ASPEN Nutrition Guidelines for Replacement of a Balloon Gastrostomy Tube in Infants and Pediatric Patients: Protocol (Finalized 8-2-24)

Introduction

Rates of gastrostomy tube (GT) placement are rising globally due in part to an increased appreciation for the role of nutrition support in growth and refined placement techniques.[1-5] Initial placement techniques for balloon gastrostomy tubes (BGT) include percutaneous endoscopic, radiologic, laparoscopic, and open surgical methods. Surgeons and interventional radiologists place most pediatric GTs. Most pediatric patients have low-profile balloon gastrostomy (LPBG) tubes, with many surgeons performing primary placement of LPBGs. Patients and caregivers appreciate the LPBG aesthetic and ease of use. These devices sit at skin level, may be readily concealed, provide limited interference with clothing, and are thought to have fewer adverse events in terms of accidental dislodgement and leakage than percutaneous tubes.[6] For the purpose of this guideline, BGT includes both LPBG and standard balloon g-tube.

BGTs require replacement for both routine wear and tear and unexpected dislodgement. Management for routine and non-routine tube replacement, including the verification of proper placement, lacks standardization, varying widely among different institutions and settings. Many institutions have developed protocols for BGT replacement. Currently, however, no widely accepted standard of care exists for placement verification following BGT replacement. Replacement may occur in pediatric inpatient units, emergency departments, outpatient clinics, residential pediatric care facilities, and outside clinical environments (i.e., at the child's home). There are no agreed-upon standards for when the initial tube change should be performed or for the subsequent frequency of routine BGT exchange.

While trained caregivers can replace the GT at home, a lack of proper equipment, difficulty in replacement, or discomfort with the procedure may prompt them to come to an emergency department (ED) for assistance.[7] This could be averted with comprehensive education and outpatient support.[8] When a GT is inadvertently displaced, the patient and caregiver often come to the ED. Gastrostomy tube (GT) displacement in children leads to ED visits in up to 61% of the patients within 30 days of initial placement.[9] Although commonly treated in the ED, emergency medical care for displaced GTs not only ties up emergency department staff, but also inconsistently addresses replacement, confirmation of placement, and

documentation, and reinforces ED use rather than access to health care through specialty clinics or advanced practice providers.[10] Timely replacement of a displaced GT is required to prevent stoma stenosis.[11]

Lack of evidence-based practice standards for BGT replacement may result in misplaced tubes. Feeding via misplaced tubes carries serious consequences leading to ED visits, hospital readmissions, additional surgical interventions, and even mortality.[12] Tract disruption is a common adverse consequence of GT replacement[7], which may subsequently lead to dislodgment, leakage of gastric contents, infection, development or worsening of granulation tissue, or peritonitis.[13] Therefore, verification of appropriate placement prior to tube use is essential to detect potential misplacement and prevent other adverse events.

In 2012 the American Society for Parenteral and Enteral Nutrition (ASPEN) convened the workgroup *New Opportunities of Verification of Enteral Tube Location (NOVEL)* as an inter-organizational, interdisciplinary, multinational assemblage including a parent member to address nasogastric tube (NGT) misplacement issues. After intense and thorough evaluation, this group identified standards of practice that are being disseminated and implemented around the world to enhance the safety of practice.[14] After that work and upon the suggestion of the ASPEN Pediatric Section, a multiorganizational workgroup has been convened to address BGT replacement verification and develop evidence-based or expert opinion clinical guidelines to enhance the safety of replacing BGT in pediatric patients.

Objective: The objective of this guideline is to provide guidance for both the routine and non-routine or emergent replacement of a balloon gastrostomy tube in infants and pediatric patients.

Audience: This guideline is intended for dietitians, nurses, pharmacists, physicians, advanced practice providers, and any other medical health professional involved in the nutrition care of infants and pediatric patients requiring a feeding gastrostomy tube.

