Supplementary Appendices

Overview of the Pediatric Endoscopy Quality Improvement Network (PEnQuIN) Quality Standards and Indicators for Pediatric Endoscopy: A Joint NASPGHAN/ESPGHAN Guideline
Supplementary Appendix 1

This search strategy was developed by a Reference and Instruction Librarian in collaboration with the PEnQuIIN co-chairs.

Figure 1: Flow diagram of records

Table 1: Overview of pediatric search results (July 24, 2018)

<table>
<thead>
<tr>
<th>Database</th>
<th>Database Date</th>
<th>Date</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
<td>Ovid MEDLINE® Epub Ahead of Print, In-Process &amp; Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® 1946 to July 23, 2018</td>
<td>1990 - July 24, 2018</td>
<td>463</td>
</tr>
<tr>
<td>Embase</td>
<td>Embase Classic+Embase 1974 to 2018 Week 30</td>
<td>1990 - July 24, 2018</td>
<td>552</td>
</tr>
<tr>
<td>Cochrane</td>
<td>EBM Reviews - Cochrane Central Register of Controlled Trials, June 2018</td>
<td>1990 - July 24, 2018</td>
<td>91</td>
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</table>

Table 2: Overview of adult search results (July 24, 2018)

<table>
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<tr>
<th>Database</th>
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<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
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<td>2015 - July 24, 2018</td>
<td>929</td>
</tr>
<tr>
<td>Embase</td>
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<td>2015 - July 24, 2018</td>
<td>2025</td>
</tr>
<tr>
<td>Cochrane</td>
<td>EBM Reviews - Cochrane Central Register of Controlled Trials, June 2018</td>
<td>2015 - July 24, 2018</td>
<td>341</td>
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Table 3: Search strategies

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, and Daily 1946 to July 23, 2018

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<th>Results</th>
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<tr>
<td>2</td>
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<td>exp colonoscopy/ or duodenoscopy/</td>
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</tr>
<tr>
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<td>(gastrointestinal adj2 endoscop*) or (intestin* adj2 endoscop*) or colonoscopy* or duodenoscopy* or eosophagoduodenoscopy* or eosophagastroduodenoscopy* or eosophagoscop* or esophagoduodenoscopy* or esophagogastroduodenoscopy* or esophagoscopy* or gastroscopy* or oesophagoduodenoscopy* or oesophagastroduodenoscopy* or oesophagoscopy* or proctoscopy* or rectoscopy* or sigmoidoscopy* or (upper adj2 endoscopy*).tw,kf.</td>
<td>54044</td>
</tr>
<tr>
<td>5</td>
<td>or/1-4</td>
<td>107863</td>
</tr>
<tr>
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<td>quality control/ or quality of health care/ or diagnostic errors/ or safety/ or &quot;adverse effects&quot;.fs.</td>
<td>1756617</td>
</tr>
<tr>
<td>7</td>
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<td>744332</td>
</tr>
<tr>
<td>8</td>
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<tr>
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<tr>
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<tr>
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<td>17 not (case reports/ or (case report or case reports or case series or case study or case studies or clinical series).ti.)</td>
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</tr>
<tr>
<td>19*</td>
<td>exp child/ or infant/ or infant, newborn/ or pediatrics/</td>
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<td>20*</td>
<td>(infan* or newborn* or &quot;new born&quot;* or perinat* or neonat* or baby or baby* or babies or toddler* or minors* or boy or boys or boyfriend or boyhood or girl* or kid or kids or child* or schoolchild* or adolescent* or juvenil* or youth* or teen* or pre-pubesc* or prepubesc* or &quot;under* age&quot;* or pubescen* or pediatric* or paediatric* or paediatric* or prematur* or pre-term or preterm)<em>.mp. or (child</em> or adolescen* or pediat* or paediat*).jn.</td>
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<tr>
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<td>463</td>
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<tr>
<td>23†</td>
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<td>929</td>
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</table>

*Limits for pediatric search; **Pediatric search results; †Adult search results

Embase Classic and Embase 1947 to 2018 Week 30

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<th>#</th>
<th>Searches</th>
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### Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials June 2018

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<th>Searches</th>
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<tr>
<td>2</td>
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<td>3</td>
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<td>1961</td>
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<tr>
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<td>201259</td>
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<td>1081</td>
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</table>

*Limits for pediatric search; **Pediatric search results; †Adult search results
or "cecum intubation rates" or "caecum intubation rate" or "caecum intubation rates" or "cecum intubation time" or "caecum intubation time" or "CIR" or "digestive tract intubation*" or gastrointestinal intubation* or "ileum intubation rate" or "ileum intubation rates" or "ileum intubation time" or "ileal intubation rate" or "ileal intubation rates" or "ileal intubation time").tw,kw.

9 intraoperative complications/ or postoperative complications/ or intestinal perforation/ 16640
10 (complication* or perforation*).tw,kw. 65275
11 professional competence/ or clinical competence/ or benchmarking/ 3118
12 (benchmark* or competenc* or wait* time*).tw,kw. 5122
13 or/6-12 269910
14 standard of care/ or quality indicators, health care/ or (standard or standards or indicator* or measure or measures).tw,kw. 225222
15 5 and 13 and 14 877
16 limit 15 to (english language and yr="1990 -Current") 756
17 16 not ((exp animals/ not humans/) or (rodent* or mice or mouse or murine* or rat or rats).ti.) 756
18 17 not (case reports/ or (case report or case reports or case series or case study or case studies or clinical series).ti.) 753
19* exp child/ or infant/ or infant, newborn/ or pediatrics/ 66404
20* (infan* or newborn* or "new born"* or perinat* or neonat* or baby or baby* or babies or toddler* or minors* or boy or boys or boyfriend or boyhood or girl* or kid or kids or child* or schoolchild* or adolescen* or juvenil* or youth* or teen* or pre-pubesc* or prepubesc* or "under* age"* or pubescen* or pediatric* or paediatric* or peadiatric* or prematur* or pre-term or preterm*).mp. or (child* or adolesc* or pediat* or paediat*).jn. 237882
21* 19 or 20 237882
22** 18 and 21 91
23† limit 18 to (english language and yr="2015 -Current") 341

*Limits for pediatric search; **Pediatric search results; †Adult search results
### Table 1: Eliminated standards and indicators

<table>
<thead>
<tr>
<th>Statement</th>
<th>Domain</th>
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<tbody>
<tr>
<td><strong>Standards</strong></td>
<td></td>
</tr>
<tr>
<td>Endoscopy facilities where pediatric procedures are performed should track the number of diagnostic procedures with gross abnormal and/or positive pathological findings.</td>
<td>Facilities</td>
</tr>
<tr>
<td>Photo/video documentation of all relevant anatomical landmarks should be obtained</td>
<td>Procedures</td>
</tr>
<tr>
<td>Endoscopists who perform procedures on pediatric patients should aim to perform a minimum number of procedures per year*, specified by procedure type.</td>
<td>Endoscopists and Endoscopists in Training</td>
</tr>
<tr>
<td>Endoscopists performing procedures on pediatric patients should track the number of diagnostic procedures which lead to a change in patient management</td>
<td>Endoscopists and Endoscopists in Training</td>
</tr>
<tr>
<td><strong>Indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Rate with which an antithrombotic therapy management plan is formulated and documented before the procedure (consistent with accepted guidelines)</td>
<td>Procedures</td>
</tr>
<tr>
<td>Diagnostic yield (number of diagnostic procedures with gross abnormal and/or positive pathological findings over the total number of diagnostic procedures completed).</td>
<td>Procedures</td>
</tr>
<tr>
<td>Rate of diagnostic procedures which lead to a change in patient management</td>
<td>Procedures</td>
</tr>
<tr>
<td>Rate with which photodocumentation of requisite anatomical landmarks is performed</td>
<td>Procedures</td>
</tr>
<tr>
<td>Rate with which photos/video documentation of terminal ileum intubation is obtained</td>
<td>Procedures</td>
</tr>
<tr>
<td>Rate with which standardized disease-related terminology and/or scales are applied to document findings, when available.</td>
<td>Procedures</td>
</tr>
<tr>
<td>Rate of procedures in which there is at least one representative photo/video of all visualized abnormal findings</td>
<td>Procedures</td>
</tr>
<tr>
<td>Percentage of endoscopy reports that record the duration of the procedure from first insertion until final removal of endoscope</td>
<td>Procedures</td>
</tr>
<tr>
<td>Withdrawal time</td>
<td>Endoscopists and Endoscopists in Training</td>
</tr>
<tr>
<td>Adenoma detection rate</td>
<td>Endoscopists and Endoscopists in Training</td>
</tr>
<tr>
<td>Polyp detection rate</td>
<td>Endoscopists and Endoscopists in Training</td>
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<tr>
<td>Polyp retrieval rate</td>
<td>Endoscopists and Endoscopists in Training</td>
</tr>
<tr>
<td>Interval cancer incidence</td>
<td>Endoscopists and Endoscopists in Training</td>
</tr>
</tbody>
</table>

*Number not discussed as standard did not reach consensus
Supplementary Appendix 3
GRADE EVIDENCE SUMMARIES
Overview of the Pediatric Endoscopy Quality Improvement Network (PEnQuIn) Quality Standards and Indicators for Pediatric Endoscopy: A Joint NASPGHAN/ESPGHAN Guideline
STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s)**
- **Standard 1**: Endoscopy facilities where pediatric procedures are performed should meet or exceed operating standards defined by the appropriate national or provincial/state regulatory authorities and be accredited to provide pediatric care.

**PICO Question:**
Does undergoing pediatric endoscopy in a facility that measures whether providers meet and/or exceed externally defined standards (i.e. by national/state/provincial regulatory bodies and/or programs) lead to improved outcomes?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Having the procedure performed in a facility that measures provider adherence to regulatory or guideline-based standards
- **Control/Comparator**: Having the procedure in facility that does not measure provider adherence to these standards
- **Outcome(s)**:
  - Provider documentation
  - Adverse event rates
  - Variation in care
  - Bowel preparation quality
  - Procedure completion rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 2 pediatric, 2 adult

**Articles excluded**: 2 pediatric, 2 adult
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
2 primary studies were found addressing this question in children: Sheu et al.1 and Pitetti et al.2 A number of other studies addressed this question in adult facilities, but only two looked at outcomes that are of interest in pediatric procedures: Conigliaro et al.3 and Lee et al.4

**Pediatric studies:**
Sheu et al.1 was a cross-sectional, prospective observational study examining the impact of participating in Maintenance of Competency (MOC) activities focused on improving completeness of documentation of endoscopic procedures in children. The study looked at baseline data of 134 participating procedures across multiple settings and compared it to data after implementation of a variety of different rapid cycle “PDSA” interventions (at the individual level, rather than system level), and 2 more rounds of collecting data (i.e., data from cycle 1 was compared to data from cycle 3; n = 6300 procedures). Results suggested that participation in the MOC activity (and adherence to its standards) led to improved completeness of documentation of reports (as defined by the MOC activities), less adverse events, and improved prep quality.

Pitetti et al.2 was a cross-sectional prospective observational study of implementation of the 2001 JCAHO Sedation Guidelines at a single, tertiary care pediatric hospital across all settings in the hospital where procedural sedation is used. The study followed clinical outcomes from baseline (prior to implementation of the guidelines) through implementation over 3 years, with several rapid cycle changes implemented at the facility level. Results of the study showed improved documentation during sedated procedures in children, including during endoscopic procedures, with less variation in care and progressively less adverse events recorded at the facility level across all 3 years.

**Adult studies:**
Conigliaro et al.3 reported prospective, cross-sectional data at 3 time points for 29 or 60 endoscopy centers in Italy, and examined whether provider education about the Italian Guidelines for Sedation in Digestive Endoscopy (published in 2000)5 had an impact from baseline to 1 year after the intervention. Results of the study suggested that in the 29 centers (which met inclusion criteria because they had collected data at all 3 time points) there were less adverse events and less variation in care (particularly around use of sedation for colonoscopy in adults (yes or no) when baseline data was compared to 12 months).

Lee et al.4 was a cross-sectional, prospective, observational study of data entered into the National Health Service Bowel Cancer Screening Program database (NHS BCSP) (from 2006-2009) in the United Kingdom. Investigators compared the data from > 36,000 procedures entered into the database at that point to data that had been collected in 2004, as part of a national audit (but no guidelines, screening program or database in place), and found that there was less adverse events, higher adenoma detection rates, better cecal intubation rates, and better scores in terms of patient comfort after implementation of the NHS BCSP.
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong> (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No</td>
<td>All studies (pediatric and adult) suffer from selection biases, performance biases (no blinding), attrition bias (only counted complete data sheets), reporting biases, etc.</td>
<td>☒ ☒ ☒ ☒ High</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong> (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Multiple different questions (documentation important?, Sedation practice important?), different interventions (guidelines vs. consensus), different outcomes</td>
<td>☒ ☒ ☒ ☒ Moderate</td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong> (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>There is at least some pediatric data which is specific to the question; in each study, comparators are to baseline</td>
<td>☒ ☒ ☒ ☒ Low</td>
</tr>
<tr>
<td><strong>Imprecision</strong> (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>Some smaller studies, some larger studies, varied outcomes, all in the same direction – adherence to “externally defined” standards are helpful for improving outcomes</td>
<td>☒ ☒ ☒ ☒ Very low</td>
</tr>
<tr>
<td><strong>Publication Bias</strong> (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Authors generally believe in guidelines and quality improvement</td>
<td>☒ ☒ ☒ ☒ Low</td>
</tr>
<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
<td></td>
<td>☒ ☒ ☒ ☒ Low</td>
</tr>
<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td>No</td>
<td></td>
<td>☒ ☒ ☒ ☒ Low</td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No</td>
<td></td>
<td>☒ ☒ ☒ ☒ Low</td>
</tr>
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</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
<th>☒ ☒ ☒ ☒ High</th>
<th>☒ ☒ ☒ Moderate</th>
<th>☒ ☒ Low</th>
<th>☒ ☒ ☒ ☒ Very low</th>
</tr>
</thead>
</table>
REFERENCES

**STEP 1: Create a PICO question(s) for your standard/indicator**

**Standard(s)/Indicator(s)**
- **Standard 2:** Endoscopy facilities where pediatric procedures are performed should have a process in place for ensuring timely performance of elective pediatric endoscopic procedures, based on procedure indications and patient characteristics, that is in line with guidelines, when available.
  - **Indicator 1:** Rate with which endoscopies are performed within a timeframe as specified in guidelines, when available (e.g., button battery removal, endoscopy for suspected inflammatory bowel disease).

**PICO Question:**
Is there evidence that elective pediatric endoscopic procedures which are performed in a timely manner based on procedure indications and patient characteristics, in line with guidelines where available, result in better outcomes?

- **Population/Patient:** Pediatric patients undergoing elective endoscopic procedures
- **Intervention:** Endoscopic procedures occurring within the indicated timeframe
- **Control:** Higher than ‘I’
- **Outcome:**
  - Patient compromise (e.g., increased emergency room visits prior to endoscopy, time with symptoms prior to proper medical treatment)
  - Patient experience
  - Diagnostic yield
  - Adverse events

**STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.**

**Studies included:** 1 pediatric, 1 adult

**Articles excluded:**
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
One pediatric retrospective observational study based on current clinical practice and 1 adult study prospectively evaluated wait times based on consensus or guideline recommended wait times. Edwards et al1 conducted a retrospective single center observational study that review of medical charts of all pediatric patients <18 years of age assessed in the pediatric gastroenterology clinic and scheduled for an elective outpatient endoscopic procedure at McMaster Children’s Hospital (Hamilton, Ontario) from January 2006 to December 2007. A total of 386 subjects met inclusion criteria, corresponding to 145 endoscopies under general anesthesia (GA) and 241 endoscopies under light sedation. The median wait time to procedure was 64 days for GA patients and 22 days for patients who underwent light sedation (P<0.0001). There was no significant difference between the two groups with regard to the number of ER visits or hospital admissions, both pre- and post-endoscopy.

Leddin et al2 compared wait times for specialist adult gastroenterology care with recent, evidence-based, consensus-defined benchmark wait times for a range of digestive diseases developed by the Canadian Association of Gastroenterology (CAG). CAG consensus recommended wait times based on acuity category were adopted by investigators a priori. ‘Point-of-care’ wait time data were collected using the Practice Audit in Gastroenterology (PAGE) Program (a national adult Canadian audit program). National median wait time, determined for 1903 patients from referral to endoscopic investigation, exceeded the consensus targets for 7 indications by 51% to 88% (probable cancer, documented iron deficiency anemia, probable inflammatory bowel disease (IBD), positive stool fecal occult blood testing, dyspepsia with alarm symptoms, refractory dyspepsia without alarm symptoms, chronic constipation and diarrhea). A minority of patients were seen within target times: probable cancer (33%); probable IBD (12%); iron deficiency anemia (46%); positive occult blood test (41%); dyspepsia with alarm symptoms (51%); refractory dyspepsia without alarm symptoms (33%); and chronic constipation and diarrhea (21%).
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong></td>
<td>No</td>
<td>No randomized studies</td>
<td>☒ High</td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong></td>
<td>No</td>
<td>Heterogeneous, mixed studies</td>
<td>☒ Moderate</td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong></td>
<td>No</td>
<td></td>
<td>☒ Low</td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Imprecision</strong></td>
<td>No</td>
<td></td>
<td>☒ Very Low</td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Publication Bias</strong></td>
<td>Not assessed</td>
<td></td>
<td>☒ Low</td>
</tr>
<tr>
<td></td>
<td>Unlikely</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Likely (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very likely (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
<td></td>
<td>☒ Very Large</td>
</tr>
<tr>
<td></td>
<td>Large (+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very large (+2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td>No</td>
<td></td>
<td>☒ Yes (+1)</td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No</td>
<td></td>
<td>☒ Yes (+1)</td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

High  Moderate  Low  Very low

REFERENCES

PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s)
- **Standard 3**: Endoscopy facilities where pediatric procedures are performed should have well-defined processes and policies in place to ensure high quality endoscopic care during after-hours and emergency procedures.

PICO Question:
Are defined processes and policies required to ensure high-quality endoscopic care during after-hours and emergency procedures?

- **Patient/Population**: Pediatric patients undergoing emergency and/or after-hours endoscopic procedures
- **Intervention**: Having the procedure performed in a facility that has well defined processes and policies regarding after-hours and emergency procedures
- **Control**: Having the procedure performed in a facility that does not have well defined processes and policies regarding after-hours and emergency procedures
- **Outcome**:
  - Time to endoscopic procedure
  - Time to therapeutic intervention
  - Adverse event rate (including mortality rate)
  - Time to discharge
  - Procedure completion rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studies included: 1 pediatric, 1 adult

Relevant guidelines:

Articles excluded:
**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
Guidelines and reviews suggest that facilities performing endoscopic procedures should have well-defined processes and policies in place to ensure that high-quality after-hours and emergency endoscopy can take place.\(^1\),\(^2\) The evidence published thus far characterizes current practice,\(^3\) with two quality improvement studies reporting outcomes after implementation of interventions aimed at improving after-hours and/or emergency endoscopic care.\(^4\),\(^5\)

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Population</th>
<th>Primary Outcome</th>
<th>Main Results</th>
<th>Conclusions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davies, 2003(^5)</td>
<td>Retrospective, observational (audit completed post-implantation of a weekend endoscopy list)</td>
<td>Adult</td>
<td>Discharge within 24 hours of endoscopy for patients admitted with trivial GI bleeding; Endoscopic or surgical intervention and mortality for patients with significant GI bleeding</td>
<td>Thirteen (33.3%) of the 39 patients with trivial hemorrhage were discharged within 24 hours of their Endoscopy, saving 23 bed days; 10 (53%) with significant hemorrhage underwent endoscopic therapy, 5 were transferred to surgical care</td>
<td>The total number of deaths was 5 (8.6%). Implementation of a weekend endoscopy list resulted in earlier discharge of a large proportion of patients with trivial upper GI hemorrhage.</td>
<td>Retrospective; No controls; Relatively small number of patients</td>
</tr>
<tr>
<td>Russell, 2014(^4)</td>
<td>Retrospective, observational with historical control (adult completed before and after implementation of a button battery triage protocol)</td>
<td>Pediatric</td>
<td>Time from arrival to the facility to the time of arrival to the operating room</td>
<td>Time from arrival in emergency room to battery removal was 183 minutes in standard treatment group (n = 4) and 33 minutes in intervention group (n=7)</td>
<td></td>
<td>Retrospective study Small number of included patients</td>
</tr>
</tbody>
</table>

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No</td>
<td>Not randomized, one study used published data for comparison</td>
<td>High □</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Notice serious differences between studies</td>
<td>Moderate □</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>One low quality pediatric study</td>
<td>Low □</td>
</tr>
</tbody>
</table>
**PEnQuIN GRADE reporting template**

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
<th>Limited patient numbers, only 2 studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Imprecision</strong></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>(Research that includes few</td>
<td>Serious (-1)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>patients and few events and</td>
<td>Very serious (-2)</td>
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<tr>
<td>thus has a wide confidence</td>
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<tr>
<td>interval around the estimate</td>
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<tr>
<td>of the effect)</td>
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</tr>
<tr>
<td><strong>Publication Bias</strong></td>
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<tr>
<td>(Systematic under or</td>
<td>Unlikely</td>
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<td>overestimate of the</td>
<td>Likely (-1)</td>
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<tr>
<td>underlying beneficial or</td>
<td>Very likely (-2)</td>
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<tr>
<td>harmful effect due to the</td>
<td></td>
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<tr>
<td>selective publication of</td>
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</tr>
<tr>
<td>studies)</td>
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<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
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<tr>
<td></td>
<td>Large (+1)</td>
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<tr>
<td></td>
<td>Very large (+2)</td>
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<tr>
<td><strong>Effects of all plausible</strong></td>
<td>No</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>confounding</td>
<td>Yes (+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No</td>
<td></td>
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<tr>
<td></td>
<td>Yes (+1)</td>
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</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- [ ] High
- [ ] Moderate
- [ ] Low
- [ ☑ ] Very low

**REFERENCES**

OVERALL RATING

- **Standard 4:** Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *preprocedure* policies that ensure best practice in pediatric care.
  - Examples: antibiotic prophylaxis guidelines, antithrombotic agent guidelines, surveillance schedules, diabetes mellitus management guidelines, sedation/anesthetic risk assessment guidelines, allergy or drug sensitivity guidelines and procedural pause.

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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</thead>
<tbody>
<tr>
<td>🟢🟢🟢🟢</td>
</tr>
<tr>
<td>High</td>
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</table>

<table>
<thead>
<tr>
<th>Very low</th>
</tr>
</thead>
<tbody>
<tr>
<td>✖</td>
</tr>
</tbody>
</table>

- See data for individual PICO statements below
PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

- **Standard 4:** Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *preprocedure* policies that ensure best practice in pediatric care.
  - Examples: antibiotic prophylaxis guidelines, antithrombotic agent guidelines, surveillance schedules, diabetes mellitus management guidelines, sedation/anesthetic risk assessment guidelines, allergy or drug sensitivity guidelines and procedural pause.
  - **Indicator 2:** Rate with which a preprocedure history and directed physical examination is performed.

