

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 replacement⁷, 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 interorganizational, 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 nonroutine 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, PPCNPBC, 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 Population, Intervention, Comparator or Control, Outcomes, and Timeframe. 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 Que	estions on Verification	of Routine Balloor	n Gastronomy T	Tube Replacement
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General Research	h Question: In infants and pediatric patients received	ving a balloon gastrostomy
tube (BGT) replacer	nent, what verification method is optimal to confirm	gastric placement?
PICO	T Questions on Verification of Routine BGT	Replacement
PICOT 1	In infants and pediatric patients receiving routine replace	cement of a balloon gastrostomy
	tube (BGT), does confirming gastric tube placement via	a gastric aspiration with pH vs.
	gastric aspiration without pH result in fewer adverse	events?
	Outcomes	Importance
Mortality		Critical
False tract into periton	ieum	Critical
Detachment of stomad	ch	Critical
Sepsis		Critical
Peritonitis/extravasatio	on	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 dislodge	ement	Important, but not Critical
Internal balloon migrat	tion	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	Acid suppressing medications.	
Limitations	Institutionally Decided	
	In infante and padiatria patients undergoing the initial re-	anlessment of a balloon
	astroctomy tubo (PCT) does waiting more time vs	loss time from initial placement
	result in fewer negative clinical outcomes?	
		Importance
Mortality		Critical
False tract into periton	heum	Critical
Patechment of stemach		Critical
Sansie		Critical
Paritanitis/avtravasation		Critical
Penest surgery		Critical
		Critical
ED visit		Important but not Critical
Additional radiation		Important, but not Critical
	tion	Important, but not Critical
		Important, but not Critical
Evternal tube dieledge	amont	Important, but not Critical
Delayed medications		Important, but not Critical
Delayeu meuications		important, but not Gnilical

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 replace tube (BGT) and in whom gastric aspirate is not obtaina tube placement via ultrasound vs radiologic contra clinical outcomes?	cement of a balloon gastrostomy ble, does confirming gastric st study result in fewer negative	
	Outcomes	Importance	
Mortality		Critical	
False tract into peritor	neum	Critical	
Sepsis		Critical	
Peritonitis/extravasatio	on	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 migra	tion	Important, but not Critical	
External tube dislodge	ement	Important, but not Critical	
Tube too short and in	snan	Important, but not Critical	
Local site infection		Important, but not Critical	
Pain Deleved feedings with	authunanluannia	Important, but not Critical	
Delayed reedings with		Important, but not Critical	
Inpatient admission		Important, but not Critical	
Increased time in FD		Important, but not Critical	
		Important, but not Critical	
Parental distress		Important, but not Critical	
Cointerventions	None	RCT's Ethical? Yes	
Confounders and	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?		cement of a balloon gastrostomy does confirming gastric tube vs. radiologic contrast study	
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	

External tube diskdgement 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 Increased cost 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 Conferventions None Readmission 30 or 90 day Important, but not Critical Conferventions None We so less severity (Ummanageable) Tri 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 Critical Pertonitis/extravasation Critical Petronitis/extravasation Critical Detachment of stomach Critical Cortical Important, but not Critical Internal balloon migration Important, but not Critical I	External tube dislodgement Imports Tube too short and in shaft Imports Local site infection Imports Pain Imports Delayed feedings without hypoglycemia Imports Delayed medications Imports Increased inter in ED Imports Increased cost Imports Parental distress Imports Readmission 30 or 90 day Imports Confounders Illness severity (Ummanageable) PICOT 5 In infants and pediatric patients receiving a routine replacement of gastrostomy tube (BGT) who also have a PD catheter or VP shunt time vs. less time post initial tube placement result in fewer negat outcomes? Outcomes Imports Mortality False tract into peritoneum Sepsis Peritonitis/extravasation Detachment of stomach Imports Additional radiation Imports Local site infections Imports Additional radiation Imports Local site infections Imports Pain Imports Additional radiation Imports Local site infections Imports Internate balloon migration Imports External tube dislodgement Imports Increased leaking at site Imports <	rtant, but not Critical
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Readmission 30 or 90 day Important, but not Critical Cointerventions None RCT's Ethical? Yes Confounders Illness severity (Unmanageable) RCT's Ethical? Yes 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? Importance Mortality Outcomes Importance Critical False tract into peritoneum Critical Critical Sepsis Critical Critical	Readmission 30 or 90 day Importa Cointerventions None RCT's Eth Confounders Illness severity (Unmanageable) RCT's Eth PICOT 6 In infants and pediatric patients with concerns of delayed wound he chronic steroid use, diabetes) and who are receiving a routine replagastrostomy tube (BGT), does waiting more time vs. less time p placement result in fewer negative clinical outcomes? Outcomes Importality False tract into peritoneum Sepsis Peritonitis/extravasation Peritonitis/extravasation	rtant, but not Critical
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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 Peritopitis/extravasation Critical	chronic steroid use, diabetes) and who are receiving a routine replayed gastrostomy tube (BGT), does waiting more time vs. less time proplacement result in fewer negative clinical outcomes? Outcomes I Mortality I False tract into peritoneum I Sepsis I Peritonitis/extravasation I	healing (heme-onc,
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	gastrostomy tube (BGT), does waiting more time vs. less time p placement result in fewer negative clinical outcomes? Outcomes I Mortality I False tract into peritoneum I Sepsis I Peritonitis/extravasation I	placement of a balloon
placement result in fewer negative clinical outcomes? Outcomes Importance Mortality Critical False tract into peritoneum Critical Sepsis Critical Peritonitis/extravasation Critical	Dutcomes I Mortality I False tract into peritoneum I Sepsis I Peritonitis/extravasation I	post initial tube
OutcomesImportanceMortalityCriticalFalse tract into peritoneumCriticalSepsisCriticalPeritonitis/extravasationCritical	Outcomes I Mortality	
Mortality Critical False tract into peritoneum Critical Sepsis Critical Peritopitis/extravasation Critical	Mortality False tract into peritoneum Sepsis Peritonitis/extravasation	Importance
False tract into peritoneum Critical Sepsis Critical Peritonitis/extravasation Critical	False tract into peritoneum	Critical
Sepsis Critical	Sepsis Peritonitis/extravasation	Critical
Peritonitis/extravasation	Peritonitis/extravasation	Critical
		Critical
	Detachment of stomach	Critical

Repeat surgery		Critical	
ICU admission		Critical	
ED visit		Important, but no	t Critical
Additional radiation		Important, but no	t Critical
Internal balloon migrat	ion	Important, but no	t Critical
Tube too short and in s	shaft	Important, but no	t Critical
Trauma to the site		Important, but no	t Critical
Delayed site healing		Important, but no	t Critical
External tube dislodge	ment	Important, but no	t Critical
Local site infection		Important, but no	t Critical
Pain		Important, but not Critical	
Delayed feedings		Important, but no	t Critical
Delayed medications		Important, but no	t Critical
Inpatient admission		Important, but no	t Critical
Increased cost		Important, but no	t Critical
Parental distress		Important, but no	t Critical
Readmission 30 or 90	day	Important, but no	t Critical
Cointerventions	None	RCT's Ethical?	Yes
Confounders	Illness severity (Unmanageable)		
PICOT 7	In infants and pediatric patients receiving a routine repl	acement of the initial l	balloon
	gastrostomy tube (BGT), does the use of a care bund	le compared to non-	use of a
	Care bundle result in rewer negative clinical outcomes	<u>{</u>	
		Importanc	`
	Outcomes	important	
Mortality			
False tract into periton	eum	Critical	
Sepsis		Critical	
Peritonitis/extravasatio	n L	Critical	
Detachment of stomad	n	Critical	
Repeat surgery		Critical	
Deleved feedings with	hunaduaamia	Critical	
ED vicit	nypogrycemia		t Critical
			t Critical
	ion	Important, but not Critical	
Tube too short and in s	shaft	Important, but not Critical	
Trauma to the site	bildit	Important, but no	t Critical
Delayed site healing		Important, but no	t Critical
Delayed site healing		iniportant, bat no	C O H H O GAI
External tube dislodge	ment	Important but no	t Critical
External tube dislodge	ment	Important, but no	t Critical t Critical
External tube dislodge Local site infection	ment	Important, but no Important, but no Important, but no	t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with	ment	Important, but no Important, but no Important, but no Important, but no	t Critical t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications	ment out hypoglycemia	Important, but no Important, but no Important, but no Important, but no Important, but no	t Critical t Critical t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission	ment out hypoglycemia	Important, but no Important, but no Important, but no Important, but no Important, but no Important, but no	t Critical t Critical t Critical t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission Increased time in ED	ment out hypoglycemia	Important, but no Important, but no Important, but no Important, but no Important, but no Important, but no Important, but no	t Critical t Critical t Critical t Critical t Critical t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission Increased time in ED Increased cost	ment out hypoglycemia	Important, but no Important, but no	t Critical t Critical t Critical t Critical t Critical t Critical t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission Increased time in ED Increased cost Parental distress	ment out hypoglycemia	Important, but no Important, but no	t Critical t Critical t Critical t Critical t Critical t Critical t Critical t Critical t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission Increased time in ED Increased cost Parental distress Readmission 30 or 90	ment out hypoglycemia	Important, but no Important, but no	t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission Increased time in ED Increased cost Parental distress Readmission 30 or 90 Dislodgement after the	ment out hypoglycemia day replacement procedure	Important, but no Important, but no	t Critical t Critical
External tube dislodge Local site infection Pain Delayed feedings with Delayed medications Inpatient admission Increased time in ED Increased cost Parental distress Readmission 30 or 90 Dislodgement after the Cointerventions	ment out hypoglycemia day replacement procedure None	Important, but no Important, but no RCT's Ethical?	t Critical t Critical

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?			on vs. no es?
	Outcomes	Importanc	e
Mortality		Critical	
False tract into peritor	neum	Critical	
Sepsis		Critical	
Peritonitis/extravasation	วท	Critical	
Detachment of stomad	ch	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 migrat	tion	Important, but not	Critical
Tube too short and in shaft		Important, but not	Critical
Trauma to the site		Important, but not	t Critical
Delayed site healing		Important, but not	t Critical
External tube dislodgement		Important, but not	t Critical
Local site infection		Important, but not	t Critical
Pain		Important, but not	t Critical
Increased time in ED		Important, but not	t Critical
Delayed feedings without hypoglycemia		Important, but not	t 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	None but Institutionally Decided		
Limitations			

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

PICOT Questions for Verification of Replacement of a Dislodged Newly Placed Balloon			
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 perito	neum	Critical	
Detachment of stoma	Detachment of stomach Critical		
Sepsis Critical		Critical	
Peritonitis/extravasation Critical		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Delayed feedings with hypoglycemia		Critical	
ED visit Important, but not Critical		Important, but not Critical	
Additional radiation	Additional radiation Important, but not Critical		

Delayed feedings without hypoglycemia		Important, but no	t Critical
Delayed medications		Important, but no	t Critical
Local site infection		Important, but not Critical	
Parental distress		Important, but no	t Critical
Trauma to the site		Important, but no	t Critical
Inpatient admission		Important, but no	t Critical
Increased time in ED		Important, but no	t Critical
Increased cost		Important, but no	t 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 does confirming placement of the gastric replacement t contents with or without pH versus a radiologic con negative clinical outcomes?	out traumatically or a tube via aspiration of ntrast study result in	ccidentally, gastric fewer
Mantality	Outcomes	Important	e e
		Critical	
Faise tract into peritor	ieum		
Detachment of stomad		Critical	
Sepsis Deriteritie/extremenetic		Critical	
Penionilis/exilavasalio	JI	Critical	
		Critical	
Delayed feedings with	hypoglycomia	Critical	
ED visit	Inypogiycemia		
Additional radiation		Important, but not Critical	
Parental distress		Important, but not Critical	
Trauma to the site		Important, but no	t Critical
Pain		Important, but no	t Critical
Premature closure of	the tract	Important, but no	t Critical
Local site infection		Important, but no	t Critical
Delayed feedings with	out hypoglycemia	Important, but no	t Critical
Delayed medications		Important, but no	t Critical
Inpatient admission		Important, but no	t Critical
Increased time in ED		Important, but no	t Critical
Increased cost		Important, but no	t Critical
Readmissions 30 or 9	0 days	Important, but no	t Critical
Cointerventions	None	RCT's Ethical?	Yes
Confounders and	None but Institutionally Decided		
PICOT 11	In infants and pediatric patients with a RGT that is diffic	rult to replace does of	onfirming
	placement of the dastric replacement tube via a radiol	onic contrast study y	/s
aspiration of gastric contents with or without pH re		sult in fewer negative	outcomes?
Outcomes		Importance	e
Mortality		Critical	
False tract into peritoneum		Critical	
Sensis		Critical	
Peritonitis/extravasation		Critical	
Repeat surgery		Critical	
ICU admission		Critical	
Detachment of the sto	mach	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 with	out 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	None but Institutionally Decided	
Limitations		
PICOT 12	In infants and pediatric patients with a BGT that is diffic	cult 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 gas	tric contents result in fewer
	negative outcomes?	
	Outcomes	Importance
Mortality		Critical
False tract into periton	ieum	Critical
Sepsis		Critical
Peritonitis/extravasatio	n	Critical
Detachment of stomad	ch in the second s	Critical
Repeat surgery		Critical
ICU admission		Critical
Detachment of the sto	mach	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 t	ract	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 with	out 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	None but Institutionally Decided	
Limitations		
PICOT 13 In infants and pediatric patients with a BGT that inadve		rtantly as man out before the treat
1100113	In mants and pediatric patients with a BGT that madve	menuly comes out before the tract
11001 13	is considered established or comes out traumatically or	accidentally, does confirming
	is considered established or comes out traumatically or placement of the gastric replacement tube via the use	r accidentally, does confirming of ultrasound vs. a
	is considered established or comes out traumatically of placement of the gastric replacement tube via the use radiographic contrast study result in fewer negative	accidentally, does confirming of ultrasound vs. a outcomes?
	is considered established or comes out traumatically of placement of the gastric replacement tube via the use radiographic contrast study result in fewer negative Outcomes	accidentally, does confirming of ultrasound vs. a putcomes?
Mortality	is considered established or comes out traumatically of placement of the gastric replacement tube via the use radiographic contrast study result in fewer negative Outcomes	r accidentally, does confirming of ultrasound vs. a outcomes? Importance Critical

Sepsis		Critical		
Peritonitis/extravasation		Critical	Critical	
Detachment of stoma	ch	Critical		
Repeat surgery		Critical		
ICU admission		Critical		
Detachment of the sto	omach	Critical		
Delayed feedings with	n hypoglycemia	Critical		
ED visit		Important, but no	t Critical	
Local site infection		Important, but no	t Critical	
Additional radiation		Important, but not Critical		
Premature closure of	the tract	Important, but no	t Critical	
Trauma to the site		Important, but no	t Critical	
Pain		Important, but no	t Critical	
Delayed feedings with	nout hypoglycemia	Important, but no	t Critical	
Delayed medications		Important, but no	t Critical	
Inpatient admission		Important, but no	t Critical	
Increased time in ED		Important, but no	t Critical	
Increased cost		Important, but no	t Critical	
Parental distress		Important, but no	t Critical	
Cointerventions	None	RCT's Ethical?	Yes	
Confounders and	None but Institutionally Decided			
Limitations	· ·			
PICOT 14	In infants and pediatric patients with a BGT that comes	out before the tract is		
	considered established or comes out traumatically/acci	dentally, does the use	e of a care	
	bundle by clinical staff compared to non-use of a c	are bundle result in fe	ewer	
	negative outcomes?			
Note: Care bundle includes patient/caregiver education				
	Note: Care bundle includes patient/caregiver education			
	Outcomes	Importanc	e	
Mortality	Outcomes	Importanc Critical	e	
Mortality False tract into peritor	Outcomes	Importanc Critical Critical	:e	
Mortality False tract into peritor Sepsis	Outcomes	Importance Critical Critical Critical Critical	:e	
Mortality False tract into peritor Sepsis Peritonitis/extravasati	Outcomes neum on	Importance Critical Critical Critical Critical Critical	:e	
Mortality False tract into peritor Sepsis Peritonitis/extravasati Detachment of stoma	Outcomes neum on ch	Importance Critical Critical Critical Critical Critical Critical	:e	
Mortality False tract into peritor Sepsis Peritonitis/extravasation Detachment of stomatic Repeat surgery	Outcomes neum on ch	Importance Critical Critical Critical Critical Critical Critical Critical	:e	
Mortality False tract into peritor Sepsis Peritonitis/extravasati Detachment of stomat Repeat surgery ICU admission	Note: Care buildle includes patien/caregiver education Outcomes neum on ch	Importance Critical Critical Critical Critical Critical Critical Critical Critical	:e	
Mortality False tract into peritor Sepsis Peritonitis/extravasation Detachment of stomatic Repeat surgery ICU admission Delayed feedings with	Note: Care buildle includes patien/caregiver education Outcomes neum on ch n hypoglycemia	Importance Critical Critical Critical Critical Critical Critical Critical Critical Critical Critical	;e	
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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 periton	neum	Critical	
Sepsis		Critical	
Peritonitis/extravasation	วท	Critical	
Detachment of stomad	ch	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		RCI's Ethical? Yes	
Confounders and	None but Institutionally Decided		
Limitations			

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 \geq 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.



If no quality data exist, use expert opinion via Delphi technique validated by an external panel.

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 scale¹⁷ 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 I² statistic. If the I² 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 is strong, we will use the term "recommend" regarding our guideline recommendation. Where the recommendation is strong strong to 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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