The Panel of Experts

The guideline is comprised of two panels of experts, a clinical expert panel and a bias panel. This list is an international mix of ASPEN and non-ASPEN members from the United States and Canada. The current clinical panel is comprised of Beth Lyman, MSN, RN, CNSC, FASPEN, FAAN (Chair; Pediatric Nutrition Support Nurse Consultant), Loren Berman, MD (Pediatric Surgeon; Program Director, Pediatric Surgery Fellowship), Kathleen Carr, DNP, MBA,

APRN, CPNP-PC, FNP-C; (Pediatric GI Nurse Practitioner), Cailin Frank, DO (Pediatric Emergency Medicine Physician, Director of Pediatric Emergency Ultrasound), Megan E. Gabel, MD (Pediatric Gastroenterologist, Medical Director of the Pediatric Advanced Nutrition Support), Peggi Guenter, PhD, RN, FASPEN (Nutrition Support Clinical Nurse Specialist, ASPEN Special Projects Consultant), Rachel Kassel, MD, PhD (Associate Professor, Pediatric Gastroenterologist), Janet Kimble, RN, CPN (Pediatric Surgery Specialty Nurse), Carol McGinnis, DNP, APRN-CNS, CNSC, FASPEN (Nutrition Support Clinical Nurse Specialist), Traci Nagy (Consumer Parent), Silvana Oppedisano, RN(EC), MN (Pediatric Nurse Practitioner), Kim Osborne, DNP, RN, CPNP-PC (Motility Nurse Practitioner), Rachel F. Oser, MD, FSIR (Interventional Radiologist), Elizabeth A. Paton, DNP, PED-BC, PNP-AC, PPCNP-BC, CPEN, FAEN (Director of Advanced Practice Nursing, Pediatric Nurse Practitioner), Gina Rempel, MD FRCPC, FASPEN (Pediatric Nutrition Support & Complex Care Physician), Derek S Wakeman, MD, FACS (Pediatric General Surgeon).

A second panel, the Bias Panel, will perform all bias analyses and provide commentary on the direct relationship between the recommendations made and the available evidence. The Bias Panel will be comprised of doctoral level researchers (Jacob Mey, PhD, RD, David Church, PhD, and Sarah Peterson, PhD, RD). The bias panel will be trained and closely overseen by the Director, Methodologist and Editor-in-Chief, Liam McKeever, PhD, RDN, who will guide the entire process and coordinate the actions of the clinical panel and the bias panel.

Conflicts of interest are as follows:

Loren Berman, Kathleen Carr, Cailin Frank, Megan E. Gabel, Peggi Guenter, Rachel Kassel, Janet Kimble, Carol McGinnis, Traci Nagy, Silvana Oppedisano, Kim Osborne, Rachel F. Oser, Elizabeth A. Paton, Gina Rempel, Derek S. Wakeman, have no conflicts of interest to disclose. Beth Lyman is consulting for Avanos, Cardinal Health, unpaid advisor for Otsuka Pharmaceuticals on issues unrelated to the current project.

Panel members will abstain from voting on any recommendations for which they have a conflict of interest. This includes conflicts of interest that become apparent as the guideline is being carried out. The Editor-in-Chief (L.M.) will be responsible for identifying and acting upon all known conflicts of interest.

Commentary Period

This version of this protocol was published and available for 8 weeks
for public commentary on the ASPEN website. Emails were sent to ASPEN members and other relevant societies to solicit feedback from its clinicians and researchers. All comments were given serious consideration by the clinical panel. This protocol was edited following this period of open commentary and is now in its final version.

PICOT Questions

Tables 1 and 2 below contains the key outcomes to be examined and the questions this guideline intends to answer. These are termed PICOT questions because they include the intended **P**opulation, **I**ntervention, **C**omparator or **C**ontrol, **O**utcomes, and **T**imeframe. In Table 1, besides each outcome is a judgement concerning the outcome's importance. If the outcome concerns life and death, or is of utmost importance in the context of the question itself, the importance is deemed 'critical'. If the outcome is not life or death, or of utmost importance, but of unquestionable importance to decision making, the outcome is deemed 'important, but not critical'. If the outcome is of questionable importance, it is deemed 'of limited importance'.[1] These importance levels are then included in the decision-making process for which outcome variables will be most directive of our recommendations. At the bottom of each PICOT question will be a list of relevant co-interventions. These are additional interventions that occur as a byproduct of receiving the main intervention that provide an alternative explanation for the outcome. Most co-interventions are part of the natural sequelae of the intervention (part of the intervention package) and part of the big picture effect the PICOT is trying to address. These types of co-interventions will not be listed in the tables below but will be captured in each study at the data extraction phase. The Co-intervention box in the tables below is reserved only for known co-interventions that are expected to differ between studies in ways that may impact the relationship between the intervention and the outcome. In most cases this box will be empty.