**PICO Question:**
Is there a lower risk of adverse events if a pre-procedure history and directed physical examination are performed?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Pre-procedure history and directed physical examination are performed
- **Control:** Pre-procedure history and directed physical examination are not performed
- **Outcome:** Adverse events

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**

**Relevant guidelines:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
Hoffman et al. conducted a pediatric study to see if the application of an AAP/ASA-structured model would reduce the risk of sedation-related adverse events. They performed prospective abstraction of 960 procedural sedation records during the study period, and adverse events or complications were identified in 40 (4.2%) sedation procedures (including hypotension,
bradycardia and hypoxemia). Performance of guided risk assessment significantly reduced the complication rate in the logistic model (OR: 0.50; \( P = 0.041 \)). After stratification by target sedation plan, complications were reduced by performance of guided risk assessment (OR: 0.10; \( P = 0.018 \)), and by adherence to all process guidelines. Both conscious and deep sedation were included (but conscious sedation is seldom used nowadays).

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td>☒</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td>☒</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td>☒</td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td>☒</td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Unlikely Likely (-1) Very likely (-2)</td>
<td>☐ ☑</td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>Large (+1) Very large (+2)</td>
<td>☒</td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td>☐</td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td>☒</td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- ☐ ☐ ☐ ☐ High
- ☐ ☐ ☐ Moderate
- ☐ ☐ ☐ Low
- ☐ ☐ ☐ ☐ Very low

REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):

- **Standard 4**: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *preprocedure* policies that ensure best practice in pediatric care.
  - Examples: antibiotic prophylaxis guidelines, antithrombotic agent guidelines, surveillance schedules, diabetes mellitus management guidelines, sedation/anesthetic risk assessment guidelines, allergy or drug sensitivity guidelines and procedural pause.
  - **Indicator 3**: Rate of appropriate prophylactic antibiotic administration in accordance with accepted guidelines.

**PICO Question:**
Is there a lower risk of procedure-related infection if prophylactic antibiotics are administered for appropriate indication (consistent with accepted guidelines)?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Prophylactic antibiotics are administered for appropriate indication (consistent with accepted guidelines)
- **Control**: Prophylactic antibiotics are not administered for appropriate indication (consistent with accepted guidelines)
- **Outcome**: Procedure-related infection

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 4 adult


**Relevant Guidelines**

**Summary of the Evidence:**
Chavez-Tapia et al\(^1\) published a Cochrane systematic review examining the use of antibiotic prophylaxis in adults with cirrhosis and upper GI bleeding. There was a positive effect on reduction of risk of infection. Jain et al\(^2\) found a reduction of peristomal wound infection with Cefazolin administration in PEG placement in adults. Lipp et al\(^3\) published a Cochrane systematic review which found a significant reduction in the incidence of peristomal infection with prophylactic antibiotics (1271 patients pooled: OR 0.36, 95% CI 0.26 to 0.50) after PEG placement. There were a total of 12 eligible randomized control trials. Finally, Thomas et al\(^4\) found a significant reduction in MRSA peristomal infection when adult patients were screened for MRSA with subsequent decontamination and administration of antibiotic prophylaxis before the procedure in patients with a positive screen.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Serious (-1) Serious very (-2)</td>
<td>High</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td>Serious (-1) Serious very (-2)</td>
<td>Moderate</td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td>Serious (-1) Serious very (-2)</td>
<td></td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the)</td>
<td></td>
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</tr>
</tbody>
</table>
# PEnQuIN GRADE reporting template

## Interventions, populations, or outcomes of interest, for example, adult literature)

<table>
<thead>
<tr>
<th>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</th>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Unlikely</td>
<td>Likely (-1)</td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>Large (+1)</td>
<td>Very large (+2)</td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

## Overall quality of the evidence (please circle/check-off):

- ☑ High
- ☑ Moderate
- ☑ Low
- ☑ Very low

## REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 4**: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *preprocedure* policies that ensure best practice in pediatric care.
  - Examples: antibiotic prophylaxis guidelines, antithrombotic agent guidelines, surveillance schedules, diabetes mellitus management guidelines, sedation/anesthetic risk assessment guidelines, allergy or drug sensitivity guidelines and procedural pause.
- **Indicator 4**: Rate with which a preprocedural team pause is conducted.

**PICO Question:**
Is there a lower risk of adverse events if a procedural team pause / time-out is conducted and documented?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Procedural team pause / time-out is conducted
- **Control**: Procedural team pause / time-out is not conducted
- **Outcome**: Adverse event rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**

**Relevant guidelines:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
There are no pediatric or adult endoscopy-related studies. There are a number of papers within the surgical literature assessing longer procedures in adult patients, but these are indirect sources of evidence and do not answer the question.

Braaf 2013: An institutional ethnographic study examining how time-out procedures are conducted at three hospital sites through video observation, focus groups, and semi-structured interviews, involving 125 healthcare professionals from surgery, anesthesia, and nursing. Analysis revealed that healthcare professionals adapted the content, timing, and number of team members involved in the time-out procedure to meet the demands of the operating theatre. Productivity, professional, and hierarchical barriers to staff engaging in the time-out procedure were identified.

Cumin 2017: This study examined the communication of clinically relevant information between members of an operating room during simulated surgical scenarios. Results indicated that information sharing was most effective during formal communication processes (including time-out procedures), compared to outside of these, as reflected in the number of team members attentive during sharing as well as in post-simulation knowledge test scores.

Erestam 2018: This survey study sought to explore surgical teams’ perceptions of a preprocedural pause routine a year after its implementation at a university hospital. Most were positive to the scheduled pauses and felt that patient safety was promoted. Surgeons reported that the pauses were often refreshing and sometimes changed their view on both anatomy and their surgical strategy.

Van Schoten 2014: This study evaluated compliance with a time-out procedure before anesthesia in the operating room following introduction of the World Health Organization’s Surgical Safety Checklist across 18 Dutch hospitals. Mean compliance with the time-out procedure was 71.3%, with large differences between hospitals observed. Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
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<td>☧</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>☧</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
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<tr>
<td></td>
<td></td>
<td>Very serious (-2)</td>
<td>☧</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
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**Publication Bias**
(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)

<table>
<thead>
<tr>
<th></th>
<th>Not assessed</th>
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<th>Likely (-1)</th>
<th>Very likely (-2)</th>
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</table>

<table>
<thead>
<tr>
<th>Large effect</th>
<th>No</th>
<th>Large (+1)</th>
<th>Very large (+2)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects of all plausible confounding</th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dose-response gradient</th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ⬤ ⬤ ⬤ ⬤ High
- ⬤ ⬤ ⬤ Moderate
- ⬤ ⬤ Low
- ⬤ ⬤ ⬤ Very low

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 4:** Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to preprocedure policies that ensure best practice in pediatric care.
  - Examples: antibiotic prophylaxis guidelines, antithrombotic agent guidelines, surveillance schedules, diabetes mellitus management guidelines, sedation/anesthetic risk assessment guidelines, allergy or drug sensitivity guidelines and procedural pause.
  - **Indicator 5:** Rate with which sedation-related fasting guidelines are followed.

**PICO Question:**
Does undergoing pediatric endoscopy in a facility that monitors adherence to pre-procedure fasting guidelines lead to improved outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Standard monitoring of adherence to pre-procedure fasting guideline
- **Control/Comparator:** No standard monitoring of pre-procedure fasting guideline
- **Outcome:**
  - Number of procedures cancelled due to violations in pre-procedure fasting guidelines
  - Procedure-related complications

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Relevant guidelines:**

**Articles excluded:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
There is no evidence that demonstrates how often pre-procedure fasting guidelines are followed or whether facilities that closely monitor adherence to pre-procedure fasting guidelines report better outcomes compared to those that do not. Based on one pediatric and one adult guideline, the recommended hours for fasting are similar between anesthesia and gastroenterology societies and are slightly modified for the pediatric population. Experts agree that incomplete evaluation of the stomach due to pre-procedure fasting violation should be monitored and described in the procedure reports in detail. The root cause of pre-procedure fasting violation should be established and process improvement measures should be implemented if fasting violations are due to poor pre-procedural education.

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn as to whether undergoing pediatric endoscopy in a facility that monitors adherence to pre-procedure fasting guidelines leads to improved outcomes.

**REFERENCES**

OVERALL RATING

- **Standard 5:** Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *intraprocedural* policies that ensure best practice in pediatric care.
  - Examples: photo/video documentation of terminal ileal intubation, patient monitoring, and evaluation of bowel preparation quality.

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<tbody>
<tr>
<td>⊕⊕⊕⊕ High</td>
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<tr>
<td>⊕⊕⊕ Moderate</td>
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<tr>
<td>⊕⊕⊕ Low</td>
</tr>
<tr>
<td>⊕⊕⊕ Very low</td>
</tr>
</tbody>
</table>

- This standard relates to several intraprocedural-related standards. Please refer to:
  - **Standard 31:** Appropriate sedation/anesthesia should be provided to ensure patient cooperation, comfort and safety in line with best practices and consistent with evidence-based guidelines, when available.
  - **Standard 33:** Bowel preparation for lower endoscopic procedures should be of adequate diagnostic quality to allow for a complete procedure and be measured using a tool with strong validity evidence or, at a minimum, using standardized language with clear definitions (e.g., poor, fair, good).
  - **Standard 35:** Photo/video documentation of all visualized abnormal findings should be obtained.
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STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 6**: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to postprocedural policies that ensure best practice around the discharge of pediatric patients after endoscopic procedures.
  - Examples: assessment of readiness for discharge, and follow-up of pathology results.

PICO Question:
Do facilities with policies regarding provision of post-procedure information and/or those which provide post-procedure information to patients/families that ensures best practice around the discharge of pediatric patients after endoscopic procedures lead to improved patient experience, rates of re-contact with the facility and/or late adverse events?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Facilities with policies regarding provision of post-procedure information and/or provision of effective post-procedure information to patients/families that ensures best practice around the discharge of pediatric patients after endoscopic procedures
- **Control/Comparator**: No policy and/or no effective information provided to patients/families
- **Outcome**:
  - Patient experience
  - Rate of re-contact with facility regarding questions or concerns
  - Late adverse event rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**:
- None

**Relevant guidelines**:

**Articles excluded**:

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence**:
There is no available direct or indirect evidence to support this standard or answer this PICO question for pediatric or adult GI endoscopic procedures.
**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn as to whether facilities with policies regarding provision of post-procedure information and/or those which provide post-procedure information to patients/families that ensures best practice around the discharge of pediatric patients after endoscopic procedures lead to improved patient experience.
STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s)
- **Standard 7**: Endoscopy facilities where pediatric procedures are performed should follow institution or facility policies regarding implementation of preprocedural and postprocedural safety and quality checklists.
  - Examples: time-out protocols, and readiness for discharge assessment tools.

PICO Question:
Do children undergoing a procedure in an endoscopy facility which use pre-procedural and post-procedural safety and quality checklists (e.g. time-out checklists, readiness for discharge checklists) have less adverse events than children who undergo procedures in facilities that do not use such checklists?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Facilities adherent to policies regarding implementation of pre-procedural and post-procedural checklists
- **Control/Comparator**: Facilities that do not adhere to policies regarding implementation of pre-procedural and post-procedural checklists (either because their institution does not have such policies or because they do not adhere to them)
- **Outcome**: Adverse event rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: non-endoscopic studies

**Relevant guidelines**:  

**Studies excluded**:  
Summary of the Evidence:
There is no applicable direct or indirect evidence regarding endoscopy checklists. Some of the available endoscopy guidelines do mention use of checklists.\textsuperscript{1,2} There is also an opinion piece written by Matharoo et al\textsuperscript{3} which outlines suggested elements of an endoscopy checklist. Additionally, a study by the same group describes the implementation of a safety checklist in an endoscopy unit over 7 days, with rapid cycle improvement processes used to increase use of checklist and decrease number of checklists left blank.\textsuperscript{4} Compliance (cases with completed checklists) increased from 53% to 66% after the rapid cycle interventions.

Although the data with regard to endoscopy limited, there is data from the surgical domain on the use of checklists:

Bergs 2014\textsuperscript{5}: Systematic review of 723 studies. Meta-analysis was highly suggestive of a reduction in complications and mortality. Potentially included study designs were randomized clinical trials, non-randomized controlled trials, controlled before–after studies, interrupted time series (ITS) and repeated-measures studies. Out of 723, only six studies were included. Meta-analysis demonstrated a significant effect of the checklist on complications and correlated with adherence to aspects of the care embedded into the check list. This only included patients 16 and older and not for endoscopic procedures, so is not direct.

Borchard 2012\textsuperscript{6}: A comprehensive systematic search of the English, French, and German language literature was performed for articles published between 1995 and April 2011. Twenty-two studies were included. This review shows that with the use of the checklist the relative risk for mortality is 0.57 (95% CI: 0.42–0.76) and for any complications 0.63 (95% CI: 0.58–0.67). Compliance with time out was higher at 91% versus the check list. Hospitals need to find implementation strategies that work best for the individual system. This review is indirect but shows added value in both time-out and checklist completion/documentation.
De Vries 2011: Retrospective review of all medical legal claims in the largest Dutch insurer. Use of pre-operative check list (SURPASS) may have prevented 29% of claims. Data is indirect but shows that pre-operative check lists may decrease adverse events and malpractice claims.

De Vries 2012a: Evaluated possible interceptions of adverse events by implementation of a surgical check list in 2 academic hospitals and 4 teaching hospitals in the Netherlands. 40% of the time the check list was able to intercept 1 or more events. This study although indirect offers evidence that surgical check lists are effective in adherence to pre and post op protocols.

De Vries 2012b: Implementation of this comprehensive checklist was associated with a reduction in surgical complications and mortality in academic hospitals. Some hospitals served as controls over the 3 months study period with no change in outcomes. Indirect but suggestive of improved outcomes after implementation of pre-op surgical checklist.

Haynes 2009: Cohort study pre and post introduction of a surgical check list. After check list was introduced, mortality and morbidity rates were significantly decreased.

Lepänluoma 2013: Retrospective chart review of evaluating safety events in relation to questionnaires of operating room staff. Studies showed that when teamwork and communications improved, adverse events declined. This is a non-randomized, uncontrolled, there was a difference in operation types between the groups. This study has a high risk of bias and is indirect.

Lingard 2008: This is a prospective study using pre-intervention/post-intervention design in Canadian academic tertiary care hospital. They found that pre-operative huddle decreased communication failure in operating teams. This is an indirect study due to adult population and does not involve endoscopy.

Van Klei 2012: Retrospective cohort study of non-day case surgery. In hospital 30-day mortality was main outcomes after introduction of the WHO surgical check list in the Netherlands. There was a significant improvement in outcomes after introduction. Study is indirect. Results varied with degree to which the check list was completed.

Zingiryan 2016: There was no significant decrease in any of the nine complications 2 years after SSC implementation. 62% response rate to a survey of medical staff regarding SSC safety check list after implementation was achieved. Survey showed agreement about improved communication, but no improvement in outcomes.

Overall, no relevant endoscopy-related studies were found addressing this PICO questions. However, there were studies from the surgical domain which provide indirect evidence.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>□</td>
<td>High</td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>□</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
**PEnQuIN GRADE reporting template**

<table>
<thead>
<tr>
<th>Indirectness of evidence</th>
<th>Studies from surgical domain, no endoscopy-related studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Serious (-1)</td>
</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td>Imprecision</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Serious (-1)</td>
</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td>Publication Bias</td>
<td></td>
</tr>
<tr>
<td>Not assessed</td>
<td></td>
</tr>
<tr>
<td>Unlikely</td>
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<tr>
<td>Likely (-1)</td>
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<tr>
<td>Very likely (-2)</td>
<td></td>
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<tr>
<td>Large effect</td>
<td></td>
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<tr>
<td>No</td>
<td>Large (+1)</td>
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<tr>
<td></td>
<td>Very large (+2)</td>
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<tr>
<td>Effects of all plausible confounding</td>
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<tr>
<td>No</td>
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<tr>
<td>Yes (+1)</td>
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<tr>
<td>Dose-response gradient</td>
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<tr>
<td>No</td>
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<tr>
<td>Yes (+1)</td>
<td></td>
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</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ![High](#)
- ![Moderate](#)
- ![Low](#)
- ![Very low](#)

**REFERENCES**


STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 8:** Endoscopy facilities where pediatric procedures are performed should implement policies to monitor and ensure the timeliness and completeness of procedure reporting.

**PICO Question:**
Does implementation of a policy to monitor and ensure the timeliness and completeness of procedure reporting improve outcomes regarding time to completion of reporting, report completion rate and patient experience?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Having the procedure performed in a facility that has a policy in place to ensure timeliness and completeness of procedure reporting
- **Control/Comparator:** Having the procedure performed in a facility that does not have a policy in place to ensure timeliness and completeness of procedure reporting
- **Outcome:**
  - Time to completion of reporting
  - Report completion rate
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.

**Relevant guidelines:**

**Articles excluded:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
Clinical Reports, Position Statements, and Quality Standards proposed by GI societies suggest that facilities performing pediatric endoscopy should implement policies to monitor and ensure the timeliness and completeness of procedure reporting. While one study identified the usefulness of
providing patients with reports, it did not address the question of whether hospital policies ensured timeliness and completeness of reporting.

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn about whether policies implemented to monitor and ensure the timeliness and completeness of procedure reporting improve outcomes regarding time to completion of reporting, report completion rate and/or patient experience.

**REFERENCES**

PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 9**: Endoscopy facilities where pediatric procedures are performed should implement policies to monitor and ensure appropriate reprocessing and traceability of all endoscopic equipment.

PICO Question:
Does failure of following standard of care for reprocessing and traceability of endoscopic equipment put patients at risk for disease transmission?

- Population/Patient: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- Intervention: Facilities that follow the standard of care for reprocessing and traceability of endoscopic equipment (e.g. microbiology testing, instrument specific tracing)
- Control/Comparator: Facilities that do not follow the standard of care for reprocessing and traceability of endoscopic equipment
- Outcome:
  - Infections post endoscopy
  - Equipment related adverse events
  - Failed completion of endoscopic procedures from failed equipment

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 3 adult

**Relevant guidelines:**
- Rutala WA, Weber DJ. Guideline for disinfection and sterilization in healthcare facilities
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STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There is no direct evidence addressing this PICO question. (ERCP duodenoscopes and carbapenem-resistant Enterobacteriaceae (CRE) outbreaks, hepatitis C infection, etc.).1–3 The importance of tracing for identification of exposed patients to benefit from early intervention is discussed in many of these. Adult guidelines recommend a systematic approach allowing for traceability of instruments to individual patients; however, this is mainly based on theoretical (and logical) rationale as opposed to evidence.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study type (Starting Quality)</th>
<th>Results</th>
<th>Risk of bias</th>
<th>Inconsistency of Results</th>
<th>Indirectness of Evidence</th>
<th>Imprecision</th>
<th>Large Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronowicki et al.¹</td>
<td>Case report (Low)</td>
<td>HCV was transmitted during colonoscopy</td>
<td>Sample size</td>
<td>Adult study</td>
<td>Number of events</td>
<td></td>
<td>Methodology strong, serious consequence</td>
</tr>
<tr>
<td>Muscarella et al.²</td>
<td>Case report (Low)</td>
<td>CRE transmitted during ERCP</td>
<td>Sample size</td>
<td>Adult study</td>
<td>Number of events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smith et al.³</td>
<td>Case report (Low)</td>
<td>CRE transmitted during ERCP</td>
<td>Sample size</td>
<td>Adult study</td>
<td>Number of events</td>
<td></td>
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</tr>
</tbody>
</table>

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No</td>
<td>Serious (-1) No</td>
<td>Serious (-1) No</td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td>Serious (-1) No</td>
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</tbody>
</table>
## PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>(Unexplained heterogeneity of results)</th>
<th>Very serious (-2)</th>
<th>Moderate</th>
<th>Low</th>
<th>Very Low</th>
</tr>
</thead>
</table>

### Indirectness of evidence
(Research that doesn't specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)

- No
- Serious (-1)
- Very serious (-2)

This evidence is indirect, no pediatric data

### Imprecision
(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)

- No
- Serious (-1)
- Very serious (-2)

Not applicable, 3 case reports

### Publication Bias
(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)

- Not assessed
- Unlikely
- Likely (-1)
- Very likely (-2)

### Large effect

- No
- Large (+1)
- Very large (+2)

### Effects of all plausible confounding

- No
- Yes (+1)

### Dose-response gradient

- No
- Yes (+1)

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**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very Low

---

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s)**
- **Standard 10:** Endoscopy facilities where pediatric procedures are performed should have a process in place for the proper handling, labeling and processing of tissue and other endoscopically obtained specimens.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility that has a process in place for the proper handling, labeling and processing of tissue and other endoscopically obtained specimens associated with improved outcomes?
- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Processes and procedures in place for the proper handling, labeling and processing of biopsies and other endoscopically obtained specimens
- **Control:** No processes and procedures in place for the proper handling, labeling and processing of biopsies and other endoscopically obtained specimens
- **Outcome:** Rate of adequate biopsy handling, labeling and processing

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 1 adult

**Relevant guidelines:**

**Articles excluded:**
- None

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
The only available evidence addressing this topic is a single study in an adult setting. Trongwongsa et al. conducted a large single center interventional study. As a first step, a quality improvement initiative was introduced at the single center pathology laboratory at a university hospital with high throughput endoscopy. Embedding technicians were trained to embed tissue in the perpendicular plane. As a second step, an endoscopy unit quality improvement initiative was introduced: endoscopic nurses were trained to spread the biopsy tissues on mesh with upward mucosal surface before fixing them into formalin. Three sets of 50 consecutive cases of GI
mucosal biopsy were retrieved from before step 1, after step 1, and after step 2. The number of high quality slides, diagnostic discrepancies, and diagnostic confidence of the pathologists were compared across the three sets. The number of high quality slides increased significantly from 23 (46%) before quality improvement to 30 (60%) after step 1 and 37 (74%) after step 2 (p = 0.017). Similarly, diagnostic discrepancy decreased, and diagnostic confidence increased after the quality improvement initiative.

Overall there is limited data exists on this topic, it is of low quality and no pediatric data is currently available.

### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

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<thead>
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<tr>
<td><strong>Outcome</strong></td>
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</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong></td>
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<td>□</td>
<td>High</td>
</tr>
<tr>
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<td>Very serious (-2)</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong></td>
<td>No</td>
<td>□</td>
<td>Moderate</td>
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<tr>
<td><strong>Imprecision</strong></td>
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<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1)</td>
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<tr>
<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Unlikely</td>
<td>□</td>
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<tr>
<td></td>
<td>Likely (-1)</td>
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<td>Very likely (-2)</td>
<td>□</td>
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<tr>
<td><strong>Large effect</strong></td>
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<td>Low</td>
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<td><strong>Dose-response gradient</strong></td>
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<td>Yes (+1)</td>
<td>□</td>
<td></td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- ☐ ☐ ☐ ☐ High
- ☐ ☐ ☐ Moderate
- ☐ ☐ ☐ Low
- ☐ ☐ ☐ ☐ Very low

REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

- **Standard 11**: Endoscopy facilities where pediatric procedures are performed should monitor their rate of mishandled, mislabeled or misprocessed tissue specimens and report the results to the appropriate institutional or facility oversight committee.
  - **Indicator 6**: Rate of mishandled, mislabeled or misprocessed tissue specimens.

