Routine gastric residual volume measurement to guide enteral feeding in mechanically ventilated infants and children: the GASTRIC feasibility study

Lyvonne N Tume,[1*] Kerry Woolfall,[2] Barbara Arch,[3] Louise Roper,[2] Elizabeth Deja,[2] Ashley P Jones,[3] Lynne Latten,[4] Nazima Pathan,[5] Helen Eccleson,[3] Helen Hickey,[3] Roger Parslow,[6] Jennifer Preston,[7] Anne Beissel,[8] Izabela Andrzejewska,[9] Chris Gale,[10] Frederic V Valla[11] and Jon Dorling[12]

[1]School of Health and Society, University of Salford, Salford, UK
[2]Department of Health Services Research, University of Liverpool, Liverpool, UK
[3]Liverpool Clinical Trials Centre, University of Liverpool, Liverpool, UK
[4]Nutrition and Dietetics, Alder Hey Children's NHS Foundation Trust, Liverpool, UK
[5]Department of Paediatrics, University of Cambridge, Cambridge, UK
[6]School of Medicine, University of Leeds, Leeds, UK
[7]Department of Women's and Children's Health, Institute of Translational Medicine (Child Health), Alder Hey Children's NHS Foundation Trust, University of Liverpool, Liverpool, UK
[8]Neonatal Unit, Hôpital Femme Mère Enfant, Hospices Civils de Lyon, Lyon-Bron, France
[9]Neonatal Unit, Chelsea and Westminster Hospital, London, UK
[10]Neonatal Medicine, School of Public Health, Faculty of Medicine, Imperial College London, Chelsea and Westminster Hospital, London, UK
[11]Paediatric Intensive Care Unit, Hôpital Femme Mère Enfant, Hospices Civils de Lyon, Lyon-Bron, France
[12]Department of Pediatrics, Division of Neonatal-Perinatal Medicine, Faculty of Medicine, Dalhousie University, Halifax, NS, Canada

*Corresponding author l.n.tume@salford.ac.uk

Declared competing interests of authors: Lyvonne N Tume was a National Institute for Health Research (NIHR) Health Technology Assessment (HTA) panel member during the conduct of the study and is the deputy chairperson of the HTA Prioritisation Committee. Chris Gale reports grants from the Medical Research Council during the conduct of the study; and grants from the NIHR (research grant and fellowship for a Doctor of Philosophy student), the Mason Medical Research Foundation (London, UK), Rosetrees Trust (Edgware, UK) and from the Canadian Institute for Health Research (Ottawa, ON, Canada), outside the submitted work. Chris Gale also reports grants and personal fees from Chiesi Pharmaceuticals (Parma, Italy), outside the submitted work (the grant is for a research study and the personal fee was to support attendance at an educational meeting). Chris Gale is vice-chairperson of the NIHR Research for Patient Benefit London Regional Assessment Panel (2016–present). Frederic V Valla reports personal fees from Baxter International (Deerfield, IL, USA) and personal fees from Nutricia (Zoetermeer, the Netherlands), outside the submitted work. Jon Dorling reports grants from the NIHR and from Nutrinia (Nazareth, Israel), outside the submitted work (the grant from Nutrinia in 2018 was for part of his salary to work as an expert advisor on a trial). Jon Dorling was a member of the NIHR HTA General Board (2017–18) and the NIHR HTA Maternity, Neonatal and Child Health Panel (2013–18).

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published May 2020
DOI: 10.3310/hta24230

Scientific summary

The GASTRIC feasibility study

Health Technology Assessment 2020; Vol. 24: No. 23
DOI: 10.3310/hta24230

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

What is gastric residual volume?

Gastric residual volume is a measurement taken to estimate the volume of fluid present in a child's stomach at a given point in time.

Intervention

Gastric residual volume measurement is the practice by which nurses try to aspirate (suck out) the whole of the child or infant's stomach contents every few hours to assess the volume and appearance of the stomach contents. This is then used to guide the progression of feeding. However, there is a lack of evidence to support routine gastric residual monitoring as part of enteral feeding protocols in both infants and children, and increasing evidence to suggest this practice may delay the achievement of full enteral feeds in neonatal units and prevent the achievement of required energy targets in paediatric intensive care units. Therefore, it is important to determine whether or not this practice can have an impact on these outcomes, and if it is possible to conduct a trial of routine gastric residual measurement compared with no gastric residual volume measurement in critically ill infants and children in the UK.

Study objectives

- To describe 'usual care practices' around enteral feeding and gastric residual volume measurement in UK paediatric intensive care units and neonatal units.
- To explore both paediatric intensive care unit and neonatal unit parents' or carers' and health-care professionals' views around gastric residual volume measurement, acceptability of not measuring gastric residual volume, willingness to agree or randomise to a future trial, barriers to recruitment, perceived information needs of parents, training needs for staff, and inclusion and exclusion criteria.
- To explore future trial design issues and gain consensus on primary and secondary outcome measures.
- To determine trial feasibility based on potentially eligible patients (from routine national data sets) to inform sample size calculations for a future trial.
- To develop a standard (control) arm (with routine gastric residual volume measurement) and an intervention arm (no routine gastric residual volume measurement) for a future trial.
- To integrate all the data and determine if a trial of no gastric residual volume measurement is feasible in UK paediatric intensive care units and neonatal units.

Methods

A mixed-methods study with five interlinked work packages.

Work package 1: survey of current practice

An electronic survey was sent via national research networks to all UK paediatric intensive care unit and neonatal units to establish 'usual care practices' around enteral feeding and gastric residual volume measurement.

Work package 2: interviews and focus groups involving parents and health-care professionals

Qualitative semistructured interviews with parents of children who have experience of mechanical ventilation and tube feeding in paediatric intensive care units and neonatal units, and semistructured interviews and focus groups with health-care professionals.

Work package 3: trial design survey, including e-Delphi

A survey and a modified two-round e-Delphi survey were sent to paediatric intensive care unit and neonatal unit health-care professionals. The survey sought views on trial design issues, including willingness to randomise and eligibility criteria. The e-Delphi survey sought consensus on outcomes for a future trial in both settings.

Work package 4: analysis of national data sets for trial feasibility

The National Neonatal Research Database and Paediatric Intensive Care Audit Network were analysed to determine potential patient population numbers based on the inclusion and exclusion criteria identified in work package 3. In addition, summary statistics for any outcome potentially relevant to a future trial were collected from each database.

Work package 5: consensus and trial design meetings

Face-to-face consensus meetings brought together key stakeholders to provide feedback on preliminary results and assess the 'acceptability' of a future trial. Meetings also sought consensus on any 'no-consensus' items from work package 3.

Results

Surveys of current practice

Two survey instruments were developed and tested by the study team: a 51-item instrument for paediatric intensive care units and a 19-item neonatal unit survey instrument around three domains (general enteral feeding and nutrition practices in the respondents' unit, the gastric residual volume measurement technique used in the respondents' unit and clinical management in response to gastric residual volume).

Eighty-nine per cent (24/27) and 52% (95/184) of surveys of current practice were returned from paediatric intensive care units and neonatal units, respectively. These surveys showed that the practice of gastric residual volume measurement to guide feeding was prevalent across the UK, with almost all of paediatric intensive care units (23/24, 96%) and 66% (59/90) of neonatal units measuring gastric residual volume routinely.

Current paediatric intensive care unit practice

Most paediatric intensive care units (15/24, 63%) used the Schofield equation to predict energy requirements and aimed to achieve these energy targets within 48–72 hours by enteral nutrition. Most paediatric intensive care units (18/24, 75%) defined feed intolerance in their guidance and, of these definitions, all included gastric residual volume (18/18, 100%), along with other signs [vomiting (12/18, 67%), diarrhoea (9/18, 50%) and abdominal appearance (8/18, 44%)]. The frequency of gastric residual volume measurement was most commonly reported as 4-hourly (18/24, 75%). Almost all (21/24, 88%) responding units reported that gastric residual volume was the main indicator to withhold enteral feeding. The decision to withhold feeds was determined most frequently by a maximum volume in body weight (ml/kg) (11/21, 52%).

Current neonatal unit practice

When units were asked about how frequently gastric residual volume is measured, 20 out of 90 (22%) measured aspirates before every feed, 26 (29%) measured when it was felt to be clinically indicated

and 39 (43%) measured gastric residual volume at regular intervals [most commonly 4- to 6-hourly (35/39, 90%)]. One unit had no guidelines on this and four (4.4%) units reported that they did not measure gastric residual volume. The bedside nurse most commonly made decisions in relation to gastric residual volume results (56/90, 62%), followed by middle-grade doctors (41/90, 46%) and the senior nurse in charge of the shift (26/90, 29%). Responding units had mixed views on how useful the volume of the aspirate was for guiding feeding decisions, with 13 out of 90 (14%) units reporting that volume affected clinical decision-making 'very much' and the most frequent response was an intermediate score. The colour of the aspirate was felt to be more important, with 37 out of 90 (41%) units reporting that colour influenced clinical decisions 'very much' and this was the most frequent response. These data have enabled us to propose 'best fit' control arms for a future trial based on current practice.

Interviews and focus groups involving parents and health-care professionals

Thirty-one parents with experience of tube feeding (17 parents with experience of neonatal units, seven parents with experience of paediatric intensive care units, and seven parents with experience of both neonatal units and paediatric intensive care units) were interviewed, and their views regarding a future trial were very positive. Most parents (28/31, 90%) said that they would hypothetically agree to their child's participation in a trial if they were approached at an appropriate time and by an individual who was caring and knowledgeable about the trial. Parents did, however, have some concerns about potential delays to recognising adverse events, such as necrotising enterocolitis or ventilator-acquired pneumonia, by not measuring gastric residual volume. Fifty-one paediatric intensive care unit and neonatal unit health-care professionals (nurses, physicians, dietitians and surgeons) participated in focus groups and interviews, and most (84%) were supportive of a future trial. Junior nurses had the most concerns about not being able to measure gastric residual volume. Health-care professionals expressed concerns about not identifying adverse events (necrotising enterocolitis and ventilator-acquired pneumonia) earlier. There was also concern about lack of knowledge of how to assess feed intolerance without gastric residual volume, with many health-care professionals expressing their concerns about the difficulty of changing an historical, embedded practice.

Trial design survey including e-Delphi study

The trial design survey (included at the beginning of round 1 of the e-Delphi study) was completed by 30 paediatric intensive care unit and 76 neonatal unit health-care professionals. Importantly, almost all health-care professionals [97% (29/30) of paediatric intensive care units and 91% (69/76) of neonatal units] were prepared to randomise a child into a future 'no gastric residual volume' trial.

Preferred inclusion criteria by paediatric intensive care unit health-care professionals were all children aged > 37 weeks (term) to 17 years (27/30, 90%) and cardiac surgical patients (24/30, 80%). However, despite the commissioning brief, 22 out of 30 (73%) respondents believed that all tube-fed children, including those on non-invasive ventilation, should be included in a trial. Preferred exclusions included children with a surgical bowel problem causing admission or active gastrointestinal bleeding (21/30, 70%), with some preference to exclude patients likely to stay < 24 hours (17/30, 57%).

The inclusion age that health-care professionals preferred for neonatal units was neonates < 32 weeks of gestational age (72/76, 95%), but there was a range of responses. The only exclusion criterion considered important by at least half of respondents was 'any infant with suspected necrotising enterocolitis' (58/76, 76%).

Following a review of prior studies and trials involving gastric residual volume (in other populations), we developed a list of outcomes. From this list, the qualitative work generated several outcomes considered important by parents, which were incorporated into the e-Delphi survey.

Twenty-two paediatric intensive care unit and 61 neonatal unit health-care professionals participated in round 2 of the e-Delphi survey to vote on trial outcomes. For paediatric intensive care units,

22 outcomes were voted on in round 2. Of these, four items achieved 'consensus in', no items achieved 'consensus out' and 18 items were neither 'consensus in' nor 'consensus out'. The most preferred (8/22, 36%) primary outcome measure was time to achieve the child's estimated energy targets. For neonatal units, 26 outcomes were voted on in round 2. Of these, five outcomes achieved 'consensus in', no items were voted 'consensus out' and 21 items were neither 'consensus in' nor 'consensus out'. The most preferred (24/61, 39%) primary outcome measure was incidence of necrotising enterocolitis.

Analysis of national data sets

For paediatric intensive care units, the Paediatric Intensive Care Audit Network database showed that in 2016 and 2017 a total of 16,122 children admitted to paediatric intensive care units met the inclusion criterion of being aged > 37 weeks (term) to 17 years and who were also mechanically ventilated (excluding those admitted with a gastrointestinal surgical diagnosis and those who did not stay in paediatric intensive care units for > 24 hours). Among this group of children, 12,629 (78%) stayed in paediatric intensive care units for ≥ 3 days and 10,341 (64%) were intubated for ≥ 3 days. Surgical admissions for children aged > 1 month old were intubated for a shorter length of time (median of 2 days).

For neonatal units, the National Neonatal Research Database showed that in 2017 and 2018 a total of 129,155 babies were admitted to a neonatal unit, 15,375 (12%) were born at < 32 weeks of gestational age, 23,868 (18%) were mechanically ventilated and 82,555 (64%) received gastric tube feeds. Median length of neonatal unit stay was 5, 50, 24 and 11 days, respectively, for these groups, and median time from birth to establishing feeds at 150 ml/kg/day was 5, 12, 11 and 6 days, respectively, for these groups of infants.

The analysis of these national neonatal unit and paediatric intensive care unit data sets showed that trials in paediatric intensive care units and neonatal units are feasible in terms of patient numbers when using the proposed inclusion and exclusion criteria in work package 3.

Consensus and trial design meetings

Two consensus meetings were held in April 2019: one paediatric intensive care unit meeting and one neonatal unit meeting. Twenty individuals (two parents, seven nurses, one paediatric and neonatal general surgeon, two dietitians, five physicians, one neonatal charity representative and two triallists) attended the neonatal unit meeting on 1 April 2019. Twenty-two paediatric intensive care unit health-care professionals (three paediatric dietitians, seven paediatric doctors, 11 paediatric nurses and one paediatric general surgeon) attended the paediatric intensive care unit meeting on 2 April 2019. Some, but not all, of the professionals who attended had been involved in the e-Delphi study. None of the parents attending had been involved in the interviews. Voting took place on items that did not reach consensus in the e-Delphi study. For paediatric intensive care units, 18 outcome items were voted on after discussion and debate and from these, eight additional items achieved 'consensus in' and six were voted 'consensus out', leaving only four items not reaching consensus. For neonatal units, 21 outcome items were voted on. Four achieved 'consensus in' and four were voted 'consensus out', leaving 13 items failing to reach consensus in or out.

Conclusions

This feasibility study has collected and synthesised evidence from different stakeholders using mixed methods, but without randomising patients, to determine the feasibility of conducting a future trial of no routine gastric residual volume measurement in UK paediatric intensive care units and neonatal units. Synthesising these results has identified several barriers to delivering definitive GASTRIC trials in both settings, but has also provided information about how these barriers can be overcome. A combined trial of both populations (paediatric intensive care units and neonatal units) cannot be conducted owing to the fundamental differences in these patient populations. However, our feasibility

work has shown that two separate trials, one in paediatric intensive care unit settings and one in neonatal unit settings, are feasible to conduct in the UK. Owing to a limitation of the commissioning brief, which precluded testing a trial protocol and randomising patients, an inbuilt pilot phase and clear progression criteria are required in both trials.

Recommendations for future research

- A definitive GASTRIC trial is feasible to conduct in the paediatric intensive care unit setting with an inbuilt pilot phase for progression to a full trial.
- A definitive GASTRIC trial is feasible to conduct in the neonatal unit setting with an inbuilt pilot phase for progression to a full trial.
- Progression criteria for the pilot phase that should be assessed include parental consent rate, staff compliance with study protocol, rate of crossover, and parent and health-care professional 'acceptability'. In addition, the pilot phase should aim to confirm the distribution of the primary outcome measure and determine the feasibility of collecting secondary outcome measures.

Ethics approval

Ethics approval for the study was received on 18 April 2018 by the University of the West of England (reference HAS.18.04.144) and Health Research Authority approval (reference 244006) was received for the conduct of the focus groups on NHS sites.

Study Oversight Committee

A Study Oversight Committee was recruited to oversee the study processes and results.

Trial registration

This trial is registered as ISRCTN42110505.

Funding

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 24, No. 23. See the NIHR Journals Library website for further project information.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.819

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics, Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 16/94/02. The contractual start date was in April 2018. The draft report began editorial review in October 2019 and was accepted for publication in January 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).