Potential known confounders in the relationship between the exposure and the outcomes will be listed and used to determine whether observations studies, with the exception of quasi-experimental designs will be accepted. In cases where there is unmanageable theoretical confounding, studies will be restricted to randomized control trials, and if not available, to quasi-experimental studies.

Another situation arises where, while there are no known confounders, an observational study within an institution would not be feasible because the intervention is standard procedure for all patients. These PICOTS will have the word "Institutionally Decided" placed in the 'Confounders

and Limitations' box. The studies will have the same restrictions as those with unmanageable confounding.

Table 1: PICOT Questions on Verification of Routine Balloon Gastronomy Tube Replacement

General Research Question: In infants and pediatric patients receiving a balloon gastrostomy tube (BGT) replacement, what verification method is optimal to confirm gastric placement?			
PICOT Questions on Verification of Routine BGT Replacement			
PICOT 1	In infants and pediatric patients receiving routine replacement of a balloon gastrostomy tube (BGT), does confirming gastric tube placement via **gastric aspiration with pH vs. gastric aspiration without pH** result in fewer adverse events?		
Outcomes		**Importance**	
Mortality		Critical	
False tract into peritoneum		Critical	
Detachment of stomach		Critical	
Sepsis		Critical	
Peritonitis/extravasation		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Local site infection		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Tube too short and in shaft		Important, but not Critical	
Delayed feedings		Important, but not Critical	
Delayed medications		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased time in ED		Important, but not Critical	
Increased cost		Important, but not Critical	
Parental distress		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	Acid suppressing medications. Institutionally Decided		
PICOT 2	In infants and pediatric patients undergoing the initial replacement of a balloon gastrostomy tube (BGT), **does waiting more time vs. less time** from initial placement result in fewer negative clinical outcomes?		
Outcomes		**Importance**	
Mortality		Critical	
False tract into peritoneum		Critical	
Detachment of stomach		Critical	
Sepsis		Critical	
Peritonitis/extravasation		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Local site infection		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Delayed medications		Important, but not Critical	

Tube too short and in shaft			Important, but not Critical
Trauma to the site			Important, but not Critical
Delayed feedings			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Parental distress			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		
PICOT 3	In infants and pediatric patients receiving routine replacement of a balloon gastrostomy tube (BGT) and in whom gastric aspirate is not obtainable, does **confirming gastric tube placement via ultrasound vs radiologic contrast study** result in fewer negative clinical outcomes?		
Outcomes			**Importance**
Mortality			Critical
False tract into peritoneum			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Repeat surgery			Critical
ICU admission			Critical
Delayed feedings with hypoglycemia			Critical
ED visit			Important, but not Critical
Additional radiation			Important, but not Critical
Internal balloon migration			Important, but not Critical
External tube dislodgement			Important, but not Critical
Tube too short and in shaft			Important, but not Critical
Local site infection			Important, but not Critical
Pain			Important, but not Critical
Delayed feedings without hypoglycemia			Important, but not Critical
Delayed medications			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Parental distress			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		
PICOT 4	In infants and pediatric patients receiving routine replacement of a balloon gastrostomy tube (BGT) who also have a PD catheter or VP shunt, does confirming gastric tube placement via **gastric aspiration with or without pH vs. radiologic contrast study** result in fewer negative clinical outcomes?		
Outcomes			**Importance**
Mortality			Critical
False tract into peritoneum			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Detachment of stomach			Critical
Repeat surgery			Critical
ICU admission			Critical
Delayed feedings with hypoglycemia			Critical
ED visit			Important, but not Critical
Additional radiation			Important, but not Critical

Internal balloon migration			Important, but not Critical
External tube dislodgement			Important, but not Critical
Tube too short and in shaft			Important, but not Critical
Local site infection			Important, but not Critical
Pain			Important, but not Critical
Delayed feedings without hypoglycemia			Important, but not Critical
Delayed medications			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Parental distress			Important, but not Critical
Readmission 30 or 90 day			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders	Illness severity (Unmanageable)		
PICOT 5	In infants and pediatric patients receiving a routine replacement of a balloon gastrostomy tube (BGT) who also have a PD catheter or VP shunt, **does waiting more time vs. less time** post initial tube placement result in fewer negative clinical outcomes?		
Outcomes		**Importance**	
Mortality			Critical
False tract into peritoneum			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Detachment of stomach			Critical
Repeat surgery			Critical
ICU admission			Critical
ED visit			Important, but not Critical
Additional radiation			Important, but not Critical
Local site infection			Important, but not Critical
Internal balloon migration			Important, but not Critical
External tube dislodgement			Important, but not Critical
Tube too short and in shaft			Important, but not Critical
Increased leaking at site			Important, but not Critical
Pain			Important, but not Critical
Delayed feedings			Important, but not Critical
Delayed medications			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Parental distress			Important, but not Critical
Readmission 30 or 90 day			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders	Illness severity (Unmanageable)		
PICOT 6	In infants and pediatric patients with concerns of delayed wound healing (heme-onc, chronic steroid use, diabetes) and who are receiving a routine replacement of a balloon gastrostomy tube (BGT), **does waiting more time vs. less time** post initial tube placement result in fewer negative clinical outcomes?		
Outcomes		**Importance**	
Mortality			Critical
False tract into peritoneum			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Detachment of stomach			Critical

Repeat surgery		Critical	
ICU admission		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Tube too short and in shaft		Important, but not Critical	
Trauma to the site		Important, but not Critical	
Delayed site healing		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Local site infection		Important, but not Critical	
Pain		Important, but not Critical	
Delayed feedings		Important, but not Critical	
Delayed medications		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased cost		Important, but not Critical	
Parental distress		Important, but not Critical	
Readmission 30 or 90 day		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders	Illness severity (Unmanageable)		
PICOT 7	In infants and pediatric patients receiving a routine replacement of the initial balloon gastrostomy tube (BGT), does the **use of a care bundle compared to non-use of a care bundle** result in fewer negative clinical outcomes? **Note**: Care bundle includes patient/caregiver education		
Outcomes		**Importance**	
Mortality		Critical	
False tract into peritoneum		Critical	
Sepsis		Critical	
Peritonitis/extravasation		Critical	
Detachment of stomach		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Delayed feedings with hypoglycemia		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Tube too short and in shaft		Important, but not Critical	
Trauma to the site		Important, but not Critical	
Delayed site healing		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Local site infection		Important, but not Critical	
Pain		Important, but not Critical	
Delayed feedings without hypoglycemia		Important, but not Critical	
Delayed medications		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased time in ED		Important, but not Critical	
Increased cost		Important, but not Critical	
Parental distress		Important, but not Critical	
Readmission 30 or 90 day		Important, but not Critical	
Dislodgement after the replacement procedure		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		

PICOT 8	In infants and pediatric patients receiving a routine replacement of a balloon gastrostomy tube (BGT), does the **use of formal focused clinician education vs. no formal focused clinician education** result in fewer negative clinical outcomes?		
Outcomes		**Importance**	
Mortality		Critical	
False tract into peritoneum		Critical	
Sepsis		Critical	
Peritonitis/extravasation		Critical	
Detachment of stomach		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Delayed feedings with hypoglycemia		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Tube too short and in shaft		Important, but not Critical	
Trauma to the site		Important, but not Critical	
Delayed site healing		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Local site infection		Important, but not Critical	
Pain		Important, but not Critical	
Increased time in ED		Important, but not Critical	
Delayed feedings without hypoglycemia		Important, but not Critical	
Delayed medications		Important, but not Critical	
Increased cost		Important, but not Critical	
Readmission 30 or 90 day		Important, but not Critical	
Dislodgement after the replacement procedure		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		

Table 2: PICOT Questions for Verification of Replacement of a Dislodged Newly Placed Balloon Gastronomy Tube (BGT) or Replacement of a Traumatically Dislodged BGT

PICOT Questions for Verification of Replacement of a Dislodged Newly Placed Balloon Gastrostomy Tube (BGT) or Replacement of a Traumatically Dislodged BGT		
PICOT 9	In infants and pediatric patients with a BGT that inadvertently comes out before the tract is considered established, does confirming placement of the gastric replacement tube via a **radiologic contrast study vs. aspiration of gastric contents with or without pH** result in fewer negative outcomes?	
Outcomes		**Importance**
Mortality		Critical
False tract into peritoneum		Critical
Detachment of stomach		Critical
Sepsis		Critical
Peritonitis/extravasation		Critical
Repeat surgery		Critical
ICU admission		Critical
Delayed feedings with hypoglycemia		Critical
ED visit		Important, but not Critical
Additional radiation		Important, but not Critical

Delayed feedings without hypoglycemia			Important, but not Critical
Delayed medications			Important, but not Critical
Local site infection			Important, but not Critical
Parental distress			Important, but not Critical
Trauma to the site			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		
PICOT 10	In infants and pediatric patients with a BGT that comes out traumatically or accidentally, does confirming placement of the gastric replacement tube via **aspiration of gastric contents with or without pH versus a radiologic contrast study** result in fewer negative clinical outcomes?		
Outcomes			**Importance**
Mortality			Critical
False tract into peritoneum			Critical
Detachment of stomach			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Repeat surgery			Critical
ICU admission			Critical
Delayed feedings with hypoglycemia			Critical
ED visit			Important, but not Critical
Additional radiation			Important, but not Critical
Parental distress			Important, but not Critical
Trauma to the site			Important, but not Critical
Pain			Important, but not Critical
Premature closure of the tract			Important, but not Critical
Local site infection			Important, but not Critical
Delayed feedings without hypoglycemia			Important, but not Critical
Delayed medications			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Readmissions 30 or 90 days			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		
PICOT 11	In infants and pediatric patients with a BGT that is difficult to replace, does confirming placement of the gastric replacement tube via a **radiologic contrast study vs. aspiration of gastric contents with or without pH** result in fewer negative outcomes?		
Outcomes			**Importance**
Mortality			Critical
False tract into peritoneum			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Repeat surgery			Critical
ICU admission			Critical
Detachment of the stomach			Critical
Delayed feedings with hypoglycemia			Critical

ED visit			Important, but not Critical
Additional radiation			Important, but not Critical
Premature closure of the tract			Important, but not Critical
Trauma to the site			Important, but not Critical
Trauma to the tract			Important, but not Critical
Local site infection			Important, but not Critical
Pain			Important, but not Critical
Delayed feedings without hypoglycemia			Important, but not Critical
Delayed medications			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Parental stress			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	No
Confounders and Limitations	None but Institutionally Decided		
PICOT 12	In infants and pediatric patients with a BGT that is difficult to replace and requires the use of a dilator to reinsert, does confirming placement of the gastric replacement tube via a **radiologic contrast study vs. aspiration of gastric contents** result in fewer negative outcomes?		
Outcomes			**Importance**
Mortality			Critical
False tract into peritoneum			Critical
Sepsis			Critical
Peritonitis/extravasation			Critical
Detachment of stomach			Critical
Repeat surgery			Critical
ICU admission			Critical
Detachment of the stomach			Critical
Delayed feedings with hypoglycemia			Critical
ED visit			Important, but not Critical
Additional radiation			Important, but not Critical
Local site infection			Important, but not Critical
Premature closure of tract			Important, but not Critical
Trauma to the site			Important, but not Critical
Trauma to the tract			Important, but not Critical
Pain			Important, but not Critical
Delayed feedings without hypoglycemia			Important, but not Critical
Delayed medications			Important, but not Critical
Inpatient admission			Important, but not Critical
Increased time in ED			Important, but not Critical
Increased cost			Important, but not Critical
Parental distress			Important, but not Critical
Cointerventions	None	**RCT's Ethical?**	No
Confounders and Limitations	None but Institutionally Decided		
PICOT 13	In infants and pediatric patients with a BGT that inadvertently comes out before the tract is considered established or comes out traumatically or accidentally, does confirming placement of the gastric replacement tube via the **use of ultrasound vs. a radiographic contrast study** result in fewer negative outcomes?		
Outcomes			**Importance**
Mortality			Critical
False tract into peritoneum			Critical