**PICO Question:**
Does undergoing pediatric endoscopy in a facility that has a process in place to document, monitor and report results of tissue sample handling lead to improved outcomes?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Having the procedure performed in a facility that has a process in place to document, monitor and report results of tissue sample handling
- **Control**: Having the procedure performed in a facility that does not have a process in place to document, monitor and report results of tissue sample handling
- **Outcome**: Rate of mishandled, mislabeled or misprocessed tissue specimens

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Relevant guidelines:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.

STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn about whether undergoing pediatric endoscopy in a facility that has a process in place to document, monitor and report results of tissue sample handling leads to improved outcomes.
PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 12**: Endoscopy facilities where pediatric procedures are performed should monitor their rate of serious adverse events from pediatric endoscopic procedures and anesthesia using a reliable system and report the results to the appropriate institutional or facility oversight committee.
  - **Indicator 7**: Rate of documented intraprocedural adverse events.
  - **Indicator 8**: Rate of documented immediate postprocedural adverse events.
  - **Indicator 9**: Rate of documented late adverse events.
  - **Indicator 10**: Rate of adverse events.

PICO Question:
Does monitoring of serious adverse effects of children at any time point following endoscopy provide evidence for potential change in practice?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Facilities that audit serious adverse events (bleeding requiring intervention, perforation, hypoxia, cardiac arrest, death, unanticipated hospitalization) related to endoscopic procedures and associated anesthesia/sedation
- **Control/Comparator**: Facilities that do not audit of serious adverse events (bleeding requiring intervention, perforation, hypoxia, cardiac arrest, death, unanticipated hospitalization) related to endoscopic procedures and associated anesthesia/sedation
- **Outcome**: Change in adverse event rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 1 pediatric, 27 adult studies


Ko CW, Riffle S, Michaels L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol* 2010;8:166–73.


Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
The vast majority of studies were retrospective audit reviews and, therefore, are observational and start at low quality. The vast majority had significant indirectness as they were adult studies. There was selection bias in some. The vast majority had significant imprecision due to the rarity of events despite some reports including very large numbers of endoscopies, and presumably numbers that would dwarf the vast majority of pediatric institutions. Most were related to therapeutic endoscopy adding to rarity of events of pediatrics. In summary, essentially all reports started at low quality and save for the single pediatric study fell to a rating of very low quality for the aforementioned reasons. The rates of serious adverse events are very low (perforation: 4/10,000, bleeding: 8/10,000; gleaned from Lin et al\(^3\)), so committees established only for reviewing serious events may not meet regularly owing to the paucity of events.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study type (Starting Quality)</th>
<th>Indicator</th>
<th>Results</th>
<th>Risk of bias</th>
<th>Inconsistency of Results</th>
<th>Indirectness of Evidence</th>
<th>Imprecision</th>
<th>Large Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sawhney et al(^2)</td>
<td>Observational (Low)</td>
<td>9</td>
<td>Resuming anticoagulation following polypectomy and polyp diameter were strongly associated with increased risk of severe delayed postpolypectomy bleeding</td>
<td>Adult study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharma et al.(^3)</td>
<td>Observational (Low)</td>
<td>7, 8</td>
<td>During GI endoscopy with conscious sedation, patient’s age, higher ASA grade, inpatient status, trainee participation, and routine use of oxygen are associated with a higher incidence of Cardiopulmonary unexplained events.</td>
<td>Adult study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seig et al.(^4)</td>
<td>Observational (Low)</td>
<td>10</td>
<td>Most of the adverse events associated with diagnostic endoscopy were attributable to use of medication.</td>
<td>Voluntary reporting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singh et al.(^5)</td>
<td>Observational (Low)</td>
<td>10</td>
<td>Number of procedures correlated with Reporting</td>
<td>Adult study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Reference</td>
<td>Study Type</td>
<td>Study Design</td>
<td>Sample Size</td>
<td>Description</td>
<td>Study Type</td>
<td></td>
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</tr>
<tr>
<td>Warren et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Complications requiring admission. Mean times were different between teaching and non-teaching hospitals</td>
<td>Adult (very old (66-95 yo))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watabe et al.</td>
<td>Observational</td>
<td>Low</td>
<td>9</td>
<td>Adverse events were low. Associated with increased age with specific comorbid conditions with polypectomy</td>
<td>Adult</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wernli et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Polyp size and hypertension were associated with the occurrence of delayed hemorrhage</td>
<td>Adult study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kramer et al.</td>
<td>Observational</td>
<td>Low</td>
<td>7, 8</td>
<td>Anesthesia use varies by region in USA. Overall risk of complications after colonoscopy higher anesthesia services. (Perforation with polypectomy, hemorrhage, abdominal pain, stroke, anesthesia complications)</td>
<td>Adult study, polyps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leffler et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Advanced patient age was seen to be a predictor of development of procedure-related hospital visit, whereas sex and involvement of a fellow in training were not</td>
<td>Adult study, Number of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anderson et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Perforations more likely in scopes that are difficult to traverse the sigmoid colon; difficult examination in females, and difficult examinations performed by trainee physicians</td>
<td>Adult study, Number of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arora et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Increasing age, significant comorbidity, obstruction as an indication for the colonoscopy, and performance of invasive interventions during colonoscopy were significant positive predictors.</td>
<td>Adult Study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buddingh et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Polyp location in the right hemi-colon seems to be an independent and substantial risk factor for delayed post-polypectomy hemorrhage.</td>
<td>Adult study, polyps, Number of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Choo et al.</td>
<td>Observational</td>
<td>Low</td>
<td>10</td>
<td>Right-colon polypectomies had a higher tendency of</td>
<td>Adult study, polyps, Number of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Study Design</td>
<td>Number of Studies</td>
<td>Study Type (Low)</td>
<td>Key Findings</td>
<td></td>
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<td>------------------------------</td>
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<td></td>
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<tr>
<td>Crispin et al.15</td>
<td>Observational</td>
<td>7, 8</td>
<td>Low</td>
<td>Male sex, higher age, non-screening indication, biopsies, polypectomies, and absence of sedation/analgesia were indicative of a higher bleeding risk. Perforations were also related to biopsies and polypectomies. Higher age was the only discernible risk indicator for cardiorespiratory effects.</td>
<td></td>
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</tr>
<tr>
<td>Dafnis et al.16</td>
<td>Observational</td>
<td>7, 8</td>
<td>Low</td>
<td>The most frequent complication was bleeding associated with therapeutic endoscopies not diagnostic, larger polyps, &lt; 100 colonoscopies; perforations: &lt; 100 colonoscopies.</td>
<td></td>
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<tr>
<td>Gatto et al.17</td>
<td>Observational</td>
<td>10</td>
<td>Low</td>
<td>Risk &gt; in colonoscopy than sigmoidoscopy, age, &gt; 2 co-morbidities, diverticulosis and obstruction. Risk declined over 8-year period.</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Gimeno-Garcia et al.18</td>
<td>Observational</td>
<td>10</td>
<td>Low</td>
<td>Multivariate logistic regression analysis: Polyp size &gt; 14 mm, villous architecture, high-grade dysplasia.</td>
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</tr>
<tr>
<td>Heldwein et al.19</td>
<td>Observational</td>
<td>10</td>
<td>Low</td>
<td>Right-sided polyp location was a significant risk factor for major complications.</td>
<td></td>
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</tr>
<tr>
<td>Hui et al.20</td>
<td>Observational</td>
<td>10</td>
<td>Low</td>
<td>The use of antiplatelet agents during polypectomy was not associated with an increase in post-polypectomy bleeding. Warfarin was.</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Imai et al.21</td>
<td>Observational</td>
<td>7, 8</td>
<td>Low</td>
<td>There is a higher risk of colonic perforation during colonoscopy among patients who received hemodialysis.</td>
<td></td>
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</tr>
<tr>
<td>Kim et al.22</td>
<td>Observational</td>
<td>7</td>
<td>Low</td>
<td>9 variables associated with immediate postpolypectomy bleeding but no serious bleeding incidences (age &gt; 65, comorbidities, anticoagulants, polyp size &gt; 1 cm, morphology, bowel prep, current, inadvertent cutting). Experience not associated.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ko et al.23</td>
<td>Observational</td>
<td>10</td>
<td>Low</td>
<td>Perforation, postpolypectomy syndrome, gastrointestinal bleeding, and diverticulitis risk factors include warfarin. Selection bias.</td>
<td></td>
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</tr>
</tbody>
</table>
### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong> (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong> (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use and polypectomy with cautery</th>
<th>Perforations associated with patient age &gt; 80, co-morbidities, polyps &gt; 1cm, and less experienced (&lt; 5 y) endoscopists. Major bleeding associated with patient age &gt; 80 years co-morbidity, polypectomy, splenic injuries, and experience</th>
<th>Adult study</th>
<th>National survey (4,088,799 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levin et al.24</td>
<td>Obs  (O)</td>
<td>10</td>
<td>Adult study</td>
</tr>
<tr>
<td>Levin et al.25</td>
<td>Observational (Low)</td>
<td>10</td>
<td>Adult Study</td>
</tr>
<tr>
<td>Levin et al.26</td>
<td>Observational (Low)</td>
<td>10</td>
<td>Adult study</td>
</tr>
<tr>
<td>Rabeneck et al.27</td>
<td>Observational (Low)</td>
<td>10</td>
<td>Adult study</td>
</tr>
<tr>
<td>Russman et al.28</td>
<td>Observational (Low)</td>
<td>9</td>
<td>Adult Study</td>
</tr>
<tr>
<td>Rutter et al.29</td>
<td>Observational (Low)</td>
<td>10</td>
<td>Adult Study</td>
</tr>
</tbody>
</table>
**Indirectness of evidence**
(Research that doesn't specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)
- No
- Serious (-1)
- Very serious (-2)

**Imprecision**
(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)
- No
- Serious (-1)
- Very serious (-2)

**Publication Bias**
(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)
- Not assessed
- Unlikely
- Likely (-1)
- Very likely (-2)

**Large effect**

<table>
<thead>
<tr>
<th>Large effect</th>
<th>No</th>
<th>Large (+1)</th>
<th>Very large (+2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☒</td>
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</tbody>
</table>

**Effects of all plausible confounding**

<table>
<thead>
<tr>
<th>Effects of all plausible confounding</th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☒</td>
<td></td>
</tr>
</tbody>
</table>

**Dose-response gradient**

<table>
<thead>
<tr>
<th>Dose-response gradient</th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☒</td>
<td></td>
</tr>
</tbody>
</table>

**Overall quality of the evidence (please circle/check-off):**

- **⊕⊕⊕⊕ High**
- **⊕⊕⊕ Moderate**
- **⊕⊕ Low**
- **⊕⊕ Very Low**

**REFERENCES**


**STEP 1: Create a PICO question(s) for your standard/indicator**

**Standard(s)/Indicator(s):**
- **Standard 13:** Endoscopy facilities where pediatric procedures are performed should maintain a comprehensive quality improvement program incorporating formal, standardized review of performance reports at both facility and endoscopist levels.
  - Examples: wait times, adverse event rates, and terminal ileal intubation rates.
  - **Indicator 11:** Participation by an endoscopy facility in a recognized quality assurance program.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility that participates in recognized quality assurance programs to maintain quality, incorporating formal, standardized review of performance reports at both the facility and endoscopist level, associated with improved outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Having the procedure performed in a facility with a comprehensive QI program
- **Control/Comparator:** Having the procedure in facility without a comprehensive QI program
- **Outcome(s):**
  - Adverse event rates
  - Terminal ileal intubation rate
  - Diagnostic yield

**STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.**

**Studies included:** 7 adult

**Relevant Guidelines:**


Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

Seven adult studies\(^1\)\(^–\)\(^7\) were found.

1. Lee 2012\(^1\): An adult large national observational study. 36000 screening colonoscopies were assessed according to a standard range of colonoscopy quality indicators. The conclusion was that regular assessment of endoscopist quality (via standard quality indicators) is necessary even before entering the screening program.

2. Deng 2016\(^2\): An adult prospective single center study comparing quality indicators in a control group of colonoscopies and an interventional group of procedures (they reported and reviewed the colonoscopy reports). On each arm there were approximately 1200 procedures. The quality indicators were much better in the interventional group of colonoscopies.

3. Keswani 2015\(^3\): An adult prospective single center observational study. 20 endoscopists performed 13000 colonoscopies. Following intervention with report card distribution of colonoscopy quality indicators for the first and second time and establishing SOP, ADR improved for 3%.

4. Kaminski 2016\(^4\): An adult, multicenter, two-year randomized control trial in Poland (38 endoscopists, 24582 procedures). Programmed course for ADR was organized for endoscopist screening group leaders or just feedback for the control leaders group. The conclusion was that intervention improved significantly the ADR.

5. Abdul-baki 2015\(^5\): An adult observational study (no control group, observation bias) to assess whether this initiative was associated with an improvement in ADR found that a public reporting initiative on colonoscopy quality was associated with an increase in ADR from 25.1% in the pre-public reporting era to 36.4% (increase of 11.3%, \(p<0.001\)) after public reporting was introduced. Detection of advanced adenomas increased from 10.0% to 12.7% (\(p<0.001\)). The hospital worked with a company to implement the public reporting system, and endoscopist participation was mandated by the insurer.


7. Ball 2004\(^7\): Adult, observational, prospective implementation of a quality improvement program using 2 completed cycles of audit. Changes to practice based on the audit took into account staff opinions regarding time for each colonoscopy (lengthened appointments) and bowel preparation (admitted failed patients for bowel preparation). The initial crude colonoscopy completion rate was 60%, improving to 71% after the first round of audit, and 88% after the second round, which approximates to the agreed audit standard of 90%. The final adjusted completion rate was 94%.
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
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<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong></td>
<td>No</td>
<td>Serious (-1)</td>
<td>⬜</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong></td>
<td>No</td>
<td>Serious (-1)</td>
<td>⬜</td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong></td>
<td>No</td>
<td>Serious (-1)</td>
<td>⬜</td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Imprecision</strong></td>
<td>No</td>
<td>Serious (-1)</td>
<td>⬜</td>
</tr>
<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Publication Bias</strong></td>
<td>Not assessed</td>
<td>Unlikely</td>
<td>⬜</td>
</tr>
<tr>
<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Likely (-1)</td>
<td>Very likely (-2)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
<td>Large (+1)</td>
<td>⬜</td>
</tr>
<tr>
<td></td>
<td>Large (+1)</td>
<td>Very large (+2)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td>No</td>
<td>Yes (+1)</td>
<td>⬜</td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No</td>
<td>Yes (+1)</td>
<td>⬜</td>
</tr>
</tbody>
</table>

**STEP 4:** Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Overall quality of the evidence (please circle/check-off):**

- ++++ High
- +++ Moderate
- +++ Low
- ++ Very Low
REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 14**: Endoscopy facilities where pediatric procedures are performed should have an internal oversight committee/team with representation from pediatric specialists to monitor adherence to best practice guidelines, implement changes and communicate closely with clinical and business operational leadership.
  - **Indicator 11**: Participation by an endoscopy facility in a recognized quality assurance program.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility where there is an oversight committee/team with representation from pediatric specialists to monitor adherence to best practice guidelines, implement changes and communicate closely with clinical and business operational leadership associated with improved outcomes?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Having the procedure performed in a facility with a quality improvement oversight committee/team with representation from pediatric specialists
- **Control/Comparator**: Having the procedure in facility without a quality improvement oversight committee/team with representation from pediatric specialists
- **Outcome(s)**:
  - Adverse event rates
  - Terminal ileal intubation rate
  - Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 2 adult

**Relevant Guidelines**:

**Articles excluded**: 


PEnQuIN GRADE reporting template


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
Two adult studies\(^1\)\(^2\) were found.

1. Kaminski 2016\(^1\): an adult, multicenter, two-year RCT in Poland (38 endoscopists, 24582 procedures). An endoscopy leadership training course was organized for endoscopist screening group leaders or just feedback for the control leaders’ group. The conclusion was that the intervention significantly improved the ADR.

2. Ball 2004\(^2\): adult, observational, prospective implementation of a quality improvement program using 2 completed cycles of audit. Changes to practice based on the audit took into account staff opinions regarding time for each colonoscopy (lengthened appointments) and bowel preparation (admitted failed patients for bowel preparation). The initial crude colonoscopy completion rate was 60%, improving to 71% after the first round of audit, and 88% after the second round, which approximates to the agreed audit standard of 90%. The final adjusted completion rate was 94%.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
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<td>High</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
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<tr>
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<td>Step</td>
<td>Description</td>
<td>Values</td>
<td>GRADE Quality</td>
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<tr>
<td>4</td>
<td>Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)</td>
<td>- Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
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<tr>
<td></td>
<td></td>
<td>- Large effect</td>
<td>-</td>
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<td></td>
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<td>- Effects of all plausible confounding</td>
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<td></td>
<td>- Dose-response gradient</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Overall quality of the evidence (please circle/check-off):</td>
<td>High, Moderate, Low, Very low</td>
<td></td>
</tr>
</tbody>
</table>
STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s)**
- **Standard 15:** Endoscopy facilities where pediatric procedures are performed should systematically and regularly review current indicators of quality and safety of all pediatric endoscopic procedures and implement appropriate changes to ensure compliance.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility that systematically and regularly reviews current indicators of quality and safety of all pediatric endoscopic procedures and implements appropriate changes to ensure compliance, associated with improved outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Having the procedure performed in a facility that systematically and regularly reviews current indicators of quality and safety of all pediatric endoscopic procedures and implements changes
- **Control/Comparator:** Having the procedure in facility that does not systematically and regularly review current indicators of quality and safety of all pediatric endoscopic procedures and implements changes
- **Outcome(s):**
  - Adverse event rates
  - Terminal ileal intubation rate
  - Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Relevant guidelines:**

**Articles excluded:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence:**
There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.
Conclusion:
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn about whether undergoing pediatric endoscopy in a facility that systematically and regularly reviews current indicators of quality and safety of all pediatric endoscopic procedures and implements appropriate changes to ensure compliance is associated with improved outcomes.
STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 16:** Endoscopy facilities where pediatric procedures are performed should ensure that the services they provide are patient- and family-centered.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility with patient and family centered services and processes associated with improved outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Patient and family centered endoscopy-related services/processes
- **Control/Comparator:** Endoscopy-related services/processes offered are not patient and family centered
- **Outcome:** Patient and/or caregiver experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 4 adult

**Relevant Guidelines:**

**Articles excluded:**

**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
There is no evidence specifically evaluating the effect of pediatric centric endoscopy areas and how this relates to outcomes or patient satisfaction. There are adult studies which indirectly address this PICO question. Overall, the pleasant environment, staff attitude, comfort, clear communication with the endoscopist, pan and wait time were some of the recurring factors influencing improved patient satisfaction in adults undergoing endoscopy. Overall, the evidence is indirect and of low quality due to inconsistency of results and, in some cases, attrition bias.

1. Sewitch 2011: Systematic review which addresses factors that improved patient satisfaction in adults undergoing endoscopic procedures. One single blinded controlled trial was included in which the investigators collected surveys preprocedure, post procedure and 24 hours after the procedure. The most important factor in this study was the wait time to beginning of the procedure. Three studies were prospective cohorts and 4 were cross sectional. Studies varied on the timing of the evaluation and the majority did not report age of the patients. Cleanliness, pain, pre-test anxiety, younger age, comfort and the physical environment were found to influence patient satisfaction. Appropriately trained staff and wait times were also found to be important. Positive effect of discussion of the procedure and results with the endoscopist and wait times was found to be significant in 5 out of 8 studies. Although this provides indirect evidence, we may infer that the nature of the staff and facility will matter to families of pediatric patients as well, especially taking into consideration longer waiting time for the family since they are not going into the procedures.

2. Sint Nicolaas 2012: In this study, the Global Rating Scale was used to evaluate adult patient satisfaction with endoscopy from making the appointment to discharge. Six teaching and 6 non-teaching hospitals in The Netherlands participated. Post procedure completion rate was 80%, which was done at home within 3 days. Relevant factors associated with increased satisfaction were waiting time, the personal manner of the endoscopist and the possibility of getting early results from staff, while “rushed staff” attitude made it less likely for
patient to return for another procedure. This study is indirect, however manner of the staff, wait time and discussion of the results with the endoscopist may be important factors for patient satisfaction for parents and children as well.

3. Ko 20093: This is a prospective single center cohort study evaluating patients with pre and post procedure satisfaction of 261 adult patients who have undergone EGD, Colonoscopy or both. Patients filled out a survey pre and post procedure during the day of the test and another mailed questionnaire at least one week later. Factors influencing patient satisfaction included: doctor’s personal manner (odds ratio [OR] 3.00 [95% CI, 1.80-5.03]), doctor’s technical skills (OR 2.65 [95% CI,1.55-4.51]), nurse’s personal manner (OR 2.84 [95% CI, 1.74-4.63]), physical environment (OR 1.75 [95% CI,1.16-2.64]), and more time with doctor discussing the procedure (OR 1.66 [95% CI, 1.02-2.69]). The authors had a 54% delayed response rate and noted a decrease in satisfaction at the follow up survey, which may be due to some residual sedation or recall bias. This is not an issue in pediatric care since parents generally fill out survey data.

4. Yanai 20074: This study sought to identify which factors should be measured in evaluating patient satisfaction from the perspectives of endoscopists, support staff and adult patients, and to make comparisons across groups. The importance of sixteen factors were rated by 81 patients, 71 gastroenterologists and 36 support staff (nurses and receptionists). Factors evaluated included: waiting time for appointment, the explanation received at various stages before and after the procedure, the reception process, the importance of premedication against pain and discomfort, privacy and satisfaction related to findings at the procedure. From the patient’s perspective, the personal manner of the medical staff and explanations of the procedure before and after were generally rated of the highest importance. Again, this study is indirect due to adult population, but we can infer that parents may feel similarly about procedures their children undergo.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td></td>
<td>⊕⊕⊕⊕ High</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
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<td>□</td>
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<tr>
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</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
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<td></td>
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</tr>
<tr>
<td></td>
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<td></td>
<td>Very serious (-2)</td>
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<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td></td>
<td>⊕⊕⊕ Low</td>
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<tr>
<td></td>
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<td>Very serious (-2)</td>
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<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
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<tr>
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### PEnQuIN GRADE reporting template

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<thead>
<tr>
<th>beneficial or harmful effect due to the selective publication of studies)</th>
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<td>Effects of all plausible confounding</td>
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<td>Dose-response gradient</td>
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<td>Yes (+1)</td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<th>Moderate</th>
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<th>Very low</th>
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<tbody>
<tr>
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</tbody>
</table>

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):

- **Standard 17**: Patients and/or caregivers should receive appropriate information about the endoscopic procedure before the procedure date.
  - **Indicator 12**: Rate of patients/caregivers who receive procedure-related instructions prior to the date of endoscopy.

**PICO Question:**
Does receipt of appropriate information about the endoscopic procedure before the procedure date improve patient and/or caregiver experience and understanding of the procedure?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Patients and/or caregivers receive appropriate information about the endoscopic procedure before the procedure date
- **Control/Comparator**: Patients and/or caregivers do not receive appropriate information about the endoscopic procedure before the procedure date
- **Outcome**:  
  - Patient and/or caregiver experience  
  - Patient and/or caregiver understanding (indications, the procedure, risks, etc.)  
  - Patient and/or caregiver anxiety

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 3 pediatric, 10 adult

**Pediatric studies**:


**Adult studies**:

PEnQuIN GRADE reporting template


**Articles excluded:**

**Adult studies:**
- Kielty LA. An investigation into the information received by patients undergoing a gastroscopy in a large teaching hospital in Ireland. *Gastroenterol Nurs.* 2008;31:212–22.

**Pediatric studies:**
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:

Pediatric studies:

- Claar 2002\textsuperscript{1}: This study assessed knowledge of EGD of children. Correlational analyses indicated that children with less knowledge of EGD exhibited significantly more procedural distress ($r = -0.20$, $P < 0.05$) and reported a less favorable attitude toward future EGDs ($r = -0.21$, $P < 0.05$). Surprisingly, children with less knowledge did not experience greater anticipatory anxiety ($r = -0.09$, not significant). However, children with higher levels of anticipatory anxiety exhibited greater distress ($r = 0.29$, $P < 0.001$). Children who experienced more distress during EGD reported the procedure to be more painful ($r = 0.23$, $P < 0.05$), more aversive ($r = 0.42$, $P < 0.001$), and that they would be more anxious and upset if required to undergo future EGDs ($r = 0.38$, $P < 0.001$).

- Jacob 2015\textsuperscript{2}: Themes that emerged from this qualitative study indicated that patients are not always given information about the procedure beforehand (via an endoscopy information leaflet) and that improvement is required.

- Mahajan 1998\textsuperscript{3}: An intervention consisting of procedure explanation using dolls or photographic material reduces anxiety compared to controls receiving routine pre-endoscopy preparation ($P < 0.0001$).

Adult studies:

- Aabakken 1997\textsuperscript{4}: Qualitative feedback indicated that a written brochure was regarded as providing important information in 79% of 136 patients.

- Levy 1989\textsuperscript{5}: 243 patients were assigned to either receive preprocedure education from either 1) the treating physician, 2) the endoscopist, 3) picture album illustrating procedure steps, 4) information video or 5) patients who have already undergone a procedure. No difference in patient anxiety was observed between the groups.

- Bytzer 2006\textsuperscript{6}: 162 patients were randomly assigned preparation with or without an information video of colonoscopy and cleansing. No difference in situational anxiety was observed between the two groups.

- De Jonge 2010\textsuperscript{7}: 1187 patients were interviewed and asked to complete pre and post procedure questionnaires. 21.8% (n=116) of patients who were not seen by the specialist before the procedure did not know the indication for their colonoscopy, compare to only 9.8% (n=61) of patients who did see the specialist ($P < 0.01$). Their recall of complications was also lower (27% vs 43%). 32.6% (n=326) of patients who received an information sheet were not aware of complications, compared to 53.8% (n=63) of those who did not receive an information sheet ($P < 0.01$).

- Felly 2008\textsuperscript{8}: This randomized controlled trial combined oral and written vs oral only information provided before endoscopy where 577 out 778 (80%) returned their study questionnaires. Quality of information was rated better when written info was given. No change in patient anxiety was observed between the two groups. Patients in the written and oral information group scored significantly higher ($P = <0.001$) regarding knowledge of complications and how to prepare for the procedure.

- Luck 1999\textsuperscript{9}: 30 patients were randomized to either a preprocedure video (n=16) or no video (n=14). A greater reduction in anxiety and better knowledge of purpose, detail and
complications of colonoscopy were seen in the group provided the video compared to controls.

- Abuksis 2001\textsuperscript{10}: Prospective controlled trial in which 142 adults were randomized to an education program group (n=91), no information (n=38), or telephone instructions (n=13) regarding an upcoming endoscopy. Colonoscopy completion rates were highest in those randomized to the education program, and satisfaction with the program was high. Those who had preliminary explanation about the procedure by a physician (as part of usual care prior to randomization) demonstrated reduced anxiety. Those with poor preparation preferred the accompaniment of another person to the procedure.

- Shaw 2001\textsuperscript{11}: 86 patients referred for colonoscopy were randomized to receive either standard instructions or standard and computer-assisted instructions. Computer-assisted instruction did not affect anxiety, but it did improve comprehension and overall satisfaction (P < 0.0001).

- Toomey 2016\textsuperscript{12}: Prospective survey conducted before (n=71) and after (n=60) process improvements were put in place. The introduction of leaflets regarding procedures as well as feedback to staff from the pre-survey appeared to improve patients’ understanding of the procedure and reduced anxiety, with 85% recalling reading the given materials, feeling better informed on preparation, reporting greater understanding of the level of sedation and discomfort, and experiencing better comfort during the procedure. Study staff were not blinded to intervention in this study.

- Van Zuuren 2006\textsuperscript{13}: A randomized controlled study that compared receipt of a brochure (n=47) with no brochure (n=48) among patients undergoing gastroscopy. Those that received the brochure reported less anxiety before the procedure than those that did not, but no group differences in anxiety during the procedure (but reported afterwards) were found.

Overall, provision of information has shown to improve knowledge of the procedure and satisfaction with procedure, as well as reduce pre-procedure anxiety and pre-procedural distress. The studies reviewed show mixed results with regard to anxiety reduction when it is measured post-procedure. With regard to the pediatric evidence, a complete understanding of the procedure is fundamental to obtain better results in terms of reduction of distress and anxiety for children and their parents. This has been demonstrated in two pediatric studies.\textsuperscript{1,2} Additionally, in one randomized trial\textsuperscript{3} those children who completely understood the procedure had a better approach to the exam and lesser need of anesthesia. Moreover, satisfaction with the exam was significantly higher as was willingness to undergo the procedure again in the future. For this reason, it is important to ensure both patients and their caregivers receive appropriate information in preparation for an endoscopic procedure. Both adult and pediatric experience suggest that different modalities (cartoon, videos, and brochures) can be useful. Written information seems to result in better outcomes as compared with information provided orally.\textsuperscript{8}

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
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</thead>
<tbody>
<tr>
<td>Outcome:</td>
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<tr>
<td>Risk of bias (study)</td>
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</table>
**PEnQuIN GRADE reporting template**

<table>
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<th>Moderate</th>
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<th>Very Low</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Very serious (-2)</td>
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</tr>
<tr>
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</tr>
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<tr>
<td>Large effect</td>
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<td>□</td>
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<tr>
<td>Effects of all plausible confounding</td>
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<tr>
<td>Dose-response gradient</td>
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<td>Yes (+1)</td>
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</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<tbody>
<tr>
<td>✪✪✪✪ High</td>
</tr>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

**REFERENCES**


STEP 1: Create a PICO question(s) for your standard/indicator

Standard 44
- **Standard 18**: Endoscopy facilities where pediatric procedures are performed should have a clear and well-defined process for communicating instructions that ensure effective, age-appropriate and patient- and family-centered bowel preparation.
  - **Indicator 13**: Rate with which patients receive adequate instructions on bowel preparation.

**PICO Question:**
Do educational interventions targeting bowel preparation instructions in pediatric patients undergoing ileocolonoscopy improve the quality of bowel preparation, procedure completion rates, and/or procedure, cecal and/or ileal intubation time?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency ileocolonoscopy
- **Intervention**: Provision of adequate bowel preparation instructions
- **Control/Comparator**: No instructions or alternate form of bowel preparation instructions provided
- **Outcome**:
  - Procedure completion rate
  - Quality of bowel preparation
  - Procedure, cecal and/or terminal ileal intubation time

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 2 pediatric, 9 adult

**Pediatric**

**Adult**


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome).**

**Summary of the Evidence:**

**Outcome 1: Quality of Bowel preparation**

There was one systematic review (adult studies), one pediatric study, one pediatric abstract and 7 adult studies that addressed this question.

The one systematic review by Kurlander et al examined 7 studies and 2660 adult patients, and found that six of the studies showed a positive effect of the intervention on the quality of bowel preparation. There was significant statistical and clinical heterogeneity (e.g., diverse patient samples and intervention formats) and three different bowel preparation scales were used.

There were two pediatric studies, one in abstract form. Maxwell et al conducted a prospective randomized single blinded pilot looking at the efficacy of an informational cartoon in patients aged 7-14 years. Patients were randomized to a control group receiving standard bowel preparation instructions or an intervention group receiving an additional educational cartoon. Data was available for 23 patients. A blinded endoscopist completed the Ottawa scale to assess quality of bowel prep. Mean Ottawa score in the intervention group compared with controls was not significantly different (mean scores 3.73 and 3.33, respectively; \( P = 0.384 \)). Objective quality of bowel preparation was good in both groups and it may have been difficult to improve on it in a statistically significant way with the small study numbers. Brief et al presented an abstract on 46 patients aged 5-18 years who were randomized to receive either written or software prep instructions. Prep quality was measured with the Boston Bowel Preparation Scale (BBPS). App users had superior mean Boston scores of 9.80 versus controls, who had scores of 7.96 (\( P = 0.014 \)).

With regard to the adult studies, Argyropoulous et al was a single center observational study looking at the effect of several quality improvement interventions including a nurse educational session/patient visit and written educational material. The Modified Aronchick scale was used. 724 patients were in the baseline group and 641 in the intervention group. No statistically significant difference in the quality of bowel prep was found for the written educational materials or nurse educational visit interventions. Cho et al conducted a prospective, endoscopist-blinded, matched, controlled single center study looking at the effect of a Smart phone application for patient education. It used the BBPS scale for assessing quality of bowel preparation. 142 patients participated: 71 received the smart phone app and 71 received written and verbal instructions.
Quality of bowel cleansing was significantly higher in the smartphone app group than in the control group (7.70±1.1 vs. 7.24±0.8, respectively, p=0.007 by t-test). Ergen et al. conducted a single center randomized single-blind controlled trial looking at the use of an educational booklet in hospitalized patients. 85 patients were included in study. The BBPS was used to assess bowel preparation. The authors found that using an educational booklet on colonoscopy preparation increases the odds of a quality bowel preparation more than 2-fold. Kang et al. carried out a prospective, colonoscopist-blinded, randomized controlled study in 3 centers including 770 patients. The study compared standard education with interactive information vs. standard education alone (verbal and booklet). Patients were randomly assigned to by computer-generated random numbers and the Ottawa score was to assess the quality of bowel prep. A higher proportion of patients in the group that received social media instruction had adequate bowel preparation (Ottawa score <6) as compared to the control group (82.2% vs 69.5%, P < 0.001). Pillai et al. conducted a single blinded randomized controlled prospective study on patients undergoing a first time screening colonoscopy. All participants received standard instructions (verbal and written). They were randomized to watch an instructional colonoscopy video (n = 56) or a video discussing gastroesophageal reflux disease (GERD) (n = 48), and the outcome of interest was blinded endoscopist-graded patient preparations using the Ottawa scale. The colonoscopy video group had significantly better Ottawa bowel preparation scores (4.77 vs. 6.85; P = 0.01) than the GERD video group. The colonoscopy video group also had less inadequate repeat bowel preparations versus the GERD video group (9% vs.23%; P < 0.01). Walter et al. conducted a prospective observational single-center feasibility study looking at automated text messaging (short message service, SMS) to supported colonoscopy preparation starting 4 days before colonoscopy appointment. All patients received a verbal explanation and leaflet. 20 patients participated. The BBPS was used for assessing bowel prep quality. Mean (standard error of the mean, SEM) total BBPS score was slightly higher in the SMS group than in the control group (7.3±0.3 vs 6.4±0.2), with similar patterns for each colonic region (left, transverse, and right colon). Finally, Walter et al. conducted a prospective feasibility study including 25 patients and 25 controls which examined the use of a smartphone app which guides the patient starting 4 days before colonoscopy through the whole colonoscopy preparation procedure, in addition to a usual information leaflet. BBPS was significantly higher in the smartphone app-supported group (mean=8.1, SD=0.3), compared to the control group (mean=7.1, SD=0.4; P = 0.02).

Compared to usual care, different patient education interventions appear efficacious in improving the quality of bowel preparation. But, the overall the quality of evidence is judged low in view of significant clinical heterogeneity, different educational interventions and formats, different bowel preparation scales and because the preponderance of evidence is from an adult context. There was a single pediatric study with very small numbers and baseline good quality bowel preparation which may have affected results.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk of bias (study limitations)</strong> (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Some bias in the randomised studies</td>
<td>⬤⬤⬤⬤ High</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong> (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Different interventions in diverse patient types</td>
<td>⬤⬤⬤ Moderate</td>
</tr>
</tbody>
</table>
**Outcome 2: Procedure Completion**

There are two relevant adult studies. Kang et al\(^7\) conducted a prospective, colonoscopist-blinded, randomized controlled study in 3 centers including 770 patients. Standard education with interactive information was compared with standard education (verbal and booklet). Patients were randomly assigned to a social media group or control group by computer-generated random numbers. A higher proportion of patients receiving social media instruction had cecal intubation (97.2% vs 93.2% in controls, \(P = 0.014\)). Abuksis et al\(^11\) conducted a prospective study looking at targeted educational intervention with a nurse. Patients were not truly randomized, as they were assigned to groups based on nurse availability to deliver education on the day of their referral. 142 patients were included, 91 received the individual instruction with a nurse and 51 did not. A higher proportion of complete colonoscopy examinations in those that received the educational intervention was observed (\(P = 0.0009\)).

Compared to usual care, additional interventions, such as use of social media, had a positive impact on procedure completion. Overall quality of evidence is judged as low due to indirectness and risk of bias with regard to the Abuksis et al\(^{11}\) study.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No Serious (-1)</td>
<td>Risk of bias in the Abuksis et al(^{11}) study (not truly randomized)</td>
<td>☑️ High</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Inconsistency of results</th>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td>Imprecision</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td>Publication Bias</td>
<td>Not assessed</td>
<td>Unlikely</td>
<td>Likely (-1)</td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>Large (+1)</td>
<td>Very large (+2)</td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Adult studies only</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Outcome 3: Procedure, Cecal and/or Terminal Ileal Intubation Time**

There is one relevant adult study. Cho et al\(^5\) conducted a prospective, endoscopist-blinded, matched, controlled single center study looking at the effect of a smartphone application for patient education in adult patients. 142 patients participated: 71 received the smartphone app and 71 received written and verbal instructions. There were no significant differences in cecal intubation times between the two groups.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
</tr>
</tbody>
</table>

- 🟩 High
- 🟩🟩 Moderate
- 🟩🟩🟩 Low
- 🟩🟩🟩🟩 Very Low

- Adult studies only
**PEnQuIN GRADE reporting template**

<table>
<thead>
<tr>
<th>outcomes of interest, for example, adult literature</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Imprecision</strong> (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
<td>☑</td>
</tr>
<tr>
<td><strong>Publication Bias</strong> (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Unlikely</td>
<td>Likely (-1)</td>
<td>Very likely (-2)</td>
</tr>
<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
<td>Large (+1)</td>
<td>Very large (+2)</td>
<td>☑</td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td>☑</td>
<td></td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ☑ High
- ☑ Moderate
- ☑ Low
- ☑ Very Low

**REFERENCES**


Standard 19: Endoscopy facilities where pediatric procedures are performed should have pediatric-specific, patient- and family-centered processes for preoperative and recovery phases of care.

- Examples: availability of child life experts, dedicated place for caregivers to wait during procedure, and parental presence at induction.

Overall quality of the evidence (please circle/check-off):

<table>
<thead>
<tr>
<th>⊕⊕⊕⊕</th>
<th>⊕⊕⊕</th>
<th>⊕⊕⊕</th>
<th>⊕⊕⊕⊕ Very low</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Moderate</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

- This standard relates to another quality of patient and caregiver experience-related standard. Please refer to:
  - Standard 16: Endoscopy facilities where pediatric procedures are performed should ensure that the services they provide are patient- and family-centered.
STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 20**: Endoscopy facilities where pediatric procedures are performed should ensure availability of pediatric-specific monitoring and resuscitation equipment.
  - Examples: capnography, endotracheal tubes, masks, and blood pressure cuffs.

PICO Question:
Does undergoing pediatric endoscopy in a facility that has pediatric-specific monitoring and resuscitation equipment, including capnography for non-ventilated patients, lead to improved outcomes?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Having the procedure performed in a facility that has pediatric-specific patient monitoring and resuscitation equipment
- **Control/Comparator**: Having the procedure in a facility that does not have pediatric-specific patient monitoring and resuscitation equipment
- **Outcome(s)**: Adverse event rate (hypoxemia, cardiac arrhythmias, death)

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 3 pediatric, 1 pediatric and adult, 3 adult

  - Pediatrics, prospective, observational study of 34 children (22 without comorbidity; 12 with neuro, cardiac or pulmonary disorders) undergoing “conscious sedation” with benzo/opioids without oxygen supplementation with open-label continuous monitoring of oxygen saturation and ECG (which was not standard at the time). 68% of children had >1 episode of oxygen desaturation <90% - with many but not all episodes happening during esophageal intubation. 82% of “normal patients” had cardiac arrhythmias in conjunction with hypoxemia. All of the cardiac patients had cardiac arrhythmias both with and without sedation.
  - Pediatric, Open label trial of monitoring using pulse oximetry and ECG, 7/60 procedures (n=57 patients) included oxygen desaturation <90%, improved with oxygen supplementation. Conclusion: you need to monitor children undergoing sedated endoscopy
  - Pediatric, RCT, standard monitoring (continuous O2, RR, HR, ECG, BP, and visual assessment) vs. standard monitoring plus capnography. 163 patients, block randomization, double-blinded, independent observers. Standard plus capnography had less O2 desaturation <95% x 5 secs vs. standard monitoring, p<0.02.
  o Pediatric AND adult; systematic review and random effects meta-analysis of capnography trials for sedation (mostly colonoscopy), 13 trials included, found addition of capnography to visual assessment and pulse oximetry was associated with a significant reduction in mild (RR 0.77 (95% CI .67-.89) and severe (.59 (.43-.81)) O2 desaturation during procedures (mostly GI procedures), as well as in use of assisted ventilation.

  o Adult, systematic review of capnography RCTs, included 6 trials (excluded RCTs that used independent observers), 2524 participants total; found capnography reduced hypoxemia, but not clear that it affected other outcomes.

  o Adults; prospective RCT; 533 patients; hypoxemia (<90% O2 sat) significantly lower in patients receiving capnography and standard versus standard only (18% vs. 32%, p<.00009)

• Jopling MW, Qiu J. Capnography sensor use is associated with reduction of adverse outcomes during gastrointestinal endoscopic procedures with sedation administration. *BMC Anesthesiol* 2017;17:157.
  o Adult, retrospective HUGE database study (Premier Database analysis), n=258, 262 patients undergoing GI procedures. Capnography was associated with 47% estimated reduction in odds of death in inpatients (10% reduction NS in outpatients); 61% reduction in odds of need for reversal prior to discharge in outpatients (OR .39 (.29, .52, p<.00001). Use of capnography recommended.

**Relevant guidelines:**


**Articles excluded:**


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

The evidence for this standard is surprisingly strong.

There is direct pediatric evidence that electronically monitoring both healthy and medically unstable infants and children undergoing sedated gastrointestinal endoscopy *in general* (i.e., with continuous pulse oximetry and ECG) leads to detection of dangerous vital signs in children, and improves their safety. 1,2 There is also a truly rigorous randomized controlled trial showing that *adding capnography* into the electronic monitoring of infants and children undergoing sedated endoscopy decreases apnea and disordered respiration, as well as incidence of hypoxemia. 3

There are a number of RCTs that show that *adding capnography* into the electronic monitoring of adults undergoing routine and advanced endoscopic procedures (i.e., screening colonoscopy vs. ERCP) reduces apnea, disordered respiration, hypoxemia and arrhythmias. 4,5
There are also several systematic evidence reviews and meta-analyses showing that adding capnography into the electronic monitoring of sedation for endoscopy (with at least one containing evidence in pediatrics)\(^6\) reduces not only moderate and severe hypoxemia, but also other morbidity (cardiovascular events) and mortality (death).\(^6,7\)

The evidence really speaks to electronic monitoring in general as being important for detecting physiologic changes in patients undergoing sedation for GI procedures, and for allowing interventions to prevent adverse events. The evidence also suggests monitoring ventilation in addition to oxygenation is superior to monitoring oxygenation alone.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Strong RCTs, well set up (power calculations, etc.); consistent results in meta-analyses and systematic reviews.</td>
<td></td>
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<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
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<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Different definitions of hypoxemia.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>Issue here is some of the studies looked at all sedated procedures, some look at GI endoscopic procedures only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>There are some highly powered studies for death; the RCTs themselves (for practical reasons) look at less severe AEs (hypoxemia, need for drug reversal) as proxies for the severe events (which are low in number – but show up in the huge databases)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unlikely</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Likely (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very likely (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>The data very strong</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Large (+1)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Very large (+2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- High
- Moderate
- Low
- Very low

REFERENCES

**STEP 1: Create a PICO question(s) for your standard/indicator**

**Standard(s)/Indicator(s):**
- **Standard 21:** Endoscopy facilities where pediatric procedures are performed should ensure availability of endoscopic equipment that is age/size/weight appropriate.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility where there is availability of endoscopic equipment that is age/size/weight appropriate associated with improved outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Problem:** Availability of endoscopic equipment that is age/size/weight appropriate
- **Intervention:** No availability of endoscopic equipment that is age/size/weight appropriate
- **Outcome:**
  - Adverse event rates
  - Terminal ileal intubation rate (procedure completion)
  - Diagnostic yield
  - Procedure efficiency

**STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.**

**Studies included:**

**Relevant guidelines:**

**Articles excluded:**
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
No pediatric studies or systematic reviews address this PICO question. Three adult1-3 studies looked at the use of ultrathin colonoscopes.

Adler et al1 carried out a prospective observational study of 12,134 consecutive screening colonoscopies and found that endoscope age/generation (older versus newer) significantly affected adenoma detection rates (P = 0.001). Ogawa et al2 conducted a prospective study which found that ultrathin colonoscopes are better tolerated in patients with ulcerative colitis. Finally, Sato et al3 conducted a randomized, prospective study of 270 patients undergoing colonoscopy (134 ultrathin, 136 pediatric colonoscope). Compared with a pediatric colonoscope, the medians of maximum pain and overall pain were significantly lower in the ultrathin colonoscope group as compared to the pediatric colonoscope group (23 vs. 38, P < 0.001; 12 vs. 22, P = 0.0003, respectively) during colonoscopy. There was no difference in adenoma detection rate.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Comparison groups not standardized</td>
<td>⊕⊕⊕⊕ High</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1)</td>
<td></td>
<td>⊕⊕ Moderate</td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td></td>
<td>⊕⊕ Low</td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td>Serious (-1)</td>
<td></td>
<td>⊕⊕⊕ Very Low</td>
</tr>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td></td>
<td>⊕⊕ High</td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>Serious (-1)</td>
<td>No pediatric data, no direct comparisons of pediatric and adult endoscopes.</td>
<td>⊕⊕ Moderate</td>
</tr>
<tr>
<td>Imprecision</td>
<td>No</td>
<td></td>
<td>⊕⊕ Low</td>
</tr>
<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1)</td>
<td></td>
<td>⊕⊕ Moderate</td>
</tr>
<tr>
<td>Publication Bias</td>
<td>Not assessed</td>
<td></td>
<td>⊕⊕⊕ Very Low</td>
</tr>
<tr>
<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Unlikely</td>
<td></td>
<td>⊕⊕ Low</td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td></td>
<td>⊕⊕ Moderate</td>
</tr>
<tr>
<td></td>
<td>Large (+1)</td>
<td></td>
<td>⊕⊕ High</td>
</tr>
</tbody>
</table>
PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Effects of all plausible confounding</th>
<th>No</th>
<th>☒</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td>☒</td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ☒ ☒ ☒ ☐ High
- ☒ ☒ ☒ Moderate
- ☒ ☒ ☐ Low
- ☐ ☐ ☐ Very low

**REFERENCES**

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STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 22**: Pediatric patients are discharged postprocedure according to predetermined standard discharge criteria, with clear documentation of readiness for discharge.
  - **Indicator 14**: Rate of discharge from an endoscopy facility in accordance with predetermined standard discharge criteria.

