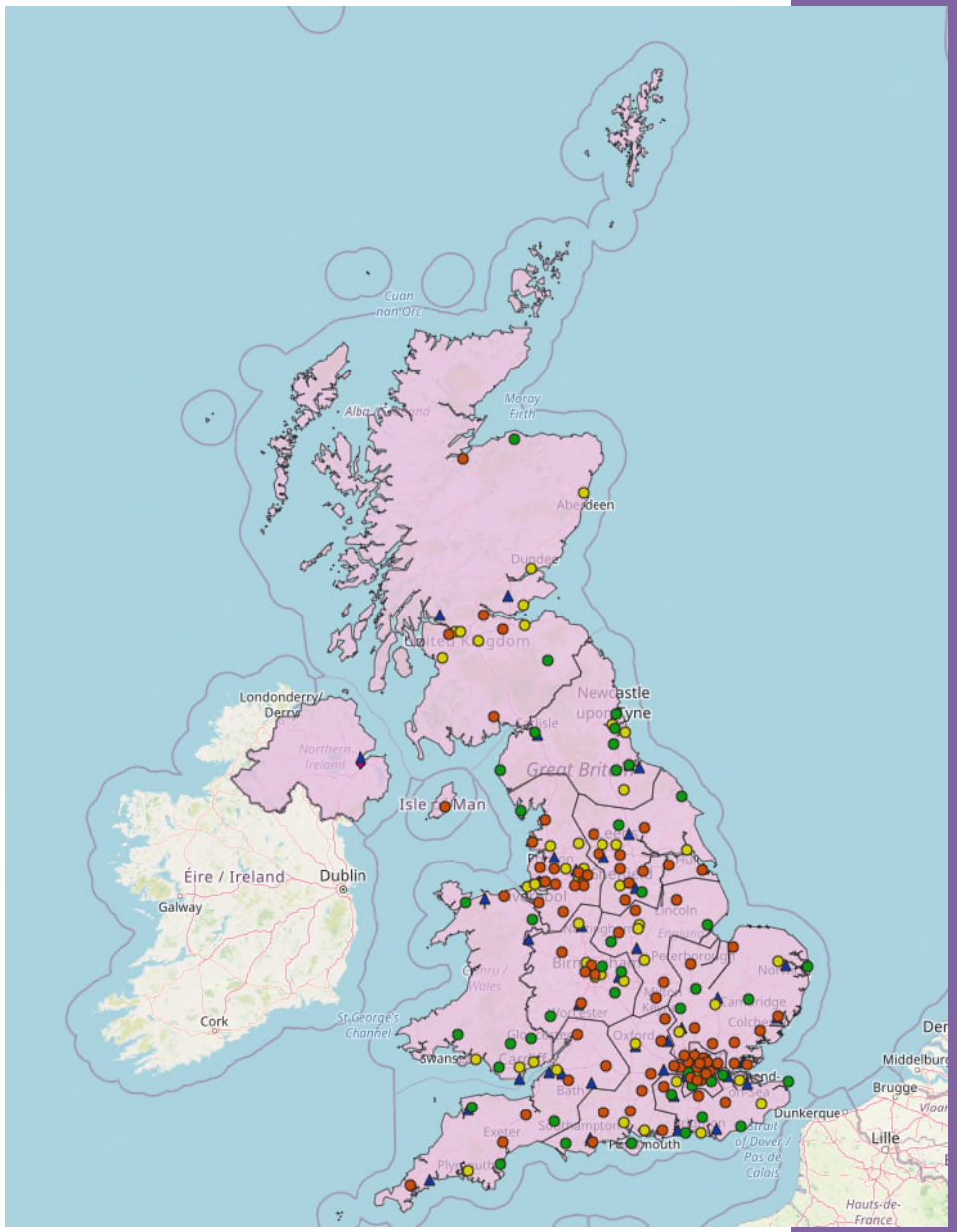
It is not…

- aspirating a small amount to confirm feeding tube position, and testing pH

Please still check tube position – it is a clinical requirement

What problems are we tackling?

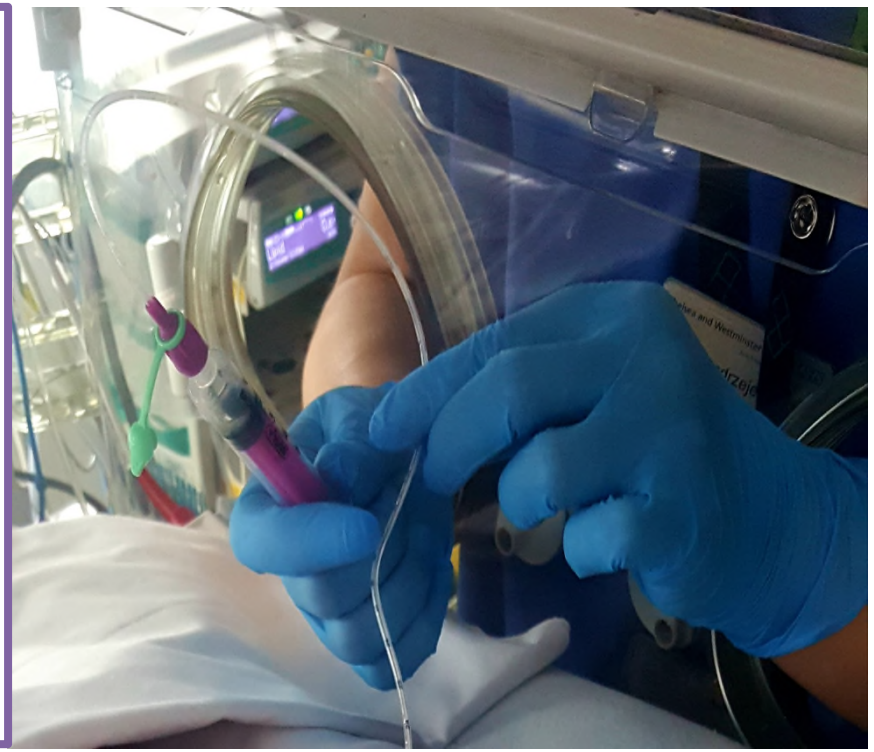
- A 2019 UK wide study demonstrated common practice is to measure gastric residual volume (GRV) every 2-6 hours to determine whether feeds are being absorbed.
- This is may be written into unit feeding guidelines and embedded into practice, but there is little evidence to support this.



Why is this an issue?

- Small studies in preterm neonates suggest that when GRV <u>was not</u> routinely measured, they were able to achieve full feeds faster, with no greater risk of NEC (necrotising enterocolitis)

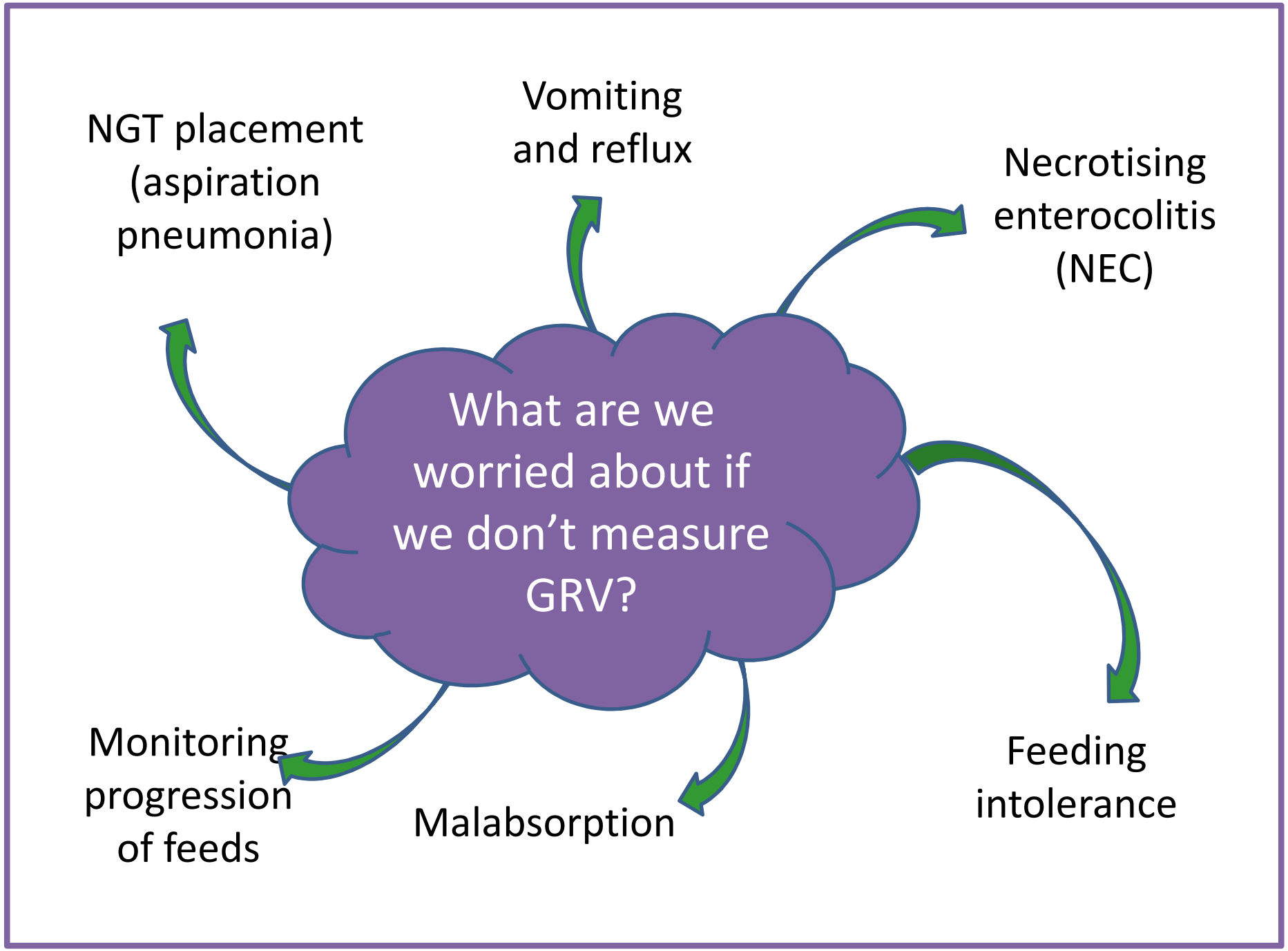
- Interrupting feeds can contribute to sub-optimal nutrition.
  Examples include:
  - Withholding feeds during procedures (lumbar punctures, cannula / line placement etc.)
  - Perceived feeding intolerance due to high GRV
  - Delays in clinical decision making



Why is GRV unreliable?

- Aspirating stomach contents (measuring GRV) is not an accurate or reliable indicator of gastric volume - *gastric enzymes also contribute to total fluid volume* - and does not guarantee gastric emptiness

- The amount obtained is dependent on the aspiration technique, gastric tube size, the consistency of the stomach contents, patient's position and/or tube position in stomach


NGT placement (aspiration pneumonia)
Vomiting and reflux
Necrotising enterocolitis (NEC)
What are we worried about if we don't measure GRV?
Monitoring progression of feeds
Malabsorption
Feeding intolerance

Why is a trial needed now?

- The only way to demonstrate that it is safe NOT to measure GRV and determine whether it might be beneficial and lead to babies reaching full feeds earlier is to conduct a large trial
- This trial, neoGASTRIC is taking place across the UK and Australia for babies <34 weeks gestation
- Babies will be randomised to either **routine GRV measurement** or **no routine GRV measurement**
- Feasibility work across the UK showed both parents and neonatal staff are generally very supportive of this trial and understand the importance of nutrition

Who is eligible?

Inclusion criteria

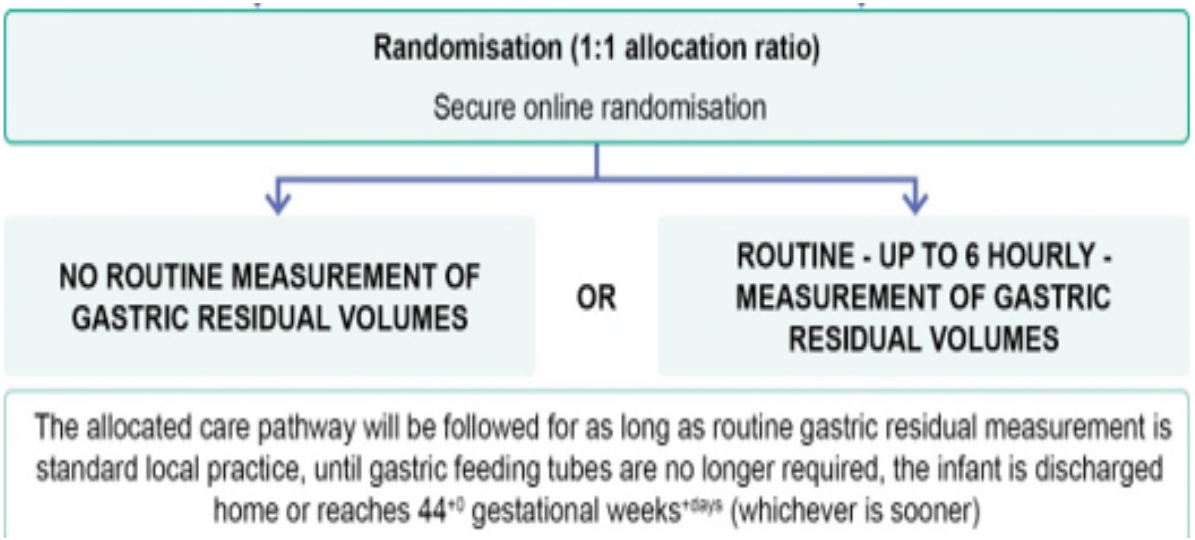
- <34 weeks gestation
- Nasogastric or orogastric tube

Exclusion criteria

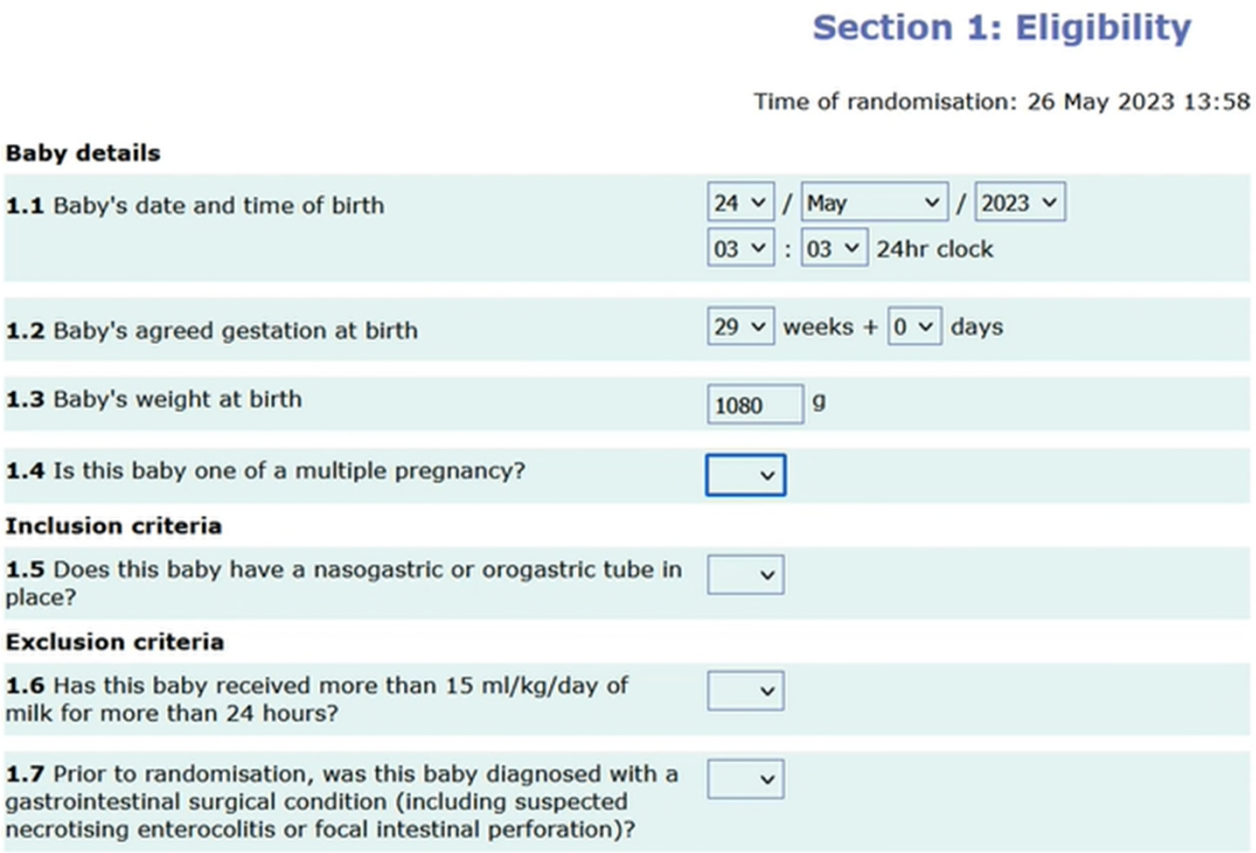
- Infant has been feeding for more than 24 hours (at >15ml/kg/day)
- Gastrointestinal surgical condition
- Major congenital abnormalities
- No realistic prospect of survival
- Parent opted out

Infants enrolled in other interventional studies are eligible for participation in neoGASTRIC

Randomisation



Randomisation system



Section 1: Eligibility

Time of randomisation: 26 May 2023 13:58

Baby details

1.1 Baby's date and time of birth	24 / May / 2023 03 : 03 24hr clock
1.2 Baby's agreed gestation at birth	29 weeks + 0 days
1.3 Baby's weight at birth	1080 g
1.4 Is this baby one of a multiple pregnancy?	

Inclusion criteria

1.5 Does this baby have a nasogastric or orogastric tube in place?	

Exclusion criteria

1.6 Has this baby received more than 15 ml/kg/day of milk for more than 24 hours?	
1.7 Prior to randomisation, was this baby diagnosed with a gastrointestinal surgical condition (including suspected necrotising enterocolitis or focal intestinal perforation)?	

- Training video to be viewed
- One username and password per site

Both arms

- Start feeds as soon as possible, preferably within 24 hrs
- Increase feed as per unit protocol
- Aim for full feeds by approx. 10 days

- Monitor for feed intolerance by clinical signs:
  - Vomiting
  - Abdominal tenderness / distention / discolouration
  - Bloody stools
  - Clinical deterioration
  - Bilious/bloody vomiting

If there are serious clinical concerns

→ **request urgent senior team member review**

Routine GRV Measurement Arm

- **GRV should be routinely measured 4-6 hourly** to guide enteral feeding
- Replace GRV as per your usual practice (unless faecal, bloody or very bilious)
- Use local guideline for management if available
- Threshold for stopping feeds: GRV > 50% of previous feed volume
  - Withhold for 2-3 hrs and reassess

If serious clinical concerns -> urgent senior review

No GRV Measurement Arm

- Do not routinely measure GRV

- Confirm feeding tube position using pH paper and NGT length - Do not aspirate the whole stomach contents

- If clinical signs of **feed intolerance** do occur and other causes are ruled out:
  - Discuss this with a senior clinical colleague
  - Stop feeds for 2 hours and re-assess patients signs. Do not measure GRV
  - Signs of improvement → restart feeds at the same rate
  - **No** signs of improvement → re-assess patients signs. Do not measure GRV

** In acute deterioration urgent aspiration of stomach contents should be done if indicated**

Identifying feed intolerance

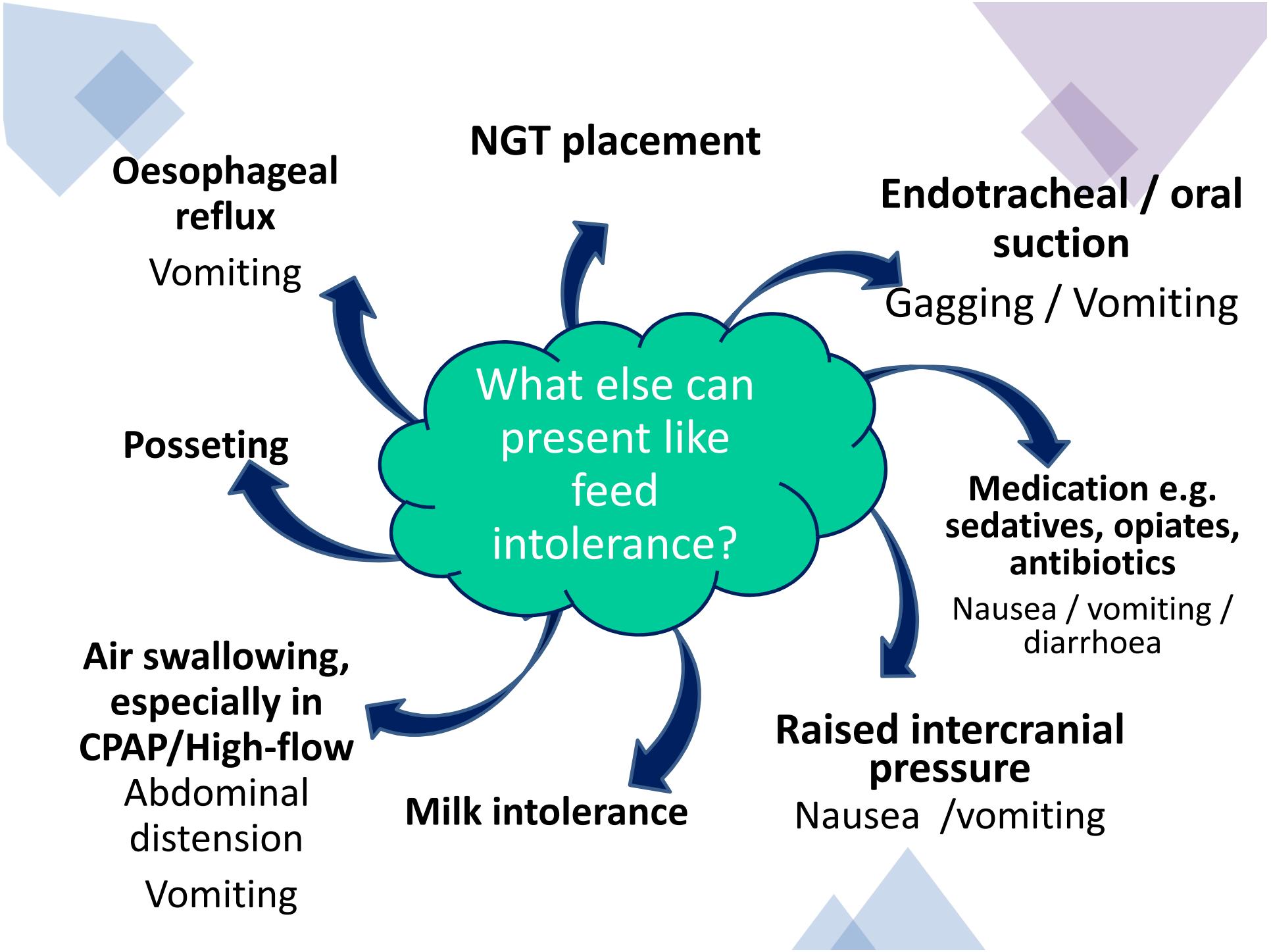
- Feed intolerance refers to the non-absorption of enteral feeds usually via NGT

- This can be due to gastric/gut motility issues, malabsorption and/or abdominal complications

Assessing feed intolerance without using GRV

- Other signs to consider include:
  - Vomiting
  - Abdominal distension / pain / discomfort
  - Bowel movements
    - Appearance of stool
    - Was meconium passed
    - Reduced bowel sounds

Signs listed above may be caused by other factors so discuss with experienced clinician BEFORE stopping feeds


What else can present like feed intolerance?
NGT placement
Oesophageal reflux
Vomiting
Endotracheal / oral suction
Gagging / Vomiting
Posseting
Medication e.g. sedatives, opiates, antibiotics
Nausea / vomiting / diarrhoea
Air swallowing, especially in CPAP/High-flow
Abdominal distension
Vomiting
Milk intolerance
Raised intercranial pressure
Nausea /vomiting

How will we measure compliance in the trial?

Routine GRV measurement arm

Non adherence = < 4 GRV measurements documented in every 24 hour period

Non routine GRV measurement arm

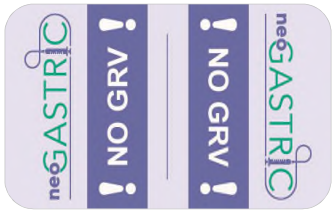
Non adherence = 1 GRV measurement documented in every 24 hour period (unless clinically indicated i.e. deterioration event)

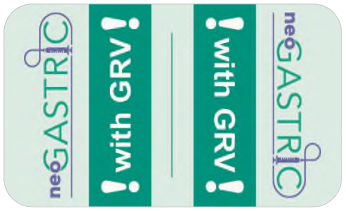
This is important to ensure babies are treated in the arm to which they are allocated - i.e. to avoid crossover and possible contamination of the trial results

Site tools

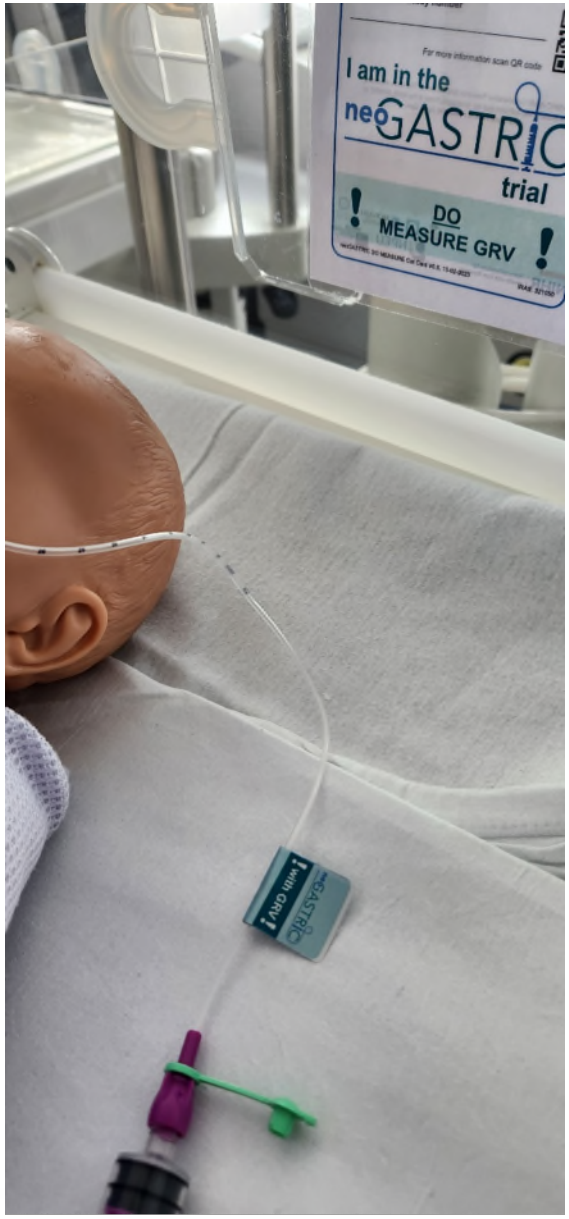
- Cot cards

- Tube labels





- Stickers


I am in the
neoGASTRIC
trial
DO
MEASURE GRV


NO GRV

Feeding Log

Allocation ☐ No routine measurement of gastric residual volumes ☐ Routine measurement of gastric residual volumes

Study number: ☐☐☐☐☐

	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
1. Date *(dd/mm)*	D D / M M	D D / M M	D D / M M	D D / M M	D D / M M	D D / M M	D D / M M
2. Weight (g) used to calculate the volume of fluids/feeds given							
3. Has the baby reached full feeds today? *(see definition)*	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐
4. Does the baby have a gastric tube in situ today? *This includes days where a baby has a gastric tube in place for any part of the day*	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐
Enteral Feeds							
5. Total milk feed volume received per day *(ml)*							
6. Was the baby breastfed (sucking at the breast) today?	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐

Feeding Log

Gastric residual volume measurements							
9. How many times were gastric residual volumes measured today?							
10. Were any of these measured for serious clinical concerns *(see definition)*?	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐
11. If any ***were measured for serious clinical concerns, please state how many:***							
12. ***If the baby is on the routine measurement arm and has had <4 GRV measurements today:*** Is the baby establishing oral feeds today *(e.g. breastfeeding or bottle feeding as well)*?	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐	Y ☐ N ☐
13. Initial here if you have completed any of the log for this day							

Take Home Messages

- Routine GRV measurement is an historical practice based on little robust evidence
- The GRV measurement arm is where GRV is measured at least every 6 hours
- The non measurement arm uses clinical signs to determine feed intolerance
- Before deciding it is ‘feed intolerance’ consider other causes and talk to a senior clinician
- Stopping the feed should not be the automatic action

Opt Out Consent

- Trial is looking at practices that are already happening
  - No new processes
  - No parent questionnaires
  - No medication to administer
- Might feel ‘new’ but many trials are already doing this successfully
  - Feasibility showed parents like the concept

Opt Out Consent

- No need to discuss with parents
  - But answer questions from parents if any
- Ensure they have received the PIS
  - No requirement to record PIS given, but can put in notes if you want to

Delegation log

NPEU Clinical Trials Unit

neoGASTRIC

neoGASTRIC Site Delegation Log

Study Name:	**neoGASTRIC**	**Title:**	The neoGASTRIC Trial: Avoiding routine gastric residual volume measurement in neonatal critical care	**Page ____1___ of _____**
Hospital:		**Principal Investigator:**		

Legend

Use this legend to complete the "Responsibilities" column on the next page. For each individual listed in the "Full Name" column, enter the letter(s) (e.g. A, C, E) from the legend below that correspond to their study-related responsibilities. If there are significant protocol related responsibilities that are not already included in the legend, add them in the empty spaces provided below.

Remove/insert additional responsibilities as required

A	Screen Patients	E	Data collection / resolution of data queries in Openclinica	I	All of the above (A-H)
B	Confirm Eligibility of infant	F	Maintain Investigator Site File (ISF)	J	Other (specify)
C	Randomisation	G	Sign off (e)CRFs for the following form*: Infection and Gut signs	K	Other (specify)
D	Providing study-related training	H	SAE clinical review/causality assessment & sign off**	L	Other (specify)

** must be undertaken by the Principal Investigator (PI) or delegated clinician*

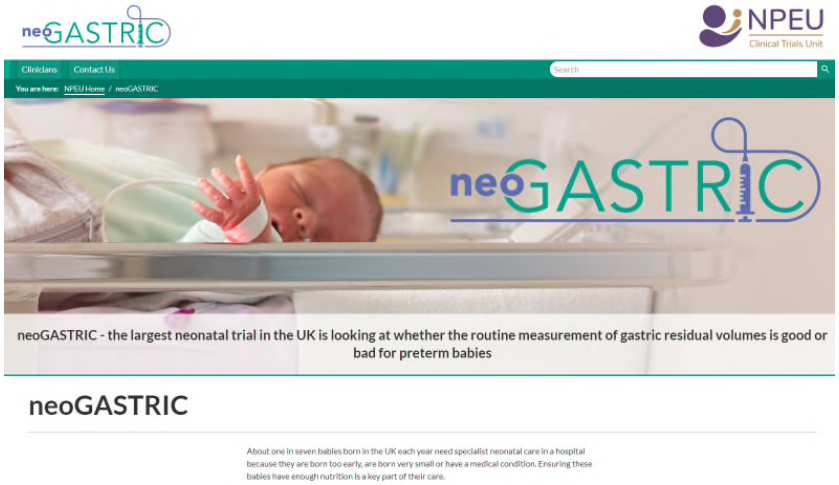
*** signed off by the PI and/or delegated safety reviewer*

The Principal Investigator should sign below during the **Site Close-Out Visit.**

I have reviewed the information on this log and have found it to be accurate. All delegated duties were performed with my authorisation.

Principal Investigator Signature: _____

Thank You for your attention



For further information, contact the study or training team and look at the study website [neoGASTRIC | NPEU (ox.ac.uk)]

This training package was adapted from the GASTRIC-PICU trial educational modules by Devan Allen (Research Nursery Specialist), Noyal Jayan (Medical Student) and the neoGASTRIC nursing team