Sepsis		Critical	
Peritonitis/extravasation		Critical	
Detachment of stomach		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Detachment of the stomach		Critical	
Delayed feedings with hypoglycemia		Critical	
ED visit		Important, but not Critical	
Local site infection		Important, but not Critical	
Additional radiation		Important, but not Critical	
Premature closure of the tract		Important, but not Critical	
Trauma to the site		Important, but not Critical	
Pain		Important, but not Critical	
Delayed feedings without hypoglycemia		Important, but not Critical	
Delayed medications		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased time in ED		Important, but not Critical	
Increased cost		Important, but not Critical	
Parental distress		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		
PICOT 14	In infants and pediatric patients with a BGT that comes out before the tract is considered established or comes out traumatically/accidentally, does the **use of a care bundle by clinical staff compared to non-use of a care bundle** result in fewer negative outcomes? **Note:** Care bundle includes patient/caregiver education		
Outcomes		**Importance**	
Mortality		Critical	
False tract into peritoneum		Critical	
Sepsis		Critical	
Peritonitis/extravasation		Critical	
Detachment of stomach		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Delayed feedings with hypoglycemia		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Tube too short and in shaft		Important, but not Critical	
Trauma to the site		Important, but not Critical	
Delayed site healing		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Local site infection		Important, but not Critical	
Pain		Important, but not Critical	
Delayed feedings without hypoglycemia		Important, but not Critical	
Delayed medications		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased time in ED		Important, but not Critical	
Increased cost		Important, but not Critical	
Parental distress		Important, but not Critical	
Readmission 30 or 90 day		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes

Confounders and Limitations	None but Institutionally Decided		
PICOT 15	In infants and pediatric patients with a BGT that inadvertently comes out before the tract is considered established or comes out traumatically or accidentally, does the **use of formal focused education of clinicians concerning gastric replacement tube placement confirmation vs. no education** result in fewer negative outcomes?		
Outcomes		**Importance**	
Mortality		Critical	
False tract into peritoneum		Critical	
Sepsis		Critical	
Peritonitis/extravasation		Critical	
Detachment of stomach		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Delayed feedings with hypoglycemia		Critical	
ED visit		Important, but not Critical	
Additional radiation		Important, but not Critical	
Internal balloon migration		Important, but not Critical	
Tube too short and in shaft		Important, but not Critical	
Trauma to the site		Important, but not Critical	
Delayed site healing		Important, but not Critical	
External tube dislodgement		Important, but not Critical	
Local site infection		Important, but not Critical	
Pain		Important, but not Critical	
Delayed feedings without hypoglycemia		Important, but not Critical	
Delayed medications		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased time in ED		Important, but not Critical	
Increased cost		Important, but not Critical	
Readmission 30 or 90 day		Important, but not Critical	
Cointerventions	None	**RCT's Ethical?**	Yes
Confounders and Limitations	None but Institutionally Decided		

The Search Strategy

PubMED/MEDLINE, EMBASE, Cochrane Central, and CINAHL Databases will be searched from 2008 to present. Articles prior to 2008 were restricted due to advances in pediatric balloon gastrostomy placement and management. The basic search strategy for PubMED/MEDLINE is given in Figure 1. Analogous strategies were conducted for EMBASE, Cochrane Central, and CINAHL.

MeSH-Terms for Gastrostomy:

"Gastrostomy" [MeSH]

MeSH-Terms for Pediatric Population

"Pediatrics"[MeSH], "Child"[MeSH], "Infant"[MeSH], "Adolescent"[MeSH]

Text-Terms for Gastrostomy:

"gastrostomy", "Gastric Tube", "G-tube"

Text Terms for Tube Placement

"placement", "replacement", "replace", "position", "positioning", "dislodge", "dislodgement" "displace", "displacement", "displaced"

Text-Terms for Pediatric Population

"pediatric", "paediatric", "child", "children", "infant", "adolescent", "teenager",

Figure 1 PubMED MEDLINE Search Strategy

Data Acquisition

Training: Twenty-five citations will be uploaded into Rayyan for the team calibration test. Using their PICOT questions and inclusion criteria, the team will individually screen the 25 studies and determine if they meet inclusion criteria. If the team achieves less than 75% overall percent agreement, the discrepancies will be discussed, 25 new citations will be uploaded, and the group will try again. This will continue until they achieve ≥ 75 overall percent agreement, at which time, they will be permitted to move onto to official citation screening in Covidence.

Screening: All citations will be uploaded into Covidence for screening. For any given article, all steps below will be performed in duplicate (by two reviewers) and discrepancies will be adjudicated by a third reviewer. First, citation titles and abstracts will be screened for relevance to our PICOT questions. Then, a full text review will be performed for any citations that were deemed relevant in the previous phase of review. Articles that meet our inclusion criteria will be moved forward to the final phase of data extraction.

Inclusion/Exclusion Criteria/Study Design Selection

To be included, an article needs to be a study of pediatric patients less than or equal to 17 years of age, whose primary or secondary objective is directly relevant to at least one of our PICOT questions. For each question, we will restrict our culling to study designs that are of highest

evidence provided they are capable of answering our PICOT question without known unmanaged confounding. The decision will be made as follows (Figure 2). If randomized control trials (RCT) are available, we will restrict to RCT's. If RCT's are not available, but are ethically feasible, we will call for RCT's and include high-quality quasi-experimental designs, defined as those designs that have a true control group and demonstrable baseline similarity between groups. If RCT's are not ethically feasible, we will assess if there are known confounders in the exposure/outcome relationship that cannot be completely managed through adjustment. If the answer is no, then we will restrict to prospective cohort studies that adjust for the known confounder and high quality quasi-experimental designs. If the answer is yes, we will restrict to only include high quality quasi-experimental designs. Co-interventions will be permitted only if they can be reasonably assumed to be similar between groups.

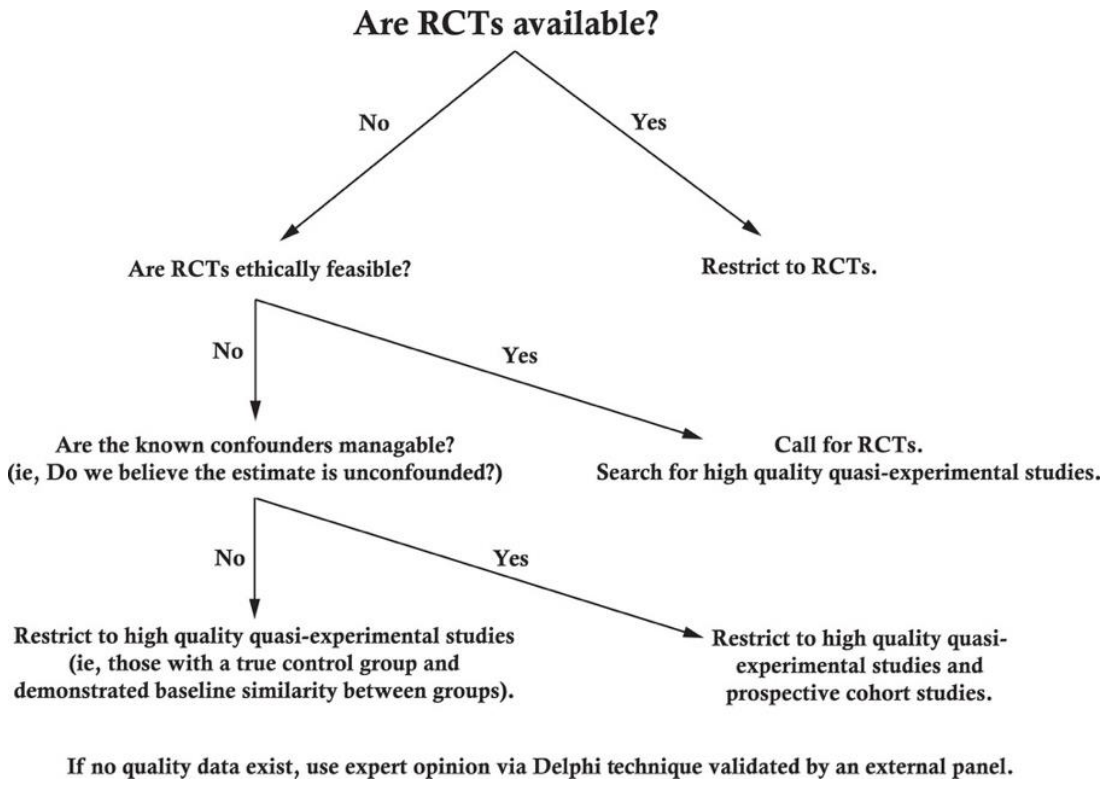

Figure 2: Algorithm for Determining Study Design Inclusion

Bias Analysis

Study quality will be assessed according to its methodologic vulnerability to bias using different tools for different study types. For RCT's, the Risk of Bias 2 (ROB2)[15] tool will be used. For quasi-experimental studies, the Risk of Bias in Non-randomized Study Interventions (ROBINS-I)[16] tool will be used. For prospective cohort studies, the Newcastle-Ottawa scale[17] will be used.

For RCT's the Clinical Panel will create a list of potential co-interventions to consider in the bias assessment. For prospective cohorts, they will determine a list of confounders that require adequate adjustment. These lists will be handed to the Bias Panel who will perform the official bias analysis. All bias analyses will be performed in duplicate. The results of all bias analyses will be published as part of the supplement for this guideline and discussed as strengths and limitations in the body of the guideline.

Quality of Evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system will be used to assess the quality of our evidence regarding its ability to answer our PICOT questions. This will be used to rate the quality of evidence for each outcome across all studies, specifically pertaining to their ability to directly answer our PICOT questions. The Clinical Panel has determined which outcomes are most critical and this will be used to inform the overall quality of the evidence for each PICOT question (Tables 2 & 3). All data will be tabulated and presented in the supplement as a Summary of Findings Table.

Statistical Analysis

Wherever three or more studies exist with interventions, comparators, outcomes, and populations similar enough to justify conflation, Forest plots will be created with summary statistics using a random effects model to account for the minor population differences between hospitals. All forest plots will utilize a Knapp-Hartung adjustment to adjust for the small number of studies.[18,19] Heterogeneity will be assess using the I^2 statistic. If the I^2 is greater than 0.5, we will perform sub-analyses as an attempt to explain the heterogeneity. Publication bias will be assessed through funnel plots and Egger tests wherever >=10 studies are available for conflation into a summary statistic and Forest plot.

Formulation of Recommendations

Recommendations will be formulated using the GRADE Criteria. The GRADE process separates the body of evidence quality rating from the strength of the recommendation permitting a benefits and harms analysis. Evidence quality will be listed underneath each recommendation. Recommendations will be labeled as strong or weak based upon the balance of potential benefits and harms of following the recommendation. Where the recommendation is strong, we will use the term "recommend" regarding our guideline recommendation. Where the recommendation strength is weak, we will use the term "suggest". Wherever possible, these

recommendations will be based upon the data analyzed. Where inadequate data is present to guide a recommendation, the clinical panel will formulate a consensus of expert opinions using a modified Delphi technique. Briefly, the clinical panel will meet to discuss the various potential benefits and harms of the intervention in question. Based on this conversation, the chair will formulate recommendations for each PICOT question. This will be sent out to the clinical panel, who will either agree with the wording of the recommendation or return it with comments. These responses will be deidentified and returned to the chair. If each expert opinion recommendation has <75% agreement, the chair will alter the questions to be more agreeable to the panel and send them out again. This process will repeat until ≥75% agreement is achieved. The process will then start over with an external panel of at least 8 outside experts who will receive the current state of the recommendations from the chair and send back de-identified responses. When the external panel has ≥80% agreement on each expert opinion recommendation, the recommendation will be considered finalized. The external panel will have at least 1 patient representative to ensure input from this often-neglected stakeholder.

Review

Upon completion, a draft of the guideline will be sent to both the ASPEN Clinical Practice Committee and the Pediatric Section for review. It will also be sent to external reviewers through the Journal of Parenteral and Enteral Nutrition for review.

Updates

This guideline will be updated every 5 years.

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