PICO Question:
Do pediatric patients being discharged after their endoscopic procedure according to predetermined criteria, with clear documentation using a standard assessment tool, have fewer late adverse events?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Use of predetermined standard discharge criteria and/or discharge assessment tool
- **Control/Comparator**: No predetermined standard discharge criteria and/or discharge assessment tool
- **Outcome**: Late adverse event rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studies included:
- None

Relevant guidelines:

Articles excluded:

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn as to whether pediatric patients being discharged after their endoscopic procedure according to predetermined criteria, with clear documentation using a standard assessment tool, have fewer late adverse events.
STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 23**: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to a policy to ensure pediatric patients and/or caregivers are notified of pathology findings in a timely manner and receive appropriate follow-up instructions.

PICO Question:
Does provision of pathology and follow-up plans improve patient/family experience and understanding of results and the follow-up plan?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Providing information to patients on pathology results and follow-up instructions
- **Control/Comparator**: No information given or delay in information provision
- **Outcome**:
  - Patient/family experience
  - Improved understanding of results and follow-up plans

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 1 pediatric, 2 adult

  - A pediatric, retrospective questionnaire study involving a phone call by one investigator 2-3 weeks after a procedure. Questions answered based on recall. It was clear that prompt communication and explanation was a good thing judging by the qualitative information reported and some of the patient replies which were also reported verbatim. Of the information in the study, only 19 patients had been seen in outpatient department or phoned with results by the time of the phone call. The outcome of the other 28 patients was not reported and there was no indication as to the average reporting time of pathology in their hospital. Eighteen of 19 caregivers remembered being told the pathology and follow-up. There is very serious risk of bias despite structured phone questionnaire, especially with regard to selection of who was called, family recall of what was said (subjective recall), patient procedure selection (some upper, some colonoscopy, some upper/colonoscopies). The authors concluded that effective pre- and post-procedure information is important, especially post-procedure information regarding the results and management plan.

  - Adult, prospective, randomized, single-center, investigator-blinded study with 115 patients randomized. Only 83 completed the study protocol. Participants were randomized to receive either discharge instructions only or discharge instructions and a copy of the endoscopy report at the time of discharge from the endoscopy suite. Receiving the report reduced post-procedure anxiety ($P = 0.001$) and increased recall of findings and recommendations. After controlling for the type of procedure, age, sex, and
race, the intervention group was found to have higher satisfaction scores than the standard group by an average of 3 points, but this was not statistically significant ($P = 0.100$). Older patients were more likely to receive the report ($P = 0.037$) and older patients had significantly lower satisfaction scores by 6 points ($P = 0.004$).

  
  An adult, prospective audit of 1187 patient’s experience with colonoscopy. 1187 patients completed the pre-questionnaire and 851 (71.9%) completed the post-questionnaire. 54% were seen in the outpatient department before the procedure. Participants reported that the indication was explained in 85% of cases, 65% said they received information on risks, 94% received information on sedation, and 23% judged their colonoscopy to be more uncomfortable than expected. Twenty-one percent of patients said they left hospital not knowing how they would get results, although 87% remembered having the endoscopic findings discussed with them. The authors concluded that effective pre- and post-procedure communication were key.

Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

The one pediatric study by Jacob et al.\(^1\) certainly suggests that it is a good idea to provide information post-procedure and that it improves satisfaction; however, at the time of the phone interview, only 19 (40.4%) of 47 families had a follow-up visit or call after the procedure. The outcome of the other 28 patients is not reported. There is very serious risk of bias with regard to patient selection bias, recall and indirectness. The study does not specifically address provision of pathology and management information.

There were 2 adult studies, both of which provide only indirect evidence. Spodik et al.\(^2\) carried out a prospective, randomized, single-center, investigator-blinded study with 115 randomized. Only 83 completed the study protocol. Participants were randomized to receive either discharge instructions only or discharge instructions and a copy of the endoscopy report at the time of discharge from the endoscopy suite. Receiving the report reduced post-procedure anxiety ($P = 0.001$) and increased recall of findings and recommendations. After controlling for the type of procedure, age, sex, and race, the intervention group was found to have higher satisfaction scores than the standard group by an average of 3 points, but this was not statistically significant ($P = 0.100$). Older patients were more likely to receive the report ($P = 0.037$) and older patients had significantly lower satisfaction scores by 6 points ($P = 0.004$). Recall bias is an issue, as patients were asked to recall findings and recommendations.
De Jong et al. conducted a prospective audit of 1187 patient experiences with colonoscopy. Although 1187 patients completed the pre-questionnaire, only 851 (71.9%) completed the post-questionnaire, therefore introducing bias into the study. 54% were seen in the outpatient department before the procedure. Participants reported that the indication was explained in 85% of cases, 65% said they received information on risks, 94% received information on sedation, and 23% judged their colonoscopy to be more uncomfortable than expected. Twenty-one percent of patients said they left hospital not knowing how they would get results, although 87% remembered having the endoscopic findings discussed with them. The authors concluded that effective pre- and post-procedure communication were key.

Due to the type of studies being observational, the evidence starts off as low quality. In the pediatric paper, participant numbers are low, reporting is inconsistent and there is bias at all stages including selection, reporting, detection and attrition, which drops the quality down to very low. Additionally, the adult papers only provide indirect evidence.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating</th>
<th>List reasons for downgrading or upgrading evidence</th>
<th>Quality of the evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td>In the pediatric paper, participant numbers are low, reporting is inconsistent and there is bias at all stages including selection, reporting, detection and attrition, which drops the quality down to very low.</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td>2 adult papers provide indirect evidence.</td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>Large (+1) Very large (+2)</td>
<td></td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>☒</td>
<td></td>
</tr>
</tbody>
</table>
### PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Yes (+1)</th>
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</thead>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

<table>
<thead>
<tr>
<th>☐</th>
<th>☐</th>
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<tbody>
<tr>
<td>High</td>
<td>Moderate</td>
<td>Low</td>
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<tr>
<td>☑</td>
<td></td>
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<tr>
<td>Very low</td>
<td></td>
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</tbody>
</table>

**REFERENCES**

PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 24**: Endoscopy facilities where pediatric procedures are performed should systematically solicit pediatric patient and/or caregiver feedback, report the results to the service and to the institution’s or facility’s quality committee and implement appropriate remediation plans in a timely manner.
  - **Indicator 15**: Quality of the patient and caregiver experience.
  - **Indicator 16**: Rate with which patient and caregiver experience data are formally obtained.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility that systematically solicits pediatric patient and/or caregiver feedback, reports the results to the service and to the institution’s quality committee, and implements appropriate remediation plans in a timely manner, associated with improved outcomes?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Experience of patient and/or caregivers is evaluated using a standard tool
- **Control/Comparator**: No evaluation of patient and/or caregiver experience
- **Outcome**: Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Relevant guidelines:**
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures. Articles evaluated different methods of assessment of the quality of experience (only pediatric abstracts) but none showed relation between systematic assessment and improvement in patient experience.

STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Conclusion:
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn regarding whether undergoing pediatric endoscopy in a facility that systematically solicits pediatric patient and/or caregiver feedback, reports the results to the service and to the institution’s quality committee, and implements appropriate remediation plans in a timely manner is associated with improved outcomes.
PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s)
- **Standard 25:** Endoscopy facilities where pediatric procedures are performed should have the personnel and technical resources required by national and/or provincial/state standards to complete all planned pediatric procedures safely and effectively.

PICO Question:
Is performing pediatric endoscopy in a facility that is fully equipped with the technical and personnel resources required by external (national/state/provincial) standards associated with increased patient safety and improved clinical outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Having the procedure performed in a facility that is fully equipped with technical and personnel resources, as mandated by external regulations or guidelines
- **Control/Comparator:** Having the procedure performed in facility that does not have all of the technical and personnel resources mandated by these standards
- **Outcome(s):**
  - Adverse event rates
  - Procedure completion rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studies included:

Articles excluded:

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There was no pediatric evidence for this standard, and adult evidence is indirect and imprecise. The two adult studies that were somewhat relevant included:
- Dellon et al\(^1\), which was a retrospective review of all colonoscopies performed at UNC hospitals from 2003-2005 (n=3631). The investigators were specifically interested in the impact of nursing experience (which they defined as either >/= or < 6 months of
experience) on polyp detection rates for providers. The study found that procedures performed with nurses with > 6 months of experience in the room, as well as procedures performed with 2 nurses involved, were associated with higher polyp detection rates.

- Shah et al\textsuperscript{2}, which was a population-based (n = 331,608) comparison of settings for procedures in Canada. The settings were academic hospitals, community-based hospitals, and private offices. The investigators explained that the practice of performing colonoscopy in private offices was increasing (at least at the time) in Canada, but at that point was unregulated, and not held to any standards for sedation, monitoring practices, endoscope disinfection or credentialing of endoscopists). In multi-variate analyses, the investigators found that regardless of patient or endoscopist factors (looking at high volume vs. low volume endoscopists, endoscopists who specialized in colonoscopy vs. other), the rate of incomplete procedures was consistently higher when performed in private offices.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Somewhat relevant data is from retrospective reviews</td>
<td>Moderate</td>
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<tr>
<td></td>
<td>Serious (-1)</td>
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<td></td>
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<td></td>
<td>Very serious (-2)</td>
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<td></td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Outcomes varied</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Serious (-1)</td>
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<td></td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>This evidence is indirect</td>
<td>Low</td>
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<td></td>
<td>Serious (-1)</td>
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<td></td>
<td>Very serious (-2)</td>
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<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>Both Shah and Dellon had good study power</td>
<td>Low</td>
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<td></td>
<td>Serious (-1)</td>
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<td></td>
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<td></td>
<td>Very serious (-2)</td>
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</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Felt like both studies were “politically motivated” – wanted experienced/more registered nurses; anti office-based colonoscopy.</td>
<td>Very Low</td>
</tr>
<tr>
<td></td>
<td>Unlikely (-1)</td>
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<td></td>
<td>Likely (-2)</td>
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<tr>
<td>Large effect</td>
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<td>High</td>
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<td></td>
<td>Large (+1)</td>
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<td>Very large (+2)</td>
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<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
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<td>Low</td>
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<td></td>
<td>Yes (+1)</td>
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<tr>
<td>Dose-response gradient</td>
<td>No</td>
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<td>Very Low</td>
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<td></td>
<td>Yes (+1)</td>
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</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- High
- Moderate
- Low
- Very low

REFERENCES


STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s)

- **Standard 26:** Endoscopy facilities where pediatric procedures are performed should facilitate attendance to appropriate high quality educational programs for all staff, including those required by endoscopy facility personnel to maintain necessary and up to date skills and certifications.

PICO Question:

Should all staff working in pediatric endoscopic centers attend appropriate high-quality educational programs to maintain necessary and up to date skills and certifications?

- **Population/Patient:** All staff working in a facility that performs pediatric endoscopy
- **Intervention:** Attendance to appropriate high-quality educational programs
- **Control:** Non-attendance in appropriate high-quality educational programs
- **Outcome:**
  - Adverse event rates
  - Improved skills (for given task(s) on which they received education)
  - Improved compliance (for given task(s) on which they received education)

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studies included: 2 systematic reviews, 8 studies; all adult-based

Step 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There was no pediatric data. Two systematic reviews addressed this question.\textsuperscript{1,2} Eight adult primary studies were found addressing this question.\textsuperscript{3–10} Overall, the studies showed that implementation of education on various aspects of endoscopy (e.g., bowel preparation, photodocumentation) can improve those skills. The improved outcomes resulting from education can likely be extrapolated to pediatric ileocolonoscopy; however, the majority of data is related to cancer-related outcomes rather than outcomes applicable to pediatrics.

Systematic reviews:
1. Corley, 2011\textsuperscript{1}: they described 7 relevant studies out of 9642 references in adults for adenoma detection rate where longer endoscopy withdrawal time was an intervention. The ADR improved after intervention in only 1 out of 7 studies.
2. Hitchins, 2017\textsuperscript{2}: they found 8 relevant full text articles out of 80 possibly relevant publications. The current literature on non-technical skills (cognitive, personal, social skills that complement technical skills) in gastrointestinal endoscopy is limited; however, it is conclusive that non-technical skills are an essential component of practice.

Adult primary studies:
1. Calderwood, 2014\textsuperscript{3}: assessment of a Boston Bowel Preparation Scale (BBPS) education program administered to endoscopists. 91% and 98% of colonoscopy reports contained the BBPS at short- and long-term follow-up.
2. Coe, 2012\textsuperscript{4}: single center prospective observational study. Adult GE performed 300 colonoscopies before and after educational intervention (PowerPoint presentation) and the quality endoscopy indicators in reports improved (polyp description, IC valve description).
3. Adler, 2013\textsuperscript{5}: prospective multicenter observational study. 21 endoscopists were included from 21 centers in Germany (12134 procedures) and were followed for 18 months. The factors that influenced adenoma detection rate (ADR) were the number of continuing medical education (CME) sessions attended and instrument quality.

4. Matharoo, 2014\textsuperscript{6}: prospective interventional study: 23 participants from endoscopy teams were involved. After intervention (one day course with practical scenarios), safety awareness and NTS improved according to questionnaire evaluation.

5. Rajasekhar, 2015\textsuperscript{7}: longitudinal cohort multicenter study. 129 endoscopists were followed for 12 months. Three months after the start of the study the central educational intervention about ADR was performed and the ADR improved statistically significantly (4351 before and 13150 after intervention).

6. Belderbos, 2016\textsuperscript{8}: one year prospective single center study. Polyp retrieval rate improved especially at right colon (1300 procedures) after educational intervention regarding polyps in the colon.

7. Kaminsky, 2016\textsuperscript{9}: two-year RCT multicenter study from Poland (38 endoscopists, 24582 procedures). Programmed course for improving ADR was organized for one group of endoscopists, while the other (control group) just received feedback. The conclusion was that the intervention significantly improved ADR.

8. Grassini, 2008\textsuperscript{10}: prospective assessment of the effectiveness of an educational program in determining a reduction in inappropriate colonoscopies in an open access system. The post-course group rate of inappropriateness was significantly lower than that of the pre-course group ($P < 0.001$).

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong> (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Comparison groups not standardized</td>
<td>☒ High ☒ Moderate ☒ Low ☒ Very Low</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong> (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td></td>
<td>☒ High ☒ Moderate ☒ Low ☒ Very Low</td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong> (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>No pediatric data, adult outcomes often not relevant (e.g., adenoma detection rate)</td>
<td>☒ High ☒ Moderate ☒ Low ☒ Very Low</td>
</tr>
<tr>
<td><strong>Imprecision</strong> (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>6 prospective observational studies and only 1 RCT in adults, two systematic reviews</td>
<td>☒ High ☒ Moderate ☒ Low ☒ Very Low</td>
</tr>
<tr>
<td><strong>Publication Bias</strong> (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed Unlikely Likely (-1) Very likely (-2)</td>
<td>More than 500k procedures</td>
<td>☒ High ☒ Moderate ☒ Low ☒ Very Low</td>
</tr>
</tbody>
</table>
### PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Large effect</th>
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<tbody>
<tr>
<td>No</td>
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<tr>
<td>Large (+1)</td>
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<tr>
<th>Effects of all plausible confounding</th>
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<tbody>
<tr>
<td>No</td>
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</tbody>
</table>

<table>
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<tr>
<th>Dose-response gradient</th>
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</thead>
<tbody>
<tr>
<td>No</td>
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</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- High
- Moderate
- Low
- Very low

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s)**

- **Standard 27**: All endoscopy facility personnel working with endoscopists, directly or indirectly, in pediatric endoscopy service delivery should be trained and certified as having competence to perform specified routine and/or emergency pediatric endoscopic procedures according to appropriate standards.

**PICO Question:**

Is undergoing pediatric endoscopy in a facility where all endoscopy facility personnel working with pediatric endoscopists have special training to become competent to perform specific pediatric procedure-related tasks according to appropriate current standards associated with improved outcomes?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Having the procedure in a facility where endoscopy facility personnel have training to become competent to perform specific pediatric procedure-related tasks according to appropriate current standards
- **Control/Comparator**: Having the procedure in a facility where endoscopy facility personnel do not have training to become competent to perform specific pediatric procedure-related tasks according to appropriate current standards
- **Outcome**:  
  - Adverse events
  - Terminal ileal intubation rate (procedure completion)
  - Procedural efficiency

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 3 adult


**Related guidelines**:  

**Articles excluded**:  
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There is no pediatric data. Three adult primary studies were found which indirectly address this question.1–3

1. Dellon 20081 was a retrospective study looking at success of polyp detection during screening colonoscopies, comparing teams with skilled (> 6 months (n=15)) and non-experienced endoscopic nurses (n=10). Non-skilled endoscopy nurses had increased odds of not detecting polyps.

2. Dellon 20092 was a retrospective study comparing completeness (time of ileal intubation, time of complete procedure, number of adverse events) of screening colonoscopies between teams with experienced and non-experienced endoscopic nurses (3600 colonoscopies). Gastrointestinal endoscopy nurse inexperience was associated with an increase in immediate complications, prolonged procedure times, and decreased cecal intubation rates for screening colonoscopies.

3. Holme 20183 was a prospective multicenter observational study (12 hospitals) comparing completeness (time of ileal intubation, time of complete procedure, number of adverse events, polyp detection rate) of screening colonoscopies between teams with experienced and non-experienced endoscopic nurses (15365 procedures, 63 assistants). The endoscopy assistant has little impact on key colonoscopy performance indicators.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>No randomized control trials</td>
<td>++++ High</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>2 studies confirm the importance of nurse skills, whereas one study did not confirm the impact of skilled nurses on performance colonoscopy indicators</td>
<td>+++++ Moderate</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>No pediatric data</td>
<td>++++ High</td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Only 3 observational studies in adults with less than 150 endoscopy assistants included in the studies</td>
<td>++++ High</td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due)</td>
<td>Not assessed Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
<td>+++++ Very Low</td>
</tr>
</tbody>
</table>
### PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>to the selective publication of studies</th>
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<td>No</td>
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<tr>
<td>Large (+1)</td>
<td>x</td>
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<tr>
<td>Very large (+2)</td>
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<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td></td>
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<tr>
<td>No</td>
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<td>Yes (+1)</td>
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<tr>
<td><strong>Dose-response gradient</strong></td>
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<tr>
<td>No</td>
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<tr>
<td>Yes (+1)</td>
<td>x</td>
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</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<tbody>
<tr>
<td>☐ ☐ ☐ ☐ High</td>
</tr>
<tr>
<td>☐ ☐ ☐ Moderate</td>
</tr>
<tr>
<td>☐ ☐ ☐ ☐ Low</td>
</tr>
<tr>
<td>☐ ☐ ☐ ☒ ☒ ☒ ☒ ☒ Very low</td>
</tr>
</tbody>
</table>

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 28**: Pediatric endoscopic procedures are performed for an appropriate, clearly documented indication, consistent with current evidence-based guidelines, when available.
  - **Indicator 17**: Rate with which the endoscopy report documents the indication for the procedure.
  - **Indicator 18**: Rate with which endoscopy is performed for an indication that is in accordance with current evidence-based guidelines and/or published standards, when available.

**PICO Question:**
Is there evidence that pediatric endoscopic procedures which are performed for an appropriate, clearly documented indication, consistent with current, evidence-based guidelines when available, result in better outcomes?

- **Population/Patients**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Clearly documented indication, consistent with current, evidence-based guidelines, when available
- **Control/Comparator**: Procedure completed for an indication that is not clearly documented and/or consistent with current, evidence-based guidelines, when available
- **Outcome**:
  - Diagnostic yield
  - Rate of change in management as a result of endoscopic and/or pathologic findings

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 3 pediatric (1 abstract), 5 adult

Relevant guidelines:

Articles excluded:

**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
There are a number of pediatric studies that are nearly all retrospective with acquisition bias. Some conform to published Guidelines, but the Guidelines themselves are open to the criticism of being based on heterogeneous studies and few in the pediatric population. All types of bias are present in this group of studies. Guidelines have identified relevant pediatric endoscopy indicators,
but there are insufficient pediatric studies to demonstrate the efficacy of indicators (appropriate vs. inappropriate use of endoscopy) or to demonstrate that the indicators are associated with high diagnostic yield.

Three pediatric retrospective single center observational studies (1 abstract) and 5 prospective adult studies address this PICO question (appropriateness of criteria for EGD and ileocolonoscopy and diagnostic yield).

With regard to the pediatric studies:

1. Thomson, 2017: A retrospective cross-sectional evaluation of 153 randomly selected pediatric cases (from 2471 children up to 16 years) identified through an electronic theater database over a 30-month period reported a positive diagnostic yield of 18.9% for esophagogastroduodenoscopy (EGD) alone, 32.6% ileocolonoscopy alone, and 39.2% with both procedures. In 45% of patients, management actively changed due to endoscopy and histopathology findings. Overall, the study reported that endoscopic procedures had a sensitivity of 71.4%, a specificity of 71.4%, an NPV of 76.9% and a PPV of 65.2%.

2. Sheiko, 2013: A single center retrospective observational cohort study with 1000 pediatric patients (< 18 years) initially reviewed, but due to exclusions (n = 642, with most common reason a history of prior endoscopy, n = 334) 358 were evaluated. The most common primary indications for endoscopy included generalized abdominal pain (28.7%), gastroesophageal reflux (11.7%), and failure to thrive (9.5%). Overall prevalence of endoscopic and histologic abnormality was 34.7% and 40.4%, respectively. The highest rates of endoscopic abnormalities were found in patients with strictures on upper GI radiology (100%), foreign body (88%), and GI bleeding (57%). The highest rates of histologic abnormalities were in patients with positive celiac screening (91%), foreign body (88%), dysphagia (51%), and GI bleeding (49%) (analysis on correlation between positive endoscopic and histologic findings not done).

3. Singh, 2017: A single center retrospective observational Australian study in children (12-16 years). Out of 652 colonoscopies performed over a 4-year period, 65 (10%) with an indication of abdominal pain were reviewed (isolated abdominal pain (n=15); the remainder had additional indications including altered bowel habit (n=15), weight loss (n =14), significant family history of IBD or polyps (n = 8), iron deficiency anemia (n = 7), food allergy (n = 3), and rectal bleeding (n=3). All had an ESR and CRP, 52% (34/65) had an Fcal done; 6% (4/65) had elevated fecal calprotectin or inflammatory markers; 11% (7/65) had positive findings at colonoscopy, which included Crohn disease (n=3), polyps (n=2), and microscopic colitis (n=2). No patient with isolated abdominal pain had positive findings. This study reinforces current criteria indicating that isolated abdominal pain is not an indication for colonoscopy unless secondary symptoms or abnormal calprotectin or inflammatory markers are present.

With regard to the adult studies:

1. Froehlich, 2000: A prospective multicenter study. The authors previously applied American Society for Gastrointestinal Endoscopy (ASGE) criteria to 442 adult outpatients who underwent EGD and found that there were no significant differences in clinically relevant findings in patients who had an appropriate vs. inappropriate EGD (Endoscopy.1996; 28(8): 661-6). 252 EGDs (57%) were judged appropriate; however, the probability of finding a significant lesion did not differ between the endoscopies judged as appropriate (50%) vs. inappropriate (46%). Expanded ASGE criteria (developed according to the RAND/UCLA panel method established in 1994) was applied to patient encounters. 2088 consecutive adult patients (60% outpatients, 57% men, 88% 1st EGD) referred for EGD to 6 centers in Switzerland prospectively included over a 6-month period. Analysis restricted to1681 patients referred for diagnostic EGD; 46% of EGDs judged appropriate, 15% uncertain, and
39% inappropriate. EGD judged appropriate or uncertain yielded significantly more relevant lesions (60%) than did those judged inappropriate (37%; OR 2.6: 95% CI [2.2, 3.2]). In multivariate analyses, diagnostic yield of EGD was significantly influenced by appropriateness, patient gender and age, treatment setting, and symptoms.

2. Bosset, 2002⁵: A similar study design to Froehlich et al.⁴ Consecutive adult patients referred for diagnostic colonoscopy at 5 Swiss centers prospectively studied over a 17-month period. 1188 patients were included. Indications for 1144 (96.3%) colonoscopies were evaluated using explicit criteria. 64.1% of colonoscopies were judged as appropriate, 13.3% uncertain and 22.6% inappropriate. Significant endoscopic lesions were found in 23.8% of colonoscopies. Similarly, to the EGD study, colonoscopies judged appropriate or uncertain yielded significantly more relevant lesions than did those judged inappropriate (25.6% vs. 17.4%; P = 0.007). In the multivariate analysis, diagnostic yield of colonoscopy was significantly influenced by appropriateness, patient gender and treatment setting.

3. Bersani, 2005⁶: A prospective adult study examined the appropriate use of colonoscopy in an open-access system with the ASGE guidelines and determined whether the guidelines were associated with relevant endoscopic findings. The rate of ‘not indicated’ colonoscopies was 37%. Relevant endoscopic diagnoses were present in 28.5% of cases with ASGE indications versus 20.1% of patients without appropriate indications, with the risk of finding relevant diagnoses being significantly increased by ASGE criteria application (OR 1.58; 99% CI 1.20–2.07; p < 0.01).

4. Gimeno García, 2012⁷: An adult prospective observational study was conducted in an open-access endoscopy unit at a tertiary care referral center to assess the appropriateness of colonoscopy based on European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) II criteria. The effectiveness of EPAGE II criteria in assessing appropriateness was measured by means of sensitivity, specificity, and positive and negative predictive values for detecting significant lesions. The authors found that EPAGE II criteria were applicable in 968 patients (96.4%). Of these patients, the indication was appropriate in 778 (80.4%), inappropriate in 102 (10.5%), and uncertain in 88 (9.1%). Patients with appropriate or uncertain indications based on EPAGE II criteria had more relevant endoscopic findings than those with inappropriate indications (38.8% vs. 24.5%; OR 1.95, 95% CI 1.22–3.13; P<0.005). Additionally, adherence to EPAGE II recommendations was an independent predictor of finding a significant lesion (OR 1.93, 95%CI 1.20–3.11; P =0.007).

5. Mangualde, 2011⁸: A prospective study using the ASGE guidelines to assess the relationship between procedure appropriateness and the presence of relevant endoscopic findings in 789 consecutive outpatients referred for gastrointestinal endoscopy (381 for esophagogastroduodenoscopy (EGD) and 408 for colonoscopy). 13.3% of endoscopies had inappropriate indications. Relevant endoscopic findings were more likely in EGDs and colonoscopies judged as appropriate or uncertain, compared to those considered inappropriate (EGD: 36.6% vs 36.4% vs 11.4%, P = 0.004; Colonoscopy: 24.3% vs 20.0% vs 3.3%, P = 0.001).

In summary, while pediatric endoscopy-related guidelines have provided a clear list of indications for EGD and ileocolonoscopy⁹–¹¹, there are no pediatric studies that have prospectively evaluated the implementation of the criteria and assessed the impact of appropriateness versus inappropriateness of the procedure on histological findings. Moreover, methodological differences in the pediatric studies limit comparisons. However, there are retrospective studies that have reported on EGD and histologic abnormality (34.7% and 40.4% respectively)⁵, diagnostic yield (18.9% for EGD alone, 32.6% ileocolonoscopy alone, and 39.2% with both procedures)⁷ and management change due to EGD and histologic findings (45%)¹. In addition, Thomson et al.¹
reported that EGD had a sensitivity of 71.4%, a specificity of 71.4%, a NPV of 76.9% and a PPV of 65.2%. Two prospective adult studies\textsuperscript{4,5} using explicit panel based appropriate EGD and colonoscopy criteria reported that 46% of EGDs were appropriate, 15% uncertain, and 39% inappropriate (EGD judged appropriate or uncertain yielded significantly more relevant lesions (60%) than did those judged inappropriate (37%; OR 2.6: 95% CI [2.2, 3.2]); and 64.1% of colonoscopies judged appropriate, 13.3% uncertain and 22.6% inappropriate (colonoscopies judged appropriate or uncertain yielded significantly more relevant lesions than did those judged inappropriate (25.6 % vs. 17.4 %; \(P = 0.007\)). Three other adult studies demonstrated increased diagnostic yield in patients undergoing upper endoscopy and/or colonoscopy for an indication in line with current guidelines as compared with those judged to be inappropriate.\textsuperscript{6–8}

### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Many retrospective studies</td>
<td>⭐⭐⭐⭐ High</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1)</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td></td>
<td>Serious (-1)</td>
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<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>Prospective studies all adult and mainly related to colorectal cancer screening</td>
<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td></td>
<td>Serious (-1)</td>
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<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td>Imprecision</td>
<td>No</td>
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<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1)</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
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<td></td>
<td>Very serious (-2)</td>
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<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
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<td></td>
<td>Unlikely (-1)</td>
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<td>⭐⭐⭐⭐⭐ High</td>
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<td>Likely (-1)</td>
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<td></td>
<td>Very likely (-2)</td>
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<tr>
<td>Large effect</td>
<td>No</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
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<td></td>
<td>Yes (+1)</td>
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<td>⭐⭐⭐⭐⭐ High</td>
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<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
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<td></td>
<td>Yes (+1)</td>
<td></td>
<td>⭐⭐⭐⭐⭐ High</td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- High
- Moderate
- Low
- Very low

REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 29**: For a patient and/or caregiver to provide informed consent/assent to undergo an elective endoscopic procedure, the patient and/or caregiver must be advised, in a timely fashion, of all relevant information about the procedure, including its risks, benefits and alternatives, if any, and be given the opportunity to raise any questions with a physician knowledgeable about the procedure. This process must be documented.
  - **Indicator 19**: Rate with which informed consent/assent is obtained.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility that provides appropriate information for provision of informed consent/assent and an opportunity to ask questions, associated with improved outcomes?

- **Population/Patients**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Receipt of appropriate information for provision of informed consent/assent, in a timely fashion, including all relevant information about the procedure, its risks, benefits and alternatives, and the opportunity to ask questions of a physician knowledgeable about the procedure
- **Control/Comparator**: Did not received information, not timely, not relevant, and/or no opportunity to ask questions
- **Outcome**:
  - Patient experience
  - Patient recall and/or understanding of information

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**

**Pediatric studies:**

**Adult studies:**


Relevant guidelines:


Articles excluded:

Pediatric studies:


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**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

**Pediatric studies:**

Friedlander, 2011: Randomized controlled trial (RCT) intervention comparing standard form-based informed consent or standard form-based informed consent plus a standardized video (electronic assisted consent; EAC). Anxiety, satisfaction, number of questions asked, and attainment of informed consent were assessed. Rates of maximum scores on the instrument assessing attainment of informed consent were higher in the EAC group (93%) compared to controls (83%), and the distribution was tighter for the EAC group, with more patients have scores closer to 40 than controls. The EAC group asked fewer questions sign off than the control group. There were no differences in satisfaction between the groups.

Jacob, 2015: This qualitative study found that parents commonly do not remember or understand alternatives to the procedure. Also, patients are not always given leaflet information. Respondents generally expressed satisfaction with the consent process.

Jubbal, 2015: 195 youth and parents were approached, and 88 youth and parent pairs participated in structured interviews post informed consent. The majority of children reported a desire to participate in the consent process. Among youth (7 to 12 years of age) and their caregivers, only 14% met all criteria for comprehensive understanding of the informed consent discussion. The majority desire discussion of informed consent at a clinic visit. 24% desire discussion to occur before procedure day, and only 3% on the procedure day. Documentation rate of informed consent and risks was 39%, benefits 39%, as well alternatives 10%.

Yeh, 2017: RCT of 77 youth (7 to 17 years old) and parent pairs, with 37 randomized to a video (2 min 43 sec) intervention group. The study found that youth and parents in the video group had a more complete understanding of procedural risks and of alternatives to the procedure, compared to controls.

There is overwhelming observational evidence that caregivers and patients (>90%) prefer when consent is done before the day of procedure. The endoscopists appear to play a significant part in
There is emerging evidence, including pediatric RCT evidence, that video-assisted informed consent improves overall comprehension as well as understanding of potential risks of the procedure and its alternatives. Consistency of the comprehension also improved. Documentation of the consent process appears poor in a study that reported this outcome. Alternatives to endoscopy, as part of the consent process, appears to have been poorly discussed in most studies. Sidhu, an adult study, demonstrated that this process should be individualized and tailored to patients’ needs.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

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<td>Serious (-1)</td>
<td>⊕⊕⊕ Moderate</td>
</tr>
<tr>
<td>results)</td>
<td></td>
<td>Very serious (-2)</td>
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<tr>
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<td>No</td>
<td>Serious (-1)</td>
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<td>specifically compare the interventions, populations,</td>
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<td>Very serious (-2)</td>
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<td>or outcomes of interest, for example, adult literature)</td>
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<tr>
<td>Imprecision (Research that includes few patients and</td>
<td>No</td>
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<td>Large effect</td>
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<td>Effects of all plausible confounding</td>
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<td>Yes (+1)</td>
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<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td>⊕⊕⊕⊕ Very Low</td>
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</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

<table>
<thead>
<tr>
<th>High</th>
<th>Moderate</th>
<th>Low</th>
<th>Very low</th>
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</thead>
<tbody>
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</tbody>
</table>

REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 30**: For all endoscopic procedures, the sedation/anesthetic plan should be documented along with a standardized measure of patient complexity.
  - **Indicator 20**: Rate with which the sedation/anesthetic plan is documented.
  - **Indicator 21**: Rate with which ASA status is documented.

PICO Question:
Do patients who have their sedation/anesthetic plan documented, along with an assessed measure of their medical complexity, have less adverse events than patients who do not have these documented prior to undergoing pediatric endoscopic procedures with sedation?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Documentation of sedation plan and patient complexity (e.g., in accordance with JCAHO guidelines and using ASA status)
- **Control/Comparator**: No documentation of sedation plan and/or patient complexity
- **Outcome(s)**:
  - Hypoxemia
  - Other sedation-related adverse events
  - Failed sedation

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 5 pediatric, 7 adult
  - Pediatrics, retrospective, chart review, descriptive - ~650 patients referred for sedation, standardized approach, what happened, how they organized it, what was used, etc. No comparators. Found standardized approach to assessing patients (using ASA classification scheme) AND employing standard approaches to sedation (a priori determining sedation plan) is an effective strategy for improving patient safety and providing efficient sedation. ASA III (more complex patients) were more likely to have AEs.
  - Pediatrics, cross-sectional prospective observational study of implementation of the 2001 JCAHO Sedation Guidelines at a single, tertiary care pediatric hospital across all settings in the hospital where procedural sedation is used. The study followed clinical outcomes from baseline (prior to implementation of the guidelines) through implementation over 3 years, with a number of rapid cycle changes implemented at the facility level. Results of the study showed improved documentation during sedated procedures in children, including ASA status and sedation plan, with progressively less adverse events recorded at the facility level across all 3 years.

- Pediatrics, cross-sectional, retrospective, multi-center (n=13) database analysis, looked at association in between recorded ASA status and rate of AEs in children undergoing EGDs. Analyzed >10,000 procedures, with 239 complications (AE rate of 2.3%, 95% CI 2.0, 2.6; anesthesiologist-administered 1.2% vs. endoscopist administered 3.7%). AEs more likely be associated with higher ASA classes (ASA I rate of 2.2%; II – 2.7%; III - 3.1%; IV – 7.3%).


- Pediatrics, cross-sectional, retrospective, multi-center (n=13) database analysis, looked at association in between recorded ASA status and rate of AEs in children undergoing colonoscopy. ~7700 procedures included; AE rate 1.1%. NO association with ASA status; AE rate was associated with type of sedation administered (more likely with endoscopist- vs. anesthesiologist-administered).


- Pediatrics, registry-based prospective study; n>21,000 reports, 12.7% did not included ASA classification. Higher ASA classes associated with poor bowel prep; p. 539 – In conclusion, authors state: “ASA class is valuable for pre-procedure risk assessment and should be assessed and recorded”.


- Adults, retrospective chart review, queried sedation type vs. perforation rates in n=>118,000 colonoscopies – Found RR of 2.5 for propofol vs. other moderate sedation in therapeutic colonoscopy (rare in children) – not found for diagnostic procedures.


- Adults, retrospective cohort analysis, 75 VA sites, n>1,500,000 procedures – found higher ASA status associated with higher rates of AEs for EGDs and Colonoscopies (not for flex sig, ERCP).


- Adults (1.6% peds), cross-sectional web-based survey of practitioners in Korea (n=1,332/5,860 KSGE members (response rate 23%). Found tremendous variation in practice – noted that up to 25% did not ever document ASA status or sedation plan; found those who did not engage in these and other high quality practice processes had higher levels of serious adverse events.


- Adults, cross-sectional study of National Anesthesia Clinical Outcomes Registry (NACOR). Looked at AE rates during anesthesiologist-administered sedation for adult procedures. N>476,000 procedures. Multi-variate analyses suggest higher
ASA status associated with higher rates of AEs in EGDs (OR 2.69; 95% CI 1.52, 4.76) and ERCPs (OR 4.15 (2.19, 7.9).

  - Adults, prospective cohort, n=210 patients, clinical assessment of airway can predict difficulty with airway intubation.

  - Adults, Cross sectional, prospective study – n=12,835 patients across 278 sites in a 2-week period across Italy – of colonoscopic practices. Did not look at whether ASA is documented. Did look at whether or not sedation was chosen to be administered. Found cecal intubation rates greatly differed when sedation was used vs. not (84% vs. 76%).

  - Adults, prospective QI study, aiming to increase use of sedation (sedation optimization) in Greek practice. Increased sedation use during study period from 38% to 70% and found associated with increased completion rates (cecal intubation) for colonoscopy 88%-96%. No ASA assessed.

**Articles excluded:**

- Jopling MW, Qiu J. Capnography sensor use is associated with reduction of adverse outcomes during gastrointestinal endoscopic procedures with sedation administration. BMC Anesthesiol 2017;17:1–10.

**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
In terms of pediatric specific evidence, some of it is directly related to pediatric GI procedures, and some of it more broadly addresses sedation practices.

At least 1 study found that lack of documentation around ASA status prior to pediatric GI procedures may be associated with adverse events.\(^1\) Two studies\(^2,3\) looked at sedation practices for a number of different procedures, including GI endoscopy, and found that documenting sedation plan and ASA status (following JCAHO recommendations) led to less adverse events. There are also a number of pediatric specific studies that show that ASA status is related to adverse events during endoscopy,\(^4,5\) suggesting that understanding ASA status of a patient may be important for preparing for risks.

In terms of adult studies, there are many others that relate higher ASA status to higher risks, even when anesthesiologists are administering the sedation.\(^6,7\)

Because not all countries are using sedation routinely for endoscopy, there are also a number of national database studies showing consistently that planning to use sedation is associated with improved procedure quality, patient satisfaction and patient safety.\(^8-11\)

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>May not be fully including all eligible procedures, different outcomes of interest</td>
<td>⊕⊕⊕⊕ High</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Different outcomes of interest</td>
<td>⊕⊕⊕ Moderate</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Mixed adult and pediatric data.</td>
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</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Both pediatric and adult studies seem to have decent study numbers</td>
<td>⊕⊕⊕⊕ Very Low</td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
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<tr>
<td>Large effect</td>
<td>No Large (+1)</td>
<td></td>
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</tr>
</tbody>
</table>
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| Very large (+2) | □ |

| Effect of all plausible confounding | No | Yes (+1) | □ |

| Dose-response gradient | No | Yes (+1) | □ |

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ☑ ☑ ☑ High
- ☑ ☑ Moderate
- ☑ ☑ Low
- ☑ ☑ ☑ ☑ Very low

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- Standard 31: Appropriate sedation/anesthesia should be provided to ensure patient cooperation, comfort and safety in line with best practices and consistent with evidence-based guidelines, when available.
  - Indicator 22: Rate with which patient monitoring during sedation/anesthesia is performed.
  - Indicator 23: Rate with which the dose and route of administration of all medications used during the procedure are documented.
  - Indicator 24: Rate with which intraoperative patient comfort is documented.
  - Indicator 25: Rate with which reversal agents are used.
  - Indicator 26: Rate with which the procedure is interrupted and/or prematurely terminated due to a sedation/anesthesia-related issue.

PICO Question:
Does administering sedation/anesthesia in line with best practice and/or evidence-based guidelines lead to improved patient outcomes?

- Population/Patient: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- Intervention: Patient monitoring (and documentation) in line with best practices (e.g., JCAHO guidelines, national guidelines)
- Control/Comparator: No documentation and/or no patient monitoring
- Outcome(s):
  - Sedation-related adverse events
  - Patient comfort

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studies included: 4 pediatric, 7 adult
  - Pediatric, retrospective, chart review, descriptive - ~650 patients referred for sedation, standardized approach, what happened, how they organized it, what was used, etc. No comparators. Found standardized approach to providing sedation to be an effective strategy for improving patient safety and providing efficient sedation.
  - Pediatric, cross-sectional prospective observational study of implementation of the 2001 JCAHO Sedation Guidelines at a single, tertiary care pediatric hospital across all settings in the hospital where procedural sedation is used. The study followed clinical outcomes from baseline (prior to implementation of the guidelines) through implementation over 3 years, with a number of rapid cycle changes implemented at the facility level. Results of the study showed improved adherence to JCAHO guidelines.
guidelines, decreased variation in care and progressively less adverse events recorded at the facility level across all 3 years.

  - Pediatric, open label trial of monitoring using pulse ox and ECG, 7/60 procedures (n=57 patients) included oxygen desaturation <90%, improved with oxygen supplementation. Conclusion: you need to monitor children undergoing sedated endoscopy.

  - Pediatric, prospective, observational study of 34 children (22 without comorbidity; 12 with neuro, cardiac or pulmonary disorders) undergoing “conscious sedation” with benzodiazepines/oxytocics without oxygen supplementation with open-label continuous monitoring of oxygen saturation and ECG (which was not standard at the time). 68% of children had >1 episode of oxygen desaturation<90% - with many but not all episodes happening during esophageal intubation. 82% of “normal patients” had cardiac arrhythmias in conjunction with hypoxemia. All of the cardiac patients had cardiac arrhythmias both with and without sedation.

  - Adult, retrospective cohort analysis, 75 VA sites, n>1,500,000 procedures -- found higher ASA status associated with higher rates of AEs for EGDs and Colonoscopies (not for flex sig. ERCP).

  - Adult (1.6% peds), cross-sectional web-based survey of practitioners in Korea (n=1,332/5,860 KSGE members (response rate 23%). Found tremendous variation in practice – noted that those who did not engage in high quality practice processes had higher levels of serious adverse events.


  - Adult, prospective, cross-sectional data at 3 time points for 29 or 60 endoscopy centers in Italy and examined whether provider education about the Italian Guidelines for Sedation in Digestive Endoscopy (published in 2000) had an impact from baseline to 1 year after the intervention. Results of the study suggested that in the 29 centers (which met inclusion criteria because they had collected data at all 3 time points), there were less adverse events and less variation in care (particularly around use of sedation for colonoscopy in adults (yes or no) when baseline data was compared to 12 months).

  - Adult, randomized trial to 8 vs. 2 hours of fasting, stratified by ASA (equal numbers of I/II in both arms – III and above excluded). Found 2 hours more associated with patient comfort (than fasting for 8 hours). Found it to be “safe” as well.
  - Adult, prospective development (n=40) and validation (n=848) of PROSAS (a brief instrument administered to patients after procedural sedation for endoscopy that reliably measures patient satisfaction and safety with the sedation). ASA was measured in the protocol and had no impact on PROSAS scores.

  - Adult, prospective development and validation of NAPCOMS (nurse assessment of patient comfort score). Looked at agreement between RN vs. MD vs. patient assessments.

**Articles excluded:**


**Summary of the Evidence:**

There are 2 studies that show that monitoring children undergoing pediatric endoscopic procedures with pulse oximetry and ECG is associated with improved patient outcomes.1,2 And 1 study in pediatrics that shows that monitoring with capnography during GI endoscopy in addition to the other modalities (O2, ECG, direct visualization) leads to further improvements in outcomes.3 There are 2 studies of pediatric sedation in general (i.e., including endoscopic procedures, but not
limited to them) that show that monitoring (and documenting) patient monitoring and medication administration is associated with better outcomes.\textsuperscript{4,5}

There are several studies of sedation in adults that show that monitoring (and documenting) patients and drugs administered leads to improved patient outcomes.\textsuperscript{6–9}

There is really no evidence for Indicators 25 (rate with which reversal agents are used), 26 (rate with which procedures are interrupted or terminated due to sedation/anesthesia-related issues) or 24 (rate with which intraoperative patient comfort is documented) as being associated with better patient outcomes – although Rostom et al.\textsuperscript{10} and Leffler et al.\textsuperscript{11} developed standardized scores (PROSAS and NAPCOMS, respectively), and Koeppel et al.\textsuperscript{12} showed that improved patient comfort (specifically around NPO status in this study) is associated with improved patient satisfaction.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
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</tr>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Concern re: detection bias/reporting bias – the AEs are hard to report</td>
<td>⬤ ⬤ ⬤ ⬤ High ⬤</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Different outcomes</td>
<td>⬤ ⬤ ⬤ ⬤ Moderate ⬤</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn't specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Real indirectness of evidence – comparisons are not necessarily of the same things or looking at the same things – different populations, etc.</td>
<td>⬤ ⬤ ⬤ ⬤ Low ⬤</td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Actually – a number of large database studies.</td>
<td>⬤ ⬤ ⬤ ⬤ Very Low ⬤</td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
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<tr>
<td>Large effect</td>
<td>No Large (+1) Very large (+2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No Yes (+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No Yes (+1)</td>
<td></td>
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</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- High
- Moderate
- Low
- Very low

REFERENCES

OVERALL RATING

- **Standard 32:** Pediatric endoscopic procedures should be performed efficiently, within a reasonable procedure time (from first insertion until final removal of endoscope).
  - **Indicator 27:** Procedure time.

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<tbody>
<tr>
<td>🙆♀️♀️♀️♀️ High</td>
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<td>🙆♀️♀️♀️ Moderate</td>
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<td>🙆♀️♀️ Low</td>
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<tr>
<td>🙆♀️ Very low</td>
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</tbody>
</table>

- See data for individual PICO statements below
STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 32**: Pediatric endoscopic procedures should be performed efficiently, within a reasonable procedure time (from first insertion until final removal of endoscope).
  - **Indicator 27**: Procedure time.

**PICO Question:**
What is the minimal and/or maximal time for pediatric endoscopy to ensure patient safety?

- **Population**: Pediatric patients undergoing routine endoscopic procedures
- **Intervention**: Mean procedure time (from first insertion until final removal of endoscope)
- **Control**: Lower or Higher than “I”
- **Outcome**:
  - Adverse event rates
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 2 adult

**Articles excluded**:

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence**:
There are no studies which address the question of pediatric endoscopic procedure time in relationship to patient safety. Adult studies have shown an increased documented procedure time correlates with polyp detection rate which is the marker for higher quality colonoscopy but have not assessed adverse event rates or patient experience directly.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
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</thead>
<tbody>
<tr>
<td>Outcome</td>
<td></td>
<td>Retrospective studies</td>
<td>++++</td>
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<tr>
<td>Risk of bias (study limitations)</td>
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<td>Retrospective studies</td>
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</tbody>
</table>
### PEnQuIN GRADE reporting template

<table>
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<th><strong>Bias</strong></th>
<th><strong>Very serious (-2)</strong></th>
<th><strong>High</strong></th>
<th><strong>Moderate</strong></th>
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<th><strong>Very Low</strong></th>
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<td><strong>Selection bias</strong>, <strong>performance bias</strong>, <strong>detection bias</strong>, <strong>attrition bias</strong>, <strong>reporting bias</strong>, <strong>other bias</strong></td>
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<td><strong>Inconsistency of results</strong></td>
<td>No Serious (-1) Very serious (-2)</td>
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<td><strong>(Unexplained heterogeneity of results)</strong></td>
<td>Studies do not address question directly</td>
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<tr>
<td><strong>Indirectness of evidence</strong></td>
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<td><strong>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</strong></td>
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<td><strong>Imprecision</strong></td>
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<tr>
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</table>

### STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Overall quality of the evidence (please circle/check-off):**

- [ ] High
- [ ] Moderate
- [ ] Low
- [ ] Very Low

### REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 32**: Pediatric endoscopic procedures should be performed efficiently, within a reasonable procedure time (from first insertion until final removal of endoscope).
  - **Indicator 27**: Procedure time.

PICO Question:
What is the minimal and/or maximal time for pediatric ileocolonoscopy to ensure optimal technical and quality related outcomes?

- **Population**: Pediatric patients undergoing routine ileocolonoscopy
- **Intervention**: Mean procedure time (from first insertion until final removal of endoscope)
- **Control**: Lower or Higher than “I"
- **Outcome**:
  - Terminal ileum intubation rate (procedure completion)
  - Cecal intubation rate
  - Diagnostic yield

---

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 1 pediatric, 2 adult


**Excluded articles**:  

---

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence**:  
Pasquarella et al.\(^1\) reports lower procedure time associated with positive TI rate. Longer procedure time associated with unsuccessful TI, likely due to prolonged time at attempting TI intubation. Thakkar et al.\(^2\) reported longer procedure time in colonoscopies with polypectomies (40.0 vs 31.2 minutes; \(P < .001\)). Adults studies\(^3,4\) correlated longer procedure time with higher polyp detection rates which is a marker for higher quality colonoscopy. There is no standard for procedure time that correlates with technical outcomes. Increase procedure time at this time only correlates with increased procedure technical difficulties and decreased technical outcomes.
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
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<td><strong>Outcome:</strong></td>
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<tr>
<td><strong>Risk of bias (study limitations)</strong></td>
<td>No</td>
<td>Serious (-1) Very serious (-2)</td>
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<td><strong>Inconsistency of results</strong></td>
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<td>Serious (-1) Very serious (-2)</td>
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<td><strong>Indirectness of evidence</strong></td>
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<tr>
<td><strong>Publication Bias</strong></td>
<td>Not assessed</td>
<td>Unlikely Likely (-1) Very likely (-2)</td>
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<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
<td>Large (+1) Very large (+2)</td>
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<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
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</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

Overall quality of the evidence (please circle/check-off):

- ☒ ☒ ☒ ☒ High
- ☒ ☒ ☒ Moderate
- ☒ ☒ Low
- ☒ ☒ ☒ ☒ Very Low
REFERENCES


OVERALL RATING

- **Standard 33**: Bowel preparation for lower endoscopic procedures should be of adequate diagnostic quality to allow for a complete procedure and be measured using a tool with strong validity evidence or, at a minimum, using standardized language with clear definitions.
  - Indicator 28: Rate of adequate bowel preparation.
  - Indicator 29: Rate with which the endoscopy report documents the quality of the bowel preparation.

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<tbody>
<tr>
<td>☐ ☐ ☐ ☐ High</td>
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<tr>
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<td>☐ ☐ ☐ Low</td>
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<td>☐ ☐ ☐ ☐ Very low</td>
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</tbody>
</table>

- See data for individual PICO statements below
PENQUIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 33**: Bowel preparation for lower endoscopic procedures should be of adequate diagnostic quality to allow for a complete procedure and be measured using a tool with strong validity evidence or, at a minimum, using standardized language with clear definitions.
  - **Indicator 28**: Rate of adequate bowel preparation.
  - **Indicator 29**: Rate with which the endoscopy report documents the quality of the bowel preparation.

**PICO Question:**
In pediatric patients undergoing colonoscopy, what is the minimum rate of adequate bowel preparation?
- **Population/Patient**: Pediatric patients undergoing ileocolonoscopy
- **Intervention**: Adequate bowel preparation rate
- **Control/Comparator**: Lower than “I”
- **Outcome**: Procedure completion (ileal intubation rate, cecal intubation rate)
- Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 3 adult, 12 adult

**Pediatric**

**Adult**
PEnQuIN GRADE reporting template


Relevant Guidelines:


Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

**Outcome 1: Ileal Intubation Rate**

Two pediatric studies\(^1,2\) and no relevant adult studies.

Singh 2017\(^1\): Retrospective review in a single center and included 652 patients. Quality of bowel preparation was described as excellent, good, fair or poor. Excellent or good occurred when there was no or minimal solid stool with large amounts of clear liquid; fair when
semisolid debris could be removed with difficulty; and poor when solid or semi solid debris could not be effectively cleared. Quality of bowel preparation was mentioned in 63% (410/ 652), of which 22% (90/410) were considered inadequate or poor. Poor quality of bowel preparation was inversely related to successful ileal intubation (p=.001). Poor bowel preparation was associated with decreased likelihood of intubation (OR 0.231; 95% CI 0.1–0.5, p<.001).

Thakkar 20162: A registry-based prospective study multi-center study looking at 21,807 colonoscopy procedures. Bowel preparations were not uniform among all centers and were judged by the endoscopist as poor, fair, good, or excellent. 56% did not report bowel preparation quality. Adequate bowel preparation (described as excellent, good, or fair) was reported in 90.3% (n = 8600) of cases. Reports from colonoscopies done with poor bowel preparation reported a lower rate of ileal intubation than bowel preparations described as excellent, good, or fair (72% vs 43%; P < .001).

Compared to adequate bowel preparation, poor bowel preparation was associated with decreased likelihood of intubation, but the overall quality of evidence is low.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
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<tbody>
<tr>
<td><strong>Outcome:</strong></td>
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<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Lack of blinding, objective outcomes</td>
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<tr>
<td>(selection bias, performance bias, detection bias,</td>
<td>Serious (-1)</td>
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<td>Inconsistency of results (Unexplained heterogeneity</td>
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<td>of results)</td>
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<tr>
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</table>

High

Moderate

Low

Very Low
Effects of all plausible confounding

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

Dose-response gradient

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

Outcome 2: Cecal intubation Rate
Six relevant adult studies and one pediatric abstract.

Studies in adult patients:

Aslinia 2006: Retrospective database review including 5477 colonoscopies. Endoscopist-assessed quality of bowel preparation was generally defined as (1) “Excellent”—having a small volume of clear liquid; (2) “Good”—having a large volume of clear liquid; (3) “Fair”—having some semisolid stool that could be suctioned or washed; (4) “Poor”—having semisolid stool that could not be suctioned or washed; (5) “Unsatisfactory”—having solid stool; and (6) “Unprepared.” Excellent, good, and fair were taken as “Adequate Preparation” and poor, unsatisfactory, and unprepared as “Inadequate Preparation.” Adequate bowel preparation significantly increased the likelihood of cecal intubation, compared to inadequate preparation (OR = 3.37; 95% CI, 2.87–3.95; p < 0.001).

Froehlich 2005: European multicenter prospective observational study. 5832 patients were included in the study. Colon cleansing quality was assessed on a 5-point scale and was categorized on 3 levels: high cleansing quality, completely clean (score 5) or clear liquid present (score 4); intermediate cleansing quality, liquid plus solid stool present that can be aspirated (score 3); low cleansing quality, liquid and solid stool present that cannot be totally aspirated (score 2); or solid stool preventing visualization (score 1). Colonoscopy was complete (intubation of cecum) in 90.4% of patients in the high-quality group, 90.1% of the intermediate-quality group, and 71.1% of the low-quality group (p< 0.001).

Hendry 2007: Single center prospective observational including 10571 colonoscopies. The bowel preparation was categorized as ‘good/satisfactory’ or ‘poor/inadequate’ by the colonoscopist at the time of the procedure. Complete colonoscopy was defined as cecal intubation. Incomplete examination was more likely with poor preparation [OR . 3.76 (95% CI, 3.38–4.18), P = 0.0005].

Nelson 2002: Prospective observational study including 3196 adults. The endoscopist graded the adequacy of the bowel preparation as “good” (mucosa well seen throughout), “fair” (liquid contents; examination adequate), or “poor” (solid contents, examination compromised). Procedure success was defined as confirmation of cecal intubation. A poor-quality colonoscopy preparation was associated with a higher rate of procedural failure, with a failure rate of 19.3% in patients with poor quality of preparation, 2.2% with good quality, and 2.8% with fair quality (p value .001).

Radaelli 2008: Multicenter prospective observational study including 12,835 patients. The quality of bowel cleansing (inadequate: too much fecal matter, complete examination impossible; poor: fecal matter preventing reliable examination; good: fecal matter not affecting the examination; and excellent: minimal or no fecal matter). The quality of bowel preparation was a strong predictor of cecal intubation (inadequate vs excellent: odds ratio [OR] 0.013, 95% confidence interval [CI]
0.009–0.018; poor vs excellent: OR 0.246, 95% CI 0.209–0.290; and good vs excellent: OR 0.586, 95% CI 0.514–0.667).

Yadlapati 2015: A retrospective single center study including 524 patients. The Aronchick scale was used and bowel preparation was defined as inadequate if the preparation was described as “poor” or “unsatisfactory” and/or when colonoscopy was delayed for over 1 day due to poor preparation. A bowel preparation was defined as adequate if the record indicated “adequate,” “good,” “excellent,” or “fair” preparation without procedural delay. Cecal intubation rate was significantly lower among procedures with an inadequate preparation compared to those with an adequate preparation (73.5 vs. 87.0 %, p< 0.001).

Study in pediatric patients
Kumar 2016: This was an abstract only and no additional details were available. A prospective single center study including 222 children. The BBPS scale used to look at bowel preparation. Adequate bowel preparation (BBPS score >= 5) and inadequate preparation (BBPS score < 5). No statistical difference between these two groups for cecal intubation rate noted.

Overall, compared to adequate bowel preparation, inadequate bowel preparation was associated with a significantly lower cecal intubation; however, the quality of evidence is low.

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Lack of blinding, objective outcomes</td>
<td>⬤⬤⬤⬤ High 🡤</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn't specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Majority of studies in adult patients</td>
<td>⬤⬤⬤ Moderate 🡤</td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed Unlikely Likely (-1) Very likely (-2)</td>
<td>✗</td>
<td></td>
</tr>
</tbody>
</table>

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PEnQuIN GRADE reporting template
### Outcome 3: Diagnostic Yield

Heron 2017\textsuperscript{10}: There was no significant association between preparation scores and adenoma detection.

Parmar 2017\textsuperscript{11}: A Boston Bowel Preparation Scale (BBPS) score of ≥5 was significantly associated with a higher polyp detection rate. Polyp detection rate increased with a higher BBPS score, with 40% detection with a score of ≥5 as compared with 24% with a score of <5 (\(P<0.02\)). Dichotomized segment scores of 0–1 vs. 2–3 showed significantly improved polyp detection with higher scores in the left colon (odds ratio=2.58 (1.34; 4.98)) than the right colon (odds ratio=1.6 (1.01; 2.55)). The association was not significant in the transverse colon (odds ratio=0.7 (0.48; 1.96)). The Harefield Cleansing Scale (HCS) grades were not discriminant for adenoma detection.

### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk of bias (study limitations)</strong></td>
<td>No (Serious (−1), Very serious (−2))</td>
<td>Lack of blinding, objective outcomes</td>
<td>☒ High</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong></td>
<td>No (Serious (−1), Very serious (−2))</td>
<td></td>
<td>☒ Moderate</td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong></td>
<td>No (Serious (−1), Very serious (−2))</td>
<td>Adult studies and outcomes adult specific (e.g. adenoma detection rate)</td>
<td>☒ Low</td>
</tr>
<tr>
<td><strong>Imprecision</strong></td>
<td>No (Serious (−1), Very serious (−2))</td>
<td></td>
<td>☒ Low</td>
</tr>
<tr>
<td><strong>Publication Bias</strong></td>
<td>Not assessed Unlikely</td>
<td></td>
<td>☒ Very Low</td>
</tr>
</tbody>
</table>
PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Large effect</th>
<th>No</th>
<th>Large (+1)</th>
<th>Very large (+2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

![Overall quality of evidence](high-moderate-low-very-low)

REFERENCES

PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 33**: Bowel preparation for lower endoscopic procedures should be of adequate diagnostic quality to allow for a complete procedure and be measured using a tool with strong validity evidence or, at a minimum, using standardized language with clear definitions.
  - **Indicator 28**: Rate of adequate bowel preparation.
  - **Indicator 29**: Rate with which the endoscopy report documents the quality of the bowel preparation.

PICO Question:
In pediatric patients undergoing colonoscopy, what is the preferred, validated measure of adequate bowel preparation?
- **Population/Patient**: Pediatric patients undergoing ileocolonoscopy
- **Intervention**: Adequate bowel preparation using a pediatric measure of adequate bowel preparation with strong validity evidence
- **Control/Comparator**: Other measure is utilized
- **Outcome**:
  - Procedure completion (ileal intubation rate, cecal intubation rate)
  - Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studie s included: 2 adult

Relevant guidelines:
### Summary of the Evidence:

**Outcome 1: Ileal Intubation Rate**
- No relevant studies

**Outcome 2: Cecal intubation Rate**

There are no relevant pediatric studies for cecal intubation but one adult study and one systematic review of adult literature looked at the preferred measure of bowel preparation for allowing detection of lesions >5mm.

Heron 2017\(^1\): Colonoscopy video recordings highlighting five colonic segments after washing were viewed independently by three physicians, and cleanliness was evaluated using the Boston Bowel Preparation Scale (BBPS), the Chicago Bowel Preparation Scale (CBPS), and the Harefield Cleansing Scale (HCS) in randomized order. 83 complete colonoscopies to the cecum were prospectively collected. Based on the colonoscopy videos, raters commented as to whether or not the preparation was adequate to exclude lesions ≥ 5mm. Intra-rater reliability ranges were 0.88 – 1.00, 0.83 – 1.00, and 0.62 – 1.00 for BBPS, CBPS, and HCS, respectively. Similarly, inter-rater reliability ranges were 0.50 – 0.79, 0.64 – 0.83, and 0.28 – 0.52. The BBPS and CBPS showed the best inter- and intra-rater reliability, and the BBPS was considered the easiest to use.

Parmar 2016\(^2\): A systematic review of adult literature included 14 citations assessing seven bowel preparation quality scales. It looked at the quality of bowel preparation allowing the detection of lesions >5mm. Five studies assessed the BBPS. Increasing BBPS scores were associated with polyp detection (left colon: odds ratio (OR)=2.58 (1.34; 4.98), right colon: OR=1.6 (1.01; 2.55), less repeat colonoscopies (cutoff of 5, P <0.001), and shorter insertion/withdrawal times (P <0.001), while displaying substantial to excellent inter- and intra-observer reliability (ICC=0.74–0.91). The BBPS was the most thoroughly validated scale and should be used in a clinical setting.

Overall, no relevant studies were found addressing this clinical question and outcome in pediatrics. However, the above adult studies suggested the BBPS scale was the most thoroughly validated scale.

### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk of bias (study limitations)</strong> (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>⧫</td>
<td>⨿</td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong> (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>⧫</td>
<td>⨿</td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong> (Research that doesn't specifically compare the</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>⧫</td>
<td>⨿</td>
</tr>
<tr>
<td>studies all in adult patients</td>
<td></td>
<td>Studies all in adult patients</td>
<td>⨿</td>
</tr>
</tbody>
</table>
**Outcome 3: Diagnostic Yield**
Heron 2017:
There was no significant association between preparation scores and adenoma detection.

Parmar 2016:
Polyp detection rate increased with higher BBPS scores, with a 40% detection rate in those with a cleansing score of ≥ 5, compared with 24% in those with a score of < 5 \( (P < 0.02) \). Dichotomized segment scores of 0–1 vs. 2–3 showed significantly improved polyp detection with higher scores in the left colon (odds ratio=2.58 (1.34; 4.98)) than the right colon (odds ratio=1.6 (1.01; 2.55)). The association was not significant in the transverse colon (odds ratio=0.7 (0.48; 1.96)). The Harefield Cleansing Scale (HCS) grades were not discriminant for adenoma detection.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

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<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Lack of blinding, objective outcomes</td>
<td>☑️ High ☑️ □</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td></td>
<td>☑️ ☑️ ☑️ Moderate ☑️ □</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn't specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Adult studies and outcomes adult specific (e.g. adenoma detection rate)</td>
<td>☑️ ☑️ ☑️ □</td>
</tr>
</tbody>
</table>
**Step 4** Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Overall quality of the evidence (please circle/check-off):**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Circle/Check-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>☐</td>
</tr>
<tr>
<td>Moderate</td>
<td>☐</td>
</tr>
<tr>
<td>Low</td>
<td>☒</td>
</tr>
<tr>
<td>Very low</td>
<td>☐</td>
</tr>
</tbody>
</table>

**References**

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 34:** Pediatric endoscopic procedures should be performed completely, including inspection of all relevant areas, acquisition of appropriate biopsies and completion of all appropriate interventions in accordance with procedural indication.
  - **Indicator 30:** Rate of procedure completeness as defined by inspection of all relevant areas, acquisition of appropriate biopsies and successful completion of interventions.
  - **Indicator 31:** Rate with which endoscopic interventions are performed or eschewed, appropriately.
  - **Indicator 32:** Rate of endoscopic intervention completion.

**PICO Question:**
Are pediatric endoscopic procedures that are performed completely in accordance with procedural indications associated with better outcomes?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Completion of endoscopic procedures and necessary interventions
- **Control/Comparator:** Incomplete procedures or lack of necessary interventions
- **Outcome:**
  - Need for repeat procedure
  - Diagnostic yield
  - Missed diagnosis
  - TI intubation rate
  - Adverse event rate

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Relevant guidelines:**

**Articles excluded:**

**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
There is no clear definition of what constitutes a complete pediatric endoscopic procedure and there is no direct evidence addressing this PICO question.

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be as to whether pediatric endoscopic procedures performed completely in accordance with procedural indications are associated with better outcomes.
STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 35:** Photo/video documentation of all visualized abnormal findings should be obtained.

**PICO Question:**
In pediatric patients undergoing routine and/or emergency endoscopic procedures, what is the best way to document the extent and completeness of the endoscopic examination and abnormal findings?

- **Patient/Population:** Pediatric patients undergoing routine and/or emergency endoscopic procedures

- **Intervention:** Photo/video documentation of requisite anatomical landmarks (EGD: duodenum, retroflexion of the fundus; Ileocolonoscopy: cecum, terminal ileum) and all abnormal findings

- **Control/Comparator:** Documentation of procedure completion and abnormal findings included only in written report (i.e., no photo or video documentation)

- **Outcome:**
  - Need for repeat procedure
  - Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**

**Relevant guidelines:**
PEnQuIN GRADE reporting template


Articles excluded:

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Population</th>
<th>Primary outcome</th>
<th>Main results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rex, 2000¹</td>
<td>Observational</td>
<td>Adult</td>
<td>Still photography versus video recording</td>
<td>Multiple still photographs of cecal landmarks is the most convincing documentation. Cecal videotaping is highly convincing 98.6% of the videotape scores were “probably” or “definitely” the cecum</td>
<td>Frequency of photodocumentation per landmark not provided</td>
</tr>
<tr>
<td>Thoufeeq &amp; Rembacken, 2015²</td>
<td>Retrospective</td>
<td>Adult</td>
<td>Correlation between quality of image documentation of the cecum (CIDS: cecal image documentation score) and polyp detection rate</td>
<td>Endoscopists who are more meticulous in cecal image documentation (CIDS &gt; 2) detect more polyps per procedure and have higher polyp detection rates as compared to those who are less meticulous (CIDS ≤ 2) (OR 2.1, 95% CI [1.45–3.59, P = 0.001)</td>
<td>Retrospective, 16 endoscopists</td>
</tr>
</tbody>
</table>

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
</table>

### Outcome:

#### Risk of bias (study limitations)
(Selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)

<table>
<thead>
<tr>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-randomized</td>
<td>□</td>
<td>✗</td>
</tr>
</tbody>
</table>

#### Inconsistency of results
(Unexplained heterogeneity of results)

<table>
<thead>
<tr>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Different outcome measures assessed</td>
<td>□</td>
<td></td>
</tr>
</tbody>
</table>

#### Indirectness of evidence
(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)

<table>
<thead>
<tr>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific comparison for the outcome of interest Primarily adult data</td>
<td>□</td>
<td></td>
</tr>
</tbody>
</table>

#### Imprecision
(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)

<table>
<thead>
<tr>
<th>No</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference not adequately assessed</td>
<td>□</td>
<td></td>
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</tbody>
</table>

#### Publication Bias
(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)

<table>
<thead>
<tr>
<th>Not assessed</th>
<th>Unlikely</th>
<th>Likely (-1)</th>
<th>Very likely (-2)</th>
</tr>
</thead>
</table>

#### Large effect

<table>
<thead>
<tr>
<th>No</th>
<th>Large (+1)</th>
<th>Very large (+2)</th>
</tr>
</thead>
</table>

#### Effects of all plausible confounding

<table>
<thead>
<tr>
<th>No</th>
<th>Yes (+1)</th>
</tr>
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</table>

#### Dose-response gradient

<table>
<thead>
<tr>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

### STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Overall quality of the evidence (please circle/check-off):**

- 🍂+++ High
- 🍂+++ Moderate
- 🍂+++ Low
- 🍂+++ Very low

### REFERENCES

1. Rex DK. Still photography versus videotaping for documentation of cecal intubation: a

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 36:** Endoscopic biopsies should be obtained as appropriate for the procedural indication, consistent with current evidence-based guidelines, when available.
  - **Indicator 33:** Rate with which biopsies are obtained or eschewed, appropriately.

**PICO Question:**
Does obtaining biopsies as appropriate for the procedural indication, consistent with current, evidence-based guidelines, improve yield?
- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Endoscopic biopsies are taken in accordance with current, evidence-based guidelines where available
- **Control:** Lower than "I"
- **Outcome:** Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 1 pediatric

  - Retrospective cross-sectional evaluation of 153 randomly selected cases (from 2471 children up to 16 years) identified through an electronic theater database over a 30-month period reported a positive diagnostic yield of 18.9% for esophagogastroduodenoscopy (EGD) alone, 32.6% IC alone, and 39.2% with both procedures. In 45% of patients management actively changed due to endoscopy and histopathology findings reinforcing that biopsy sampling is required. Overall, the study reported that endoscopic procedures had a sensitivity of 71.4%, a specificity of 71.4%, a NPV of 76.9% and a PPV of 65.2%. Using the Fagan likelihood ratio nomogram with a pretest probability of making a positive diagnosis before endoscopy set at 42.8% with likelihood ratio of a positive test of 2.49, the authors calculated a post-test probability of 65% indicating a high degree of diagnostic contribution.

**Relevant guidelines:**
  - A systematic literature review of articles studying application of diagnostic and therapeutic endoscopy in the pediatric population (PubMed and/or EMBASE and/or Cochrane publication year 2000 - May 2015 or before if needed).
  - ESGE/ESPGHAN suggests routine tissue sampling even in the absence of visible endoscopic abnormalities in all children undergoing EGD: Weak recommendation, low quality of evidence. ESGE/ESPGHAN suggests using ESPGHAN guidelines
(eosinophilic esophagitis, \textit{H. pylori}, celiac disease, and inflammatory bowel disease (IBD)) for precise indications and preferred sites for biopsy during EGD in children suspected of a specific disease.

- eosinophilic esophagitis: at least 3 biopsy sites with 1-2 biopsies from proximal, middle, and distal esophagus, regardless of the endoscopic appearance of the esophagus.
- \textit{H. pylori} infection: 6 biopsies (2 from antrum and 2 from corpus for Sydney classification; 2 for specific \textit{H. pylori} diagnosis: CLO and culture).
- Celiac disease: at least 1 biopsy from the duodenal bulb and at least 4 biopsies from the 2nd or 3rd portion of the duodenum.
- IBD: multiple biopsies (2 or more per section) from all sections of the visualized GI tract, even in the absence of macroscopic lesions.

  - Systematic literature search (PubMed and/or EMBASE and/or Cochrane, (2000-May 2015, or before if strictly needed), and graded according to the GRADE system. Reiterated the sites of tissue sampling during upper and lower endoscopy suggested by Thomson et al, 2017, however for \textit{H. pylori} suggested 2 biopsies from both antrum and corpus (±fundus) but did not include the 2 additional biopsies for specific \textit{H. pylori} diagnosis (CLO and culture). Grading of the literature for the 2 questions remained unchanged. For colonoscopy, ESGE/ESPGHAN suggest routine biopsy even in the absence of visible endoscopic abnormalities in all children with suspected IBD undergoing ileocolonoscopy: weak recommendation, low quality evidence.

  - A systematic review of the literature (performed on 8 databases of relevance including publications from January 2000 to December 2009). Statements and recommendations were formulated in the following areas: whom to test, how to test, whom to treat, and how to treat. Grades of evidence were assigned to each recommendation based on the GRADE system. For the statement on the diagnosis of \textit{H pylori} infection during EGD, it is recommended that gastric biopsies (antrum and corpus) for histopathology are obtained. Agreement: 93% (agree strongly +33%, agree moderately 40%, just agree 20%, just disagree 7%). Grade of evidence: moderate. It was noted that 2 biopsies should be obtained from both the antrum and the corpus, and the findings should be reported according to the updated Sydney classification.

**Articles excluded:** Adult systematic review and meta-analysis, 3 single center retrospective observational pediatric studies, 1 single center retrospective observational adult study and 1 pediatric systematic review and meta-analysis.

  - Systematic review on the ‘minimum rate of biopsies taken per protocol’ conducted as part of the published guidelines. Bibliographic searches performed on Cochrane Library, PubMed, Embase (1/1/2000-28/2/2015). Systematic reviews and meta-analysis performed on adult studies, the 1st assessed incidence of dysplasia and the 2nd focused on neoplasia detection rate. For the 1st question, “In patients undergoing diagnostic colonoscopy for chronic diarrhea/first diagnostic colonoscopy
in suspected IBD what is the minimum rate of biopsies taken per protocol?,” the authors concluded that no conclusion can be drawn about the minimum number of biopsies or on random versus targeted biopsies because the study did not report this information.

  - Retrospective single center observational study on 170 pediatric patients with crohn disease who underwent computed tomography enterography (CTE) or magnetic resonance enterography and ileocolonoscopy (IC) with TI intubation within a 30-day period (July 2004 - April 2014). PGA used as reference standard for small bowel crohn disease activity. TI macroscopically normal or showed nonspecific inflammation in 73 patients (43%); 36 (49%) had radiologically active disease, 17(47%) had multifocal SB involvement and 5 (14%) had penetrating complications. This study supports the need for cross-sectional imaging in the evaluation of pediatric patients with crohn disease.

  - Single center retrospective observational study that examined rate of concordance between macro and microscopic findings in 51 pediatric patients (0-18 years) who underwent colonoscopy (February 2007 - November 2010), (12 patients excluded a priori due to inadequate bowel prep, and 16 additional patients subsequently excluded from the analysis due to polyps); 35 patients finally evaluated. In the 35 cases, macroscopic findings considered normal in 15 (42.8%) and abnormal in 20 (some alteration detected); on microscopic analysis of normal exams, 10 (67%) showed alteration (eosinophilic colitis), and in the 20 with macroscopic alteration, only 1 was normal. Considering biopsies as a gold standard for the diagnosis of bowel alterations, the authors reported a sensitivity of the colonoscopy without biopsy was 65.52% and specificity was 33.3% (kappa index 0.3063, p< 0.01), which demonstrates a low concordance between macro and microscopic findings. While this study in uncontrolled, has a very small sample size and the majority of patients were investigated for IBD and GI bleed (75%) and doesn't address the specific PICO question, it does demonstrate a low concordance between macro and microscopic findings reinforcing the need for standardized biopsy sampling even in the absence of macroscopic abnormality.

  - A retrospective single center chart review of 100 consecutive pediatric patients (age 11 months to 18 years) who underwent EGD. Quality measures investigated for the intra-procedure period included appropriate number of biopsies for evaluation of celiac disease and biopsies obtained at multiple levels of the esophagus for evaluation of eosinophilic esophagitis. In 8 patients in whom celiac disease was suspected, 63% had at least 6 duodenal biopsies; however, there was insufficient data to determine whether biopsies were obtained from the post-bulbar region and/or bulb. In 28 cases where EGD was performed for either suspicion of eosinophilic esophagitis or surveillance of known eosinophilic esophagitis, 89% had biopsies taken at multiple levels in the esophagus. This study indicates that a suboptimal biopsy number was taken in the evaluation of celiac disease, but for eosinophilic esophagitis sampling appeared adequate. However, no information is provided on histology.

• Single center retrospective chart review (Mayo clinic). Analyzed data from 189 consecutive patients (median age, 41 years; range, 14–80 years, 55% women) with Crohn disease in 2009 evaluated by CTE and ileocolonoscopy (IC). Of 153 patients (80.1%) who had TI intubation; 67 (43.8%) had normal results from IC based on endoscopic appearance. Despite their normal results from ileoscopy, 36 of these patients (53.7%) had active, small bowel crohn disease. The ileum appeared normal at ileoscopy because the disease had skipped the distal ileum of 11 patients (30.6%), developed only in the intramural and mesenteric distal ileum of 23 patients (63.9%), and appeared only in the upper gastrointestinal region of 2 patients (5.6%). CTE detected extracolonic Crohn disease in 26% of patients.

  • Evaluated published data (1980-2016) on the practice of pediatric digestive endoscopy. Of 301 articles identified, 23 articles selected. Cecum and TI intubation rates were respectively 88.7% ± 2.3% and 83.9% ± 0.2% (n = 3 studies). EGDs were macroscopically normal in 51.8% ± 4.3% of cases (n = 6 studies) and microscopically normal in 47.8% ± 11.8% (n = 2 studies). Colonoscopies were macroscopically normal in 41.6% ± 1.7% (n = 4 studies) and microscopically normal in 40.0% ± 10.0% (n = 2 studies). Data too incomplete for adequate evaluation; i.e., no information provided on indications for biopsies, sites of biopsies, whether there was any correlation between macroscopic and microscopic findings and the relevance of the findings.

  • They reaffirm that a macroscopically normal colonoscopy does not exclude all causes of diarrhea. A study of 809 cases found clinically relevant abnormalities in 15% with a macroscopically normal examination

  • In this study, the most common diagnosis was microscopic colitis (80 cases, 10%), including lymphocytic and collagenous colitis


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
Currently the quality of evidence from the pediatric studies addressing this question is low; however, the pediatric consensus statements recommend routine tissue sampling even in the absence of visible endoscopic abnormalities in all children undergoing EGD: weak recommendation, low quality of evidence. ESGE/ESPGHAN¹ suggests using ESPGHAN guidelines (eosinophilic esophagitis, H. pylori, celiac disease, and IBD) for precise indications and preferred sites for biopsy during EGD in children suspected of a specific disease. For colonoscopy, ESGE/ESPGHAN¹ suggest routine biopsy even in the absence of visible endoscopic abnormalities in all children with suspected IBD undergoing ileocolonoscopy: weak recommendation, low quality evidence. Moreover the colonoscopy statement should be extended to all colonoscopy procedures (e.g., the adult study by Ress et al² reaffirmed that a macroscopically normal colonoscopy does not exclude all causes of diarrhea, having found clinically relevant abnormalities in 15% of cases with a macroscopically normal examination).
One pediatric\(^3\) and one adult study\(^4\) that were excluded didn't address the primary question but did demonstrate that evaluation of the SB is required in the evaluation of Crohn disease patients (49% of pediatric patients with macroscopically normal TI or nonspecific inflammation and 53.7% of adult patients with macroscopically normal TI had active small bowel disease). The systematic review by Shema et al\(^5\) was excluded, however the study reported that EGDs were macroscopically normal in 51.8% ± 4.3% of cases (n = 6 studies) and microscopically normal in 47.8% ± 11.8% (n = 2 studies), and colonoscopies were macroscopically normal in 41.6% ± 1.7% (n = 4 studies) and microscopically normal in 40.0% ± 10.0% (n = 2 studies).

In conclusion, more studies are required to validate the current consensus statements with correlation between macroscopic and microscopic findings and how this impacts clinical decisions.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Small sample size, selection bias</td>
<td>High</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td>Studies mostly limited to specific diseases, histology data not always provided, guidelines not always followed</td>
<td>Moderate</td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td>Small sample size, few events</td>
<td>Low</td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imprecision</td>
<td>No</td>
<td></td>
<td>Very Low</td>
</tr>
<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication Bias</td>
<td>Not assessed</td>
<td></td>
<td>Very Low</td>
</tr>
<tr>
<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Unlikely (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>Large (+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- High
- Moderate
- Low
- Very low

REFERENCES

OVERALL RATING

- **Standard 37**: Pediatric endoscopic procedures should be reported in a manner that allows for full documentation of all necessary and mandated clinical and quality measures.

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌟🌟🌟🌟 High</td>
</tr>
<tr>
<td>🌟🌟🌟 Moderate</td>
</tr>
<tr>
<td>🌟🌟 Low</td>
</tr>
<tr>
<td>🌟🌟🌟🌟🌟 Very low</td>
</tr>
</tbody>
</table>

- See data for individual PICO statements below
STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 37**: Pediatric endoscopic procedures should be reported in a manner that allows for full documentation of all necessary and mandated clinical and quality measures.
  - **Indicator 34**: Rate with which the endoscopy report documents findings.

**PICO Question:**
In pediatric patients undergoing routine and/or emergency endoscopic procedures, what is the best way to document the extent and completeness of the endoscopic examination and abnormal findings?

- **Patient/Population**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Photo-documentation of requisite anatomical landmarks (EGD: duodenum, retroflexion of the fundus; Ileocolonoscopy: cecum, terminal ileum) and all abnormal findings
- **Control/Comparator**: Documentation of procedure completion and abnormal findings included only in written report (i.e., no photodocumentation)
- **Outcome**:
  - Need for repeat procedure
  - Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**

**Relevant guidelines:**


Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

### Summary of the Evidence:

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Population</th>
<th>Primary outcome</th>
<th>Main results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rex, 2000¹</td>
<td>Observational</td>
<td>Adult</td>
<td>Still photography versus video recording</td>
<td>Multiple still photographs of cecal landmarks is the most convincing documentation. Cecal videotaping is highly convincing 98.6% of the videotape scores were “probably” or “definitely” the cecum</td>
<td>Frequency of photodocumentation per landmark not provided</td>
</tr>
<tr>
<td>Thoufeeq &amp; Rembacken, 2015²</td>
<td>Retrospective</td>
<td>Adult</td>
<td>Correlation between quality of image documentation of the cecum (CIDS: cecal image documentation score) and polyp detection rate</td>
<td>Endoscopists who are more meticulous in cecal image documentation (CIDS &gt; 2) detect more polyps per procedure and have higher polyp detection rates as compared to those who are less meticulous (CIDS &lt; 2) (OR 2.1, 95% CI [1.45–3.59], P = 0.001)</td>
<td>Retrospective, 16 endoscopists</td>
</tr>
</tbody>
</table>

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study)</td>
<td>No</td>
<td>□ Non-randomized</td>
<td>☀ ☀ ☀ ☀ ☀</td>
</tr>
</tbody>
</table>
# PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Limitations</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
<th>High</th>
<th>Moderate</th>
<th>Low</th>
<th>Very Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inconsistency of results</th>
<th>No Serious (-1)</th>
<th>Very serious (-2)</th>
<th>Different outcome measures assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indirectness of evidence</th>
<th>No Serious (-1)</th>
<th>Very serious (-2)</th>
<th>No specific comparison for the outcome of interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Imprecision</th>
<th>No Serious (-1)</th>
<th>Very serious (-2)</th>
<th>Difference not adequately assessed</th>
</tr>
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<tbody>
<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Publication Bias</th>
<th>Not assessed</th>
<th>Unlikely</th>
<th>Likely (-1)</th>
<th>Very likely (-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Large effect</th>
<th>No Large (+1)</th>
<th>Very large (+2)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects of all plausible confounding</th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dose-response gradient</th>
<th>No</th>
<th>Yes (+1)</th>
</tr>
</thead>
</table>

## STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Overall quality of the evidence (please circle/check-off):**

- [ ] High
- [ ] Moderate
- [ ] Low
- [x] Very Low

## REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 37**: Pediatric endoscopic procedures should be reported in a manner that allows for full documentation of all necessary and mandated clinical and quality measures.
  - **Indicator 35**: Rate with which the endoscopy report documentation is complete.
  - **Indicator 36**: Rate with which the endoscopy report documentation is finalized.
  - **Indicator 37**: Rate with which endoscopy report documentation is finalized in a timely manner.

**PICO Question:**
How should endoscopic procedures be reported to ensure documentation of all necessary and mandated clinical and quality measures?

- **Patient/Population**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Standardized report
- **Control**: No intervention
- **Outcome**:
  - Time to report completion
  - Report completion rate
  - Rate of complete documentation (i.e. all relevant and required information included)
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 1 pediatric, 3 adult

**Relevant guidelines**:
PEnQuIN GRADE reporting template


**Articles excluded:**
### Summary of the Evidence:

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Population</th>
<th>Aim</th>
<th>Main results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Israel, 2012</td>
<td>Observational</td>
<td>Pediatric</td>
<td>To create and evaluate a quality measures program for colonoscopy procedures</td>
<td>Measures of documentation, such as bowel preparation quality, are most easy to improve upon with proper training in documentation</td>
<td>Abstract; methodology details are missing</td>
</tr>
<tr>
<td>Coe, 2012</td>
<td>Observational; historical control</td>
<td>Adult</td>
<td>To determine degree of compliance to the intra-procedure colonoscopy quality indicator (QI) prior to intervention, design an educational intervention to improve those with low compliance, and to compare the degree of compliance after intervention</td>
<td>Four QIs; documentation of bowel preparation adequacy, appendiceal orifice, photographs of cecum, and polyp shape, had significant improvement</td>
<td>Historical control</td>
</tr>
<tr>
<td>Groenen, 2009</td>
<td>Observational</td>
<td>Adult</td>
<td>To evaluate the costs of three different ways of producing reports; by hand, by dictation, or by computer</td>
<td>The electronic production of an endoscopic report was the most expensive during the first 5 years; Cost-benefit analysis showed a positive financial benefit for computerized reports after 3 years</td>
<td></td>
</tr>
<tr>
<td>Soekho, 2007</td>
<td>Observational</td>
<td>Adult</td>
<td>To compare time aspects of different methods of report writing</td>
<td>Computerized, pre-defined reports could be composed in almost the same amount of time as handwritten and dictated reports</td>
<td></td>
</tr>
</tbody>
</table>

### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Non-randomized</td>
<td>☭✭✭✭ High</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☭✭✭✭✭✭ Moderate</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Different outcome measures assessed</td>
<td>☭✭✭✭✭✭ Low</td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>No specific comparison for the outcome of interest Primarily adult data</td>
<td>☭✭✭✭✭✭ Low</td>
</tr>
</tbody>
</table>
### PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Imprecision</th>
<th>No Serious (-1)</th>
<th>Very serious (-2)</th>
<th>Difference not adequately assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication Bias</td>
<td>Not assessed</td>
<td>Unlikely</td>
<td>Likely (-1)</td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>Large (+1)</td>
<td>Very large (+2)</td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
</tbody>
</table>

**Very Low**

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**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- **⊕⊕⊕⊕** High
- **⊕⊕⊕⊕** Moderate
- **⊕⊕⊕** Low
- **⊕⊕** Very low

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**REFERENCES**

PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 38**: Pediatric endoscopic procedures should be reported using standardized disease-related terminology and/or scales, when available.

PICO Question:
In pediatric patients undergoing routine and/or emergency endoscopic procedures, what is the best way to document abnormal findings?

- **Patient/Population**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Application of standardized disease-related terminology and/or scales, when available
- **Control**: Standardized disease-related terminology and/or scales not used to describe abnormal findings
- **Outcome**:
  - Need for repeat procedure
  - Diagnostic yield
  - Agreement between clinical diagnostic impression and histology

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

Studies included:
- None

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.

STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Conclusion:
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn regarding the best way to document abnormal findings in pediatric patients undergoing routine and/or emergency endoscopic procedures.
STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 39:** All patients and/or caregivers, on discharge, should be given written information regarding potential symptoms that may indicate a procedure-related adverse event and instructions on what to do should these symptoms develop.
  - **Indicator 38:** Rate with which patients/caregivers receive written postprocedure instructions upon discharge.

**PICO Question:**
Is undergoing pediatric endoscopy in a facility that provides written information regarding potential symptoms that may indicate a procedural related adverse event, and instructions on what to do should these symptoms develop, associated with improved outcomes?

- **Population:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Provision of written information regarding potential symptoms that may indicate a procedural related adverse event, and instructions on what to do should these symptoms develop
- **Control:** Written information not provided
- **Outcome:**
  - Patient experience
  - Patient recall of information
  - Delay in seeking medical attention
  - Adverse event-related outcomes

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 3 adult, 1 pediatric

Adult studies:

Pediatric studies:

**Articles excluded:**

Adults studies:
PEnQuIN GRADE reporting template


Pediatric studies:

**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
There is very little evidence available and the quality is low on the role of written information provided on discharge. The available evidence is based in observational, non-randomized studies and qualitative studies.

Only one pediatric study has assessed this question. Jacob et al.\(^1\) evaluated patients’ satisfaction by using a specific questionnaire. Those patients who received clear and written information after procedure discharge had higher satisfaction.

Regarding the adult literature, Spodik et al.\(^2\) conducted a two-group study (non-randomized) which compared those receiving an endoscopy report and discharge information with those receiving discharge information only. Provision of an endoscopy report which included discharge information, taken directly from the discharge instructions sheet which participants also received, reduced patients’ post-procedure anxiety, improved their recall of findings and recommendations and improved adherence to recommendations as compared to those receiving the discharge information only. Other studies have shown that patients are aware of what to do in the event of an adverse event and they have higher satisfaction if they are given written information.\(^3,4\)
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias (study limitations)</strong> (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Single center studies, non-randomized</td>
<td></td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong> (Unexplained heterogeneity of results)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Indirectness of evidence</strong> (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Mainly based on adult studies, only 1 pediatric study</td>
<td></td>
</tr>
<tr>
<td><strong>Imprecision</strong> (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Number of events</td>
<td></td>
</tr>
<tr>
<td><strong>Publication Bias</strong> (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Large effect</strong></td>
<td>No Large (+1) Very large (+2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td>No Yes (+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No Yes (+1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**STEP 4:** Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

---

**Overall quality of the evidence (please circle/check-off):**

- High
- Moderate
- Low
- Very Low

---

3
REFERENCES


STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):

- **Standard 40:** Before discharge, all patients and/or caregivers should be given written and/or verbal information regarding the endoscopic findings, plans for conveying pathology results and follow-up. This process must be documented.
  - **Indicator 39:** Rate with which the plan for pathology follow-up is communicated to patients/caregivers.

**PICO Question:**
Does provision of written and verbal information about the endoscopic findings and plans for communication of results and follow-up improve patient/family experience and understanding of pathology results?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Providing written and/or verbal information regarding the endoscopic findings, plans for conveying pathology results and follow-up
- **Control/Comparator:** No information provided or there is a delay in providing information
- **Outcome:**
  - Understanding of results and follow-up plan
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 1 pediatric, 4 adult

  - A pediatric, retrospective questionnaire study involving a phone call by one investigator 2-3 weeks after a procedure. Questions answered based on recall. It was clear that prompt communication and explanation was a good thing judging by the qualitative information reported and some of the patient replies which were also reported verbatim. Of the patients in the study, only 19 had been seen in outpatient department or phoned with results by the time of the phone call. The outcome of the other 28 patients was not reported and there was no indication as to the average reporting time of pathology in their hospital. Eighteen of 19 caregivers remembered being told the pathology and follow-up. There is very serious risk of bias despite structured phone questionnaire, especially with regard to selection of who was called, family recall of what was said (subjective recall), patient procedure selection (some upper, some colonoscopy, some upper/ colonoscopies). The authors concluded that effective pre- and post-procedure information is important, especially post-procedure information regarding the results and management plan.

  - Adult, prospective, randomized, single-center, investigator-blinded study with 115 randomized. Only 83 completed the study protocol. Participants were randomized to receive either discharge instructions only or discharge instructions and a copy of the
endoscopy report at the time of discharge from the endoscopy suite. Receiving the report reduced post-procedure anxiety \((P = 0.001)\) and increased recall of findings and recommendations. After controlling for the type of procedure, age, sex, and race, the intervention group was found to have higher satisfaction scores than the standard group by an average of 3 points, but this was not statistically significant \((P = 0.100)\). Older patients were more likely to receive the report \((P = 0.037)\) and older patients had significantly lower satisfaction scores by 6 points \((P = 0.004)\).

  - An adult, prospective audit of 1187 patient’s experience with colonoscopy. 1187 patients completed the pre-questionