MEDICAL UNIVERSITY OF SOUTH CAROLINA
VALUE INSTITUTE
Evidence-Based Practice Brief
Perioperative Enteral Feeding in Adult Surgical/Trauma Patients with Protected Airways

Author(s): Amanda Davis, MPH, RD, CHES

ASK THE QUESTION

Question(s): In adult surgical/trauma patients with a protected airway, what is the effect of continuous enteral feeding around the time of a surgical procedures patient safety compared with NPO status?

SEARCH FOR EVIDENCE

Databases: PubMed, Scopus, CINHAL


Filters: Age: Adults (19+ years); Publication date: last 10 years

CRITICALLY ANALYZE THE EVIDENCE

Existing External Guidelines/Pathways/Order Sets

<table>
<thead>
<tr>
<th>External Guideline</th>
<th>Organization and Author</th>
<th>Last Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures</td>
<td>American Society of Anesthesiologists</td>
<td>2011</td>
</tr>
</tbody>
</table>
The 2 published clinical guidelines have been evaluated for this review using the University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale. The scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

<table>
<thead>
<tr>
<th>Guideline Issuer</th>
<th>ASA 2011</th>
<th>ESPEN 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Transparency</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>2. Conflict of interest</td>
<td>NR</td>
<td>A</td>
</tr>
<tr>
<td>3. Development group</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>4. Systematic Review</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>5. Supporting evidence</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>6. Recommendations</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>7. External Review</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>8. Currency and updates</td>
<td>B</td>
<td>A</td>
</tr>
</tbody>
</table>

See appendix B for full description of the Trustworthy Guideline grading system.

Guideline Evidence Evaluation Systems

<table>
<thead>
<tr>
<th>Evidence Evaluation</th>
<th>ASA 2011</th>
<th>ESPEN 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Categorizes literature and opinions, but not recommendations.</td>
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</tr>
<tr>
<td><strong>Category A: Supportive literature</strong> - Randomized controlled trials report</td>
<td></td>
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<tr>
<td>statistically significant (p &lt; 0.01) differences between clinical interventions for</td>
<td></td>
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<tr>
<td>a specified clinical outcome</td>
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<tr>
<td>• Level 1. The literature contains multiple randomized controlled trials. Aggregated</td>
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<tr>
<td>findings are supported by meta-analysis.</td>
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<tr>
<td>• Level 2. The literature contains multiple randomized controlled trials, but there</td>
<td></td>
<td></td>
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<tr>
<td>is an insufficient number of studies to conduct a viable meta-analysis for the</td>
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<tr>
<td>purpose of these Guidelines.</td>
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<tr>
<td>• Level 3. The literature contains a single randomized controlled trial. Category</td>
<td></td>
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<tr>
<td>B: Suggestive Literature - Information from observational studies permits inference</td>
<td></td>
<td></td>
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<tr>
<td>of beneficial or harmful relationships among clinical</td>
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</tbody>
</table>

Levels of Evidence:

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1 - Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2+++ High quality systematic reviews of case control or cohort or studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 - Case control or cohort studies with a high risk of confounding or bias
interventions and clinical outcomes

- Level 1. The literature contains observational comparisons (e.g., cohort, case-control research designs) of clinical interventions or conditions and indicates statistically significant differences between clinical interventions for a specified clinical outcome.
- Level 2. The literature contains non-comparative observational studies with associative (e.g., relative risk, correlation) or descriptive statistics.
- Level 3. The literature contains case reports.

Category C: Equivocal Literature - Literature cannot determine whether there are beneficial or harmful relationships among clinical interventions and clinical outcomes

- Level 1. Meta-analysis did not find significant differences among groups or conditions.
- Level 2. The number of studies is insufficient to conduct meta-analysis, and (1) randomized controlled trials have not found significant differences among groups or conditions, or (2) randomized controlled trials report inconsistent findings.
- Level 3. Observational studies report inconsistent findings or do not permit inference of beneficial or harmful relationships.

Category D: Insufficient Evidence from Literature

- Silent. No identified studies address the specified relationships among interventions and outcomes.
- Inadequate. The available literature cannot be used to assess relationships among clinical interventions and clinical outcomes.

Opinion Categories

Category A: Expert Opinion
Task Force-appointed expert consultants

Category B: Membership Opinion
active ASA members

Category C: Informal Opinion
Open-forum testimony, Internet-based comments, letters, and editorials

Guidelines:
The American Society of Anesthesiologists (ASA, 2011) Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures recommends the following preoperative fasting periods.

Summary of Fasting Recommendations

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</td>
<td>2 h</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 h</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 h</td>
</tr>
<tr>
<td>Nonhuman milk</td>
<td>6 h</td>
</tr>
<tr>
<td>Light meal</td>
<td>6 h</td>
</tr>
</tbody>
</table>

and a significant risk that the relationship is not causal.

3 Non-analytic studies, e.g. case reports, case series
4 Expert opinion

Grades of Recommendation:

A: At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.

B: A body of evidence including studies rated as 2++, directly applicable to the target population; or A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+

0: Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2++or 2+

GPP: Good practice points/expert consensus - Recommended best practice based on the clinical experience of the guideline development group.
However, ASA also notes that these guidelines may not apply to, or may need to be modified for (1) patients with coexisting diseases or conditions that can affect gastric emptying or fluid volume (e.g., pregnancy, obesity, diabetes, hiatal hernia, gastroesophageal reflux disease, ileus or bowel obstruction, emergency care, enteral tube feeding) and (2) patients in whom airway management might be difficult. **Level of Evidence not provided**

European Society of Parenteral and Enteral Nutrition (ESPEN, 2006) guidelines on Enteral Nutrition: Surgery including Organ Transplantation recommends that preoperative fasting from midnight is unnecessary in most patients. **Grade A**

**Primary Literature:**

There were 7 studies found addressing perioperative enteral nutrition strategies in adult surgical/trauma patients with protected airways. One study (Schneider et al., 2009) described trends in US institutional practices regarding withholding enteral nutrition from intubated patients. Five studies were observational (McElroy et al., 2012; Parent et al., 2016; Pousman et al., 2009; Segaran et al., 2016; Yeh et al., 2015) and one (Gonik et al., 2016) was a small, randomized controlled trial.

Schneider et al., (2009) reported the results of a survey of US anesthesia and critical care training programs regarding institutional practices for withholding enteral nutrition from intubated patients. The results showed there was significant variation between: 1) withholding times in intubated patients scheduled for extubation by department: anesthesia (6 hr); anesthesia critical care (4 hr); surgical critical care (2 hr); and medical critical care (1.5 hr) (Kruskal–Wallis: $x^2 = 8.77$, df=3, $p=0.032$); and 2) withholding times in intubated patients scheduled for tracheostomy by department: surgical critical care (4 hr); all others (6 hr) (Kruskal–Wallis: $x^2 = 7.28$, df=3, $p=0.063$). Schneider and colleagues also reported that the mean withholding times for other procedures were as follows: 1) abdominal surgery: median 6 hr; 2) non-abdominal surgery: median 6 hr; 3) MRI or CT: median 0 hr; 4) placing patient in Trendlenberg position: median 0 hr; and 5) placing patient in prone position: median 6hr. These results indicate that there is variation in the length of time for withholding enteral nutrition at institutions across the US between procedures, as well as significant variation in the “appropriate” length of withholding between anesthesia and critical care specialists for some procedures.

Gonik et al. (2016) compared 24 intubated patients randomly assigned to a 6hr or 45 minute fast prior to bedside tracheotomy, and found that **total kilocalories provided on preoperative day 1 were 244% higher in the intervention group with no adverse aspiration or pneumonia events.** Similarly, all five observational studies reported that reduced fasting protocols were effective in maximizing kilocalorie (kcal) intake, with varying levels of significance, without increasing adverse events.

- McElroy et al. (2012) evaluated the safety of a new enteral protocol where feedings were continued perioperatively until the time of the transfer to the OR in 14 intubated patients with a postpyloric feeding tube. They found that patients received an additional 11.9±4.7 hours of enteral nutrition over the course of their hospitalization and an additional 1064.9±490 kcal/day per operation as a result of not having their nutrition stopped at midnight on the evening prior to operation.
- Parent et al. (2016) evaluated the effects of implementing a reduced fasting protocol for critically ill trauma patients with orogastric, nasogastric or postpyloric feeding tubes. **Patients in the post-implementation cohort (n=368) received an average of 1,965 kcal/person per week more (95% CI, 1,237–2,694; p < 0.001) than the pre-implementation cohort (n=245), when adjusted for age, gender, BMI, ISS, APACHE II score, and recent laparotomy. Mortality also decreased significantly post-implementation (adjusted RR, 0.67; 95% CI, 0.46–0.99; p = 0.04).**
- Pousman et al. (2009) evaluated the implementation of a reduced enteral fasting protocol (45 min prior to procedure) in 94 mechanically ventilated, adult trauma patients undergoing selected non-abdominal procedures. **Total time without enteral nutrition [median (IQR): pre: 2280 (1620-3540) vs post: 1770 (675-2685); p=0.07] and total mL of enteral nutrition [median (IQR): pre: 5095 (2925-8480) vs post: 7458 (4259-9394); p=0.29] both trended higher post-intervention, but not significantly so.** Infection rates were not significantly different between the two groups, but hypoglycemia was more common in the post-intervention group.
- Segaran et al. (2016) evaluated 22 adult patients treated before and after development of an EN fasting guideline for general/trauma ICU patients that continued enteral feedings until the patient left for the operating theater. They found that **total kcals/day were higher post-implementation, but not statistically significant [median (kcal): pre: 1136 (IQR 759-1478); post: 1465 (IQR 1003-1573); p=0.327] with similar estimated needs in both groups. But,**
the total kcal deficit over 4 weeks was significantly lower post-implementation [median (kcal): pre: 5058 (IQR 4271-8425); post: 2423 (IQR 1955-3452); p=0.003] without any impact on major pulmonary aspiration.

- Yeh et al. (2015) used a case-control methodology to assess 32 adult surgical ICU patients receiving enteral nutrition scheduled for bedside tracheostomy with and without a continuous enteral feeding protocol. The median caloric deficit on the day of the procedure was significantly lower in the “fed” group [175 kcal (IQR 49-340) vs 1133 kcal (IQR 660-1365); p < 0.0001] with no differences in infection or aspiration complications between groups.

**Primary Literature:**

<table>
<thead>
<tr>
<th>Author/Date/Journal</th>
<th>Purpose of Study</th>
<th>Study Design</th>
<th>Sample &amp; Setting</th>
<th>Outcomes</th>
<th>Design Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonik et al., 2016, Otolaryngology-Head and Neck Surgery</td>
<td>To evaluate whether decreasing length of preoperative fasting allows for better nutrition delivery and patient outcomes in intubated patients on enteral nutrition (EN) without increasing risk</td>
<td>RCT</td>
<td>24 intubated ICU patients undergoing bedside tracheotomy (medical, surgical, cardiac, cardiothoracic)</td>
<td>Median length of fast was statistically significant between groups (22.5 hr for controls vs 14.5 hr for intervention; p &lt; 0.001)</td>
<td>Study Limitations = None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-6 hr fast (control)</td>
<td>24 hr fast (intervention)</td>
<td>Kilocalories delivered were higher in all periods for the intervention group, but this difference was statistically significant (p = 0.01) in only the pre-operative 24 hours</td>
<td>RCT &amp; Quasi-Experimental Studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-45 min fast (intervention)</td>
<td>-12 intervention</td>
<td>-244% higher on preoperative day 1 [pre: median 429.0 kcal (IQR 57-1125); post: 1050 kcal (IQR 825-1410)]</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>-12 control</td>
<td></td>
<td>Adverse events:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Albert Einstein College of Medicine</td>
<td>-no important adverse events related to the tracheotomy procedures</td>
<td>- No cases of blue dye or gastrointestinal aspiration</td>
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<tr>
<td></td>
<td></td>
<td>-Assessed for aspiration (via blue food coloring pushed through the enteral tube to stomach), caloric delivery, metabolic markers and infectious and non-infectious complications (for 30 days or until d/c)</td>
<td>- No patients developed a pulmonary consolidation in the intervention group</td>
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<tr>
<td></td>
<td></td>
<td>-Gastric suction preoperatively and during procedure</td>
<td>- No meaningful differences in glucose measurements and quantity of insulin delivered</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- No meaningful differences UTI, wound and gastrointestinal infections</td>
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<td></td>
<td></td>
<td></td>
<td>Study Limitations =</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

**GRADE CRITERIA**

(See Appendix A)

Lower Quality Rating if:

- High risk of bias (When design limitations for one or more criteria impact the quality of studies sufficiently enough to lower confidence in the estimate of effect)
- Studies inconsistent (When there are differences in the direction of the effect, populations, interventions or outcomes between studies)
- Studies are indirect (Your PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)
- Studies are imprecise (When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)
- Publication Bias (e.g. pharmaceutical company sponsors study)
<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Design</th>
<th>Methods</th>
<th>Results</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>McElroy et al., 2012, <em>Nutrition in Clinical Practice</em></td>
<td>To pilot test the safety of continuing postpyloric enteral nutrition in intubated patients during surgical procedures</td>
<td>Prospective observational</td>
<td>14 patients admitted to the surgical ICU treated using a continuous postpyloric enteral feeding schedule during surgery (78.5% trauma patients) - Froedtert Memorial Lutheran Hospital (Medical College of Wisconsin) over 1 year (2010-11) - Institutional policy change: feedings were continued perioperatively until the time of the transfer to the OR, and restarted at the previous rate immediately postoperatively unless otherwise ordered by the physician - Monitored for adverse events (aspiration, gastric residuals &gt;300 cc/6hr, sepsis, pneumonia, perioperative death) and nutrition advantage (additional nutrition past midnight day of surgery)</td>
<td>Overall mean length of enteral nutrition interruptions for a single procedure was 222.4±206.9 minutes</td>
<td>Patients received an additional 11.9±4.7 hours of enteral nutrition over the course of their hospitalization and an additional 1064.9±490 kcal/d per operation as a result of not having their nutrition stopped at midnight on the evening prior to operation</td>
</tr>
<tr>
<td>Parent et al., 2016, <em>The Journal of Trauma and Acute Care Surgery</em></td>
<td>To report on a strategy to increase calorie intake in critically ill trauma patients by continuing feeds until transfer for operations and procedures</td>
<td>Quality Improvement (pre, post)</td>
<td>613 critically ill trauma patients at Harborview Medical Center (Seattle, WA) - Pre: n=245 (2003-05); historical control w/ 6hr fast - Post: n=368 (2006-10)</td>
<td>During the first week, patients in the post-implementation cohort had significantly higher caloric intake [pre: median 3,787 kcal/person per week (IQR 0–8,599); post: median 6,662 kcal/person per week (IQR 1,980–10,778; p &lt; 0.0001]</td>
<td>Study Limitations = None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Increase Quality Rating if:</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Large effect</td>
<td>(When the relative risk of association between two factors is large or very large)</td>
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<tr>
<td>Dose response</td>
<td>(When the dose-response relationship increases the confidence that an effect is real and substantial)</td>
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<tr>
<td>Plausible confounders</td>
<td>(When plausible residual confounding is directly impacting the magnitude of effect)</td>
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</tbody>
</table>

Level of evidence for studies as a whole: | High | Moderate | Low | Very Low |
-institutional policy change: enteral nutrition (EN) support continued up to the time of operations or procedures if the patient was not undergoing surgery on the GI tract and was to remain intubated postoperatively; gastric residual volume threshold for holding EN increased to 300mL (from 150mL)
-changes made in 1 hospital of a consortium studying acute trauma care
-oro- or nasogastric tubes, postpyloric if patient could not tolerate 50% of goal rate in 48hr
-monitored for adverse events (pulmonary complications, duration of mechanical ventilation, death) and nutrition advantage (kcal)

| Pousman et al., 2009, Journal of Parenteral and Enteral Nutrition | To determine the feasibility of implementing a reduced enteral fasting protocol in mechanically ventilated trauma patients undergoing selected operative | Quality Improvement (pre, post) -Prospective | 94 sequential adult patients admitted to the trauma ICU receiving enteral nutrition (EN) and expected mechanical ventilation for ≥72hr Pre: n=41 (3 mo); protocol w/ minimum 19 patients in the post-intervention group were inadvertently NPO before procedures (35.8%) – lack of awareness among providers Per-protocol subgroup analysis:
-Total time without EN was lower post-intervention, but patients in the population as a whole

| -Mean daily kcal/kg over the first week was also higher post-implementation (12.2 vs. 4.4, p < 0.001)
Patients in the post-implementation cohort received an estimated mean 1,965 kcal/person per week more than did the pre-implementation cohort, when adjusted for age, gender, BMI, ISS, APACHE II score, and recent laparotomy (95% CI, 1,237–2,694; p < 0.001).
Adverse events:
-Mortality decreased from 15% of the pre-implementation cohort to 8% of the post-implementation cohort (adjusted RR, 0.67; 95% CI, 0.46–0.99; p = 0.04)
-no change in risk of ARDS or VAP

Study Limitations = None
Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)
Insufficient sample size
Sample not representative of patients in the population as a whole
and non-operative procedures

8hr fast
Post: n=53 (3 mo)
- Vanderbilt University over 6 consecutive months (2006)
  - excluded: patients undergoing intrathoracic, abdominal, or neurological procedures; patients requiring prone positioning

New protocol: EN until 45 min prior to procedure in patients undergoing selected operative interventions (orthopedic limited to extremity surgery and not requiring prone positioning, otolaryngeal trauma, ophthalmologic surgery, tracheostomy, percutaneous feeding tube placements, and nonoperative procedures such as bronchoscopy and inferior venacaval filter placement) and with a protected airway (cuffed endotracheal or tracheostomy tube); gastric residual volume threshold for holding EN increased to 300mL (from 150mL)

not significantly so [median (IQR): pre: 2280 (1620-3540) vs post: 1770 (675-2685); p=0.07]
- Total EN (mL) was higher post-intervention, but not significantly so [median (IQR): pre: 5095 (2925-8480) vs post: 7458 (4259-9394); p=0.29]
- Hypoglycemic episodes were significantly more common post-intervention [median (IQR): pre: 0 (0-2) vs post: 2 (0-3); p=0.03]
- Incidence of VAP (p=0.75), bacteremia (p=0.91), UTI (p=0.34) and wound infection (p=0.54) were not different pre- and post-intervention

No statistically significant difference between the 2 groups was detected (p = 0.387) for time to pneumonia, with similar rates for not experiencing pneumonia (pre: 75% vs post: 69%)

ICU LOS was not significantly different [median (IQR): pre: 7 (5-15) vs post: 7 (5-12); p = 0.94], nor were ventilator days [median (IQR): pre: 8 (4.2-14) vs 7 (3-11); p = 0.37]

Adverse events:
- no episodes of regurgitation or aspiration

Schneider et al., 2009, Critical

To compare the practices for

Descriptive (survey)
Survey of anesthesia and
Median times for withholding EN from intubated patients

Study Limitations =
- Variables (confounders, exposures, predictors) were not described
- Outcome criteria not objective or not applied in blind fashion
- Insufficient follow-up, if applicable
- For prognostic study, sample not defined at common point in course of disease/condition
- For diagnostic study, gold standard not applied to all patients
- For diagnostic study, no independent, blind comparison between index test and gold standard

Quality Improvement (pre-post, controlled pre-post, historical comparison, time series)
- Intervention not evidence-based
- Improvement method was not clearly identified or the need for improvement was not described
- Stakeholders, organizational culture, patients, or interventions were not clearly described or appropriate
- Interventions were not described in enough detail to be replicated by others
- Baseline and outcome data were not collected and reported appropriately or in the same manner
- Data collection tools were not validated to measure intended outcomes
- Any modifications made to the intervention were not based on pilot studies

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☐ Data collection tools were not validated to measure intended outcomes
☐ Any modifications made to the intervention were not based on pilot studies
| Care Medicine | withholding enteral nutrition (EN) from intubated patients in anesthesia, anesthesia critical care, surgical critical care, and medical critical care departments in the United States | critical care training programs (response rate 27%; 80/297) | scheduled for extubation were significantly different by department: anesthesia (6 hr); anesthesia critical care (4 hr); surgical critical care (2 hr); and medical critical care (1.5 hr) (Kruskal–Wallis: \( X^2 = 8.77, df = 3, p=0.032 \)). Median times for withholding EN from intubated patients scheduled for tracheostomy were significantly different by department: surgical critical care (4 hr); all others (6 hr) (Kruskal–Wallis: \( X^2 = 7.28, df = 3, p=0.063 \)). Median times for withholding EN from intubated patients for other procedures was not significantly different by department and were as follows: - abdominal surgery: median 6 hr - non-abdominal surgery: median 6 hr - MRI or CT: median 0 hr - placing patient in Trendelenburg position: median 0 hr - placing patient in prone position: median 6 hr |
| Segaran et al., 2016, Journal of the Intensive Care Society | To describe the specific enteral nutrition (EN) interruptions in critically ill patients in a general/trauma ICU and the impact they have on nutrition delivery before and after implementation of a fasting guideline | Quality Improvement (pre, post) | 22 adult patients treated before and after development of an EN fasting guideline for general/trauma ICU patients in a London teaching hospital - Pre: n=11; 62 interruptions (4 wks) - Post: n=11; 64 interruptions (4 wks) - 1 year apart - institutional policy | Average EN cessation times were significantly affected by the EN fasting guideline: - Before all procedures: [median (hr)]: pre: 6 (IQR 1.4-8.9); post: 3 (IQR 0.2-6.1); \( p=0.01 \) - time to restart of EN (all procedures): [median (hr)]: pre: 6 (IQR 2-8); post: 3.2 (IQR 0.2-4.8); \( p=0.001 \) - time to restart of EN (imaging): [median (hr)]: pre: 1.5 (IQR 0.6-2); post: 0.1 (IQR 0.08-0.4); \( p=0.03 \) |
| Study Limitations = None | Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey) | | | Insufficient sample size | Sample not representative of patients in the population as a whole | Variables (confounders, exposures, predictors) were not described | Outcome criteria not objective or were not applied in blind fashion | Insufficient follow-up, if applicable | For diagnostic study, gold standard not applied to all patients | For diagnostic study, no independent, blind comparison between index test and gold standard |
change: No fasting interruption of EN for imaging, non-airway surgery, airway procedures; EN continued until patient leaves for surgical theater, then aspirated and gastric contents discarded

-98% nasogastric tubes, remaining gastrostomy and jejunostomy
--monitored for aspiration events and nutrition advantage (kcal, calorie deficits)

-median fasting time before airway procedures was reduced from 11h to 5h (p=0.002)

Nutrition (kcal):
-kcal/day were higher post-implementation, but not statistically significant [median (kcal): pre: 1136 (IQR 759-1478); post: 1465 (IQR 1003-1573); p=0.327] with similar estimated needs in both groups
-kcal deficit over 4 weeks was significantly higher pre-implementation [median (kcal): pre: 5058 (IQR 4271-8425); post: 2423 (IQR 1955-3452); p=0.003]

Adverse events: no incidents of major pulmonary aspiration were observed

Nutrition (kcal): 4

For diagnostic study, no independent, blind comparison between index test and gold standard
Quality Improvement (pre-post, controlled pre-post, historical comparison, time series)

For prognostic study, sample not defined at common point in course of disease/condition
For diagnostic study, gold standard not applied to all patients
For diagnostic study, no independent, blind comparison between index test and gold standard

Insufficient sample size
Sample not representative of patients in the population as a whole
Variables (confounders, exposures, predictors) were not described
Outcome criteria not objective or were not applied in blind fashion
Insufficient follow-up, if applicable
For diagnostic study, no independent, blind comparison between index test and gold standard
For diagnostic study, gold standard not applied to all patients

Yeh et al., 2015, The Journal of Surgical Research

To evaluate whether in surgical ICU patients undergoing elective tracheostomy, continuing perioperative nutrition or providing compensatory nutrition would improve caloric delivery on the day of procedure without increasing morbidity

Prospective observational (case/control)

32 adult surgical ICU patients receiving EN who were scheduled for elective bedside percutaneous tracheostomy
-10 cases: “fed” group
-22 controls: ASA NPO guideline applied (all with fasting lasting ≥ 1hr)
-Massachusetts General Hospital from 2012-14

-“fed” group: continuous perioperative

On the day of procedure, the fed group received a higher percentage of prescribed calories [92% (IQR 82-97%) vs 34% (IQR 24-51%); p < 0.0001] and more actual calories [1706 kcal (IQR 1481-2009) vs 588 kcal (IQR 353-943); p < 0.0001].

Median caloric deficit on the day of the procedure was significantly lower in the fed group [175 kcal (IQR 49-340) vs 1133 kcal (IQR 660-1365); p < 0.0001] and cumulative ICU caloric deficit was also lower in the fed group [1924 kcal (IQR 1044-3309) vs 3543 kcal (IQR 2395-6126); p < 0.0001].

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Study Limitations =

Insufficient sample size
Sample not representative of patients in the population as a whole
Variables (confounders, exposures, predictors) were not described
Outcome criteria not objective or were not applied in blind fashion
Insufficient follow-up, if applicable
For diagnostic study, gold standard not applied to all patients
For diagnostic study, no independent, blind comparison between index test and gold standard

Insufficient sample size
Sample not representative of patients in the population as a whole
Variables (confounders, exposures, predictors) were not described
Outcome criteria not objective or were not applied in blind fashion
Insufficient follow-up, if applicable
For diagnostic study, sample not defined at common point in course of disease/condition
For diagnostic study, gold standard not applied to all patients
feeding (n=8) or “compensatory” tube feeds by temporarily increasing rate (n=2)
- nasogastric and postpyloric positioning
- monitored for aspiration events and nutrition advantage (kcal, calorie deficits)

= 0.012

There were no differences in complications between groups, including GI complications on the day of procedure:
- pneumonia: 19 in fed vs 22 unfed
- UTI: 1 in fed vs 2 in unfed
- intra-abdominal abscess: 1 in fed vs 1 in unfed
- SSI: 0 in fed vs 1 in unfed

☐ For diagnostic study, no independent, blind comparison between index test and gold standard

### Existing External Protocols

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Organization and Author</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Operative Protocol for Enteral Nutrition</td>
<td>Vanderbilt University, Nashville TN (Pousman et al., 2009)</td>
<td>2006</td>
</tr>
</tbody>
</table>

#### Patients undergoing bedside or operative procedures:
- **For Non-Abdominal Surgery:** Gastric Feeds / Post-Pyloric Feeds – Feeds will be turned off just prior to departure to Operating Room or bedside procedure. Gastric tube will be flushed and aspirated.
- **For Abdominal Surgery:** Patient should be NPO 6 hours to planned anesthesia. Gastric tube will be flushed and aspirated prior to departure to the Operating Room.
- **For Upper GI Endoscopy** - Gastric Feeds / Post-Pyloric Feeds – Feeds will be turned off 4 hours prior to “elective endoscopy”

#### When to Hold Enteral Feeding:
- a. 1/2 hour prior to procedures requiring the Trendelenberg position
- b. 6 hours prior to general anesthesia for non-intubated patients
- c. Intubated patients having either airway surgery (includes tracheostomy) or planned reintubation (such as thoracotomy/thoracoscopy) NPO a minimum of 6 hours.
- d. Intubated patients having planned surgery on the GI tract, NPO from Midnight.
- e. All other intubated patients, enteral feeds can be continued until the time of departure to the operating room. This includes any patient who will be proned during surgery or extubated post-operatively

#### Stopping enteral nutrition:
1. Before non-airway surgery and procedures (e.g., Orthopedic surgery, Plastic surgery and Neurosurgery) – No Fasting. EN should be continued until patient leaves for theatres; nasogastric tube (NGT) should be aspirated and gastric contents discarded. The NGT should be capped. Accompanying insulin infusions should be stopped at the same time or before, and blood glucose should be monitored hourly. If feed is off for over 2 h, then maintenance fluid should be started.
2. Before percutaneous tracheostomy – These will be undertaken on the AICU between 2 and 5 pm; therefore, EN should not be stopped until at least 10 am. The EN should be stopped 4 h before. Accompanying insulin infusions should be stopped at the same time or before. Blood glucose should be monitored hourly. Maintenance fluids should be started if EN cessation is over 2 h. If insulin is felt necessary to control blood sugar, then glucose must be provided intravenously while EN is ceased.
3. Before laparotomy and all abdominal surgery – EN should be stopped 4 h before. Accompanying insulin infusions should be stopped at the same time or before. Blood glucose should be monitored hourly.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Organization and Author</th>
<th>Date</th>
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<tbody>
<tr>
<td>St Mary’s Hospital, London UK (Segaran et al., 2016)</td>
<td>After 2010 (date unconfirmed)</td>
<td>2016</td>
</tr>
</tbody>
</table>
Maintenance fluids should be started if EN cessation is over 2 h. If insulin is felt necessary to control blood sugar, then glucose must be provided intravenously while EN is ceased.

4. Before surgical tracheostomy/airway procedure or airway change – Time for the procedure must be confirmed with theatres and EN stopped 4 h before the procedure. Accompanying insulin infusions should be stopped at the same time or before. Blood glucose should be monitored hourly. Maintenance fluids should be started if EN cessation is over 2 h. If insulin is felt necessary to control blood sugar, then glucose must be provided intravenously while EN is ceased.

5. Before scans – No EN cessation is required before transfer to scans. The NG tube should be aspirated and gastric contents discarded. The NGT should be capped before transfer. Accompanying insulin infusions should be stopped at the same time or before. Blood glucose should be monitored hourly. Maintenance fluids should be started if EN cessation is over 2 h. If insulin is felt necessary to control blood sugar, then glucose must be provided intravenously while EN is ceased.

6. Before extubation – Planned extubation should be discussed with the on-call registrar or ICU Consultant and the EN stopped 4 h before. Accompanying insulin infusions should be stopped at the same time or before. Blood glucose should be monitored hourly. Maintenance fluids should be started if EN cessation is over 2 h. If insulin is felt necessary to control blood sugar, then glucose must be provided intravenously while EN is ceased.

REFERENCES


Appendix A: GRADE criteria for rating a body of evidence on an intervention
Developed by the GRADE Working Group

Grades and interpretations:
High: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low: Any estimate of effect is very uncertain.

Type of evidence and starting level
Randomized trial–high
Observational study–low
Any other evidence–very low

Criteria for increasing or decreasing level
Reductions
Study quality has serious (−1) or very serious (−2) problems
Important inconsistency in evidence (−1)
Directness is somewhat (−1) or seriously (−2) uncertain
Sparse or imprecise data (−1)
Reporting bias highly probable (−1)

Increases
Evidence of association† strong (+1) or very strong (+2)
Dose-response gradient evident (+1)
All plausible confounders would reduce the effect (+1)

†Strong association defined as significant relative risk (RR 2-5 or 0.5-0.2) based on consistent evidence from two or more studies with no plausible confounders;
Very strong association defined as significant relative risk (RR >5 or <0.2) based on direct evidence with no threats to validity
Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania’s Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guideline does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

1. Transparency

A Guideline development methods are fully disclosed.
B Guideline development methods are partially disclosed.
C Guideline development methods are not disclosed.

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:
- Who wrote the initial draft
- How the committee voted on or otherwise approved recommendations

Evidence review, external review and methods used for updating are not addressed in this standard.

2. Conflict of interest

A Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members.
B Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.
C Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline project was funded by industry sponsor with no assurance of independence.
NR Guideline does not report on potential conflict of interests.

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

3. Guideline development group

A Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties.
B Guideline development group includes one of the above, but not both.

C Guideline developers all from one specialty or organization, and no methodologists.

NR Affiliations of guideline developers not reported

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

4. Systematic review

A Guideline includes a systematic review of the evidence or links to a current review.

B Guideline is based on a review which may or may not meet systematic review criteria.

C Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:
- Describe itself as systematic or report search strategies using multiple databases
- Define the scope of the review (including key questions and the applicable population)
- Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.

Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

5. Grading the supporting evidence

A Specific supporting evidence (or lack thereof) for each recommendation is cited and graded

B Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded

C Recommendations are not supported by specific evidence.

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.

6. Recommendations

A Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form.

B Either one or the other of the above criteria is met.

C Neither of the above criteria are met

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like "should" or "should not" for strong recommendations, and passive language like "consider" for weak
recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

### 7. External review

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<table>
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<tbody>
<tr>
<td>A</td>
<td>Guideline was made available to external groups for review.</td>
</tr>
<tr>
<td>B</td>
<td>Guideline was reviewed by members of the sponsoring body only.</td>
</tr>
<tr>
<td>C</td>
<td>Guideline was not externally reviewed.</td>
</tr>
<tr>
<td>NR</td>
<td>No external review process is described.</td>
</tr>
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</table>

### 8. Updating and currency of guideline

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<tbody>
<tr>
<td>A</td>
<td>Guideline is current and an expiration date or update process is specified.</td>
</tr>
<tr>
<td>B</td>
<td>Guideline is current but no expiration date or update process is specified.</td>
</tr>
<tr>
<td>C</td>
<td>Guideline is outdated.</td>
</tr>
</tbody>
</table>

A guideline is considered current if it is within the developers’ stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst’s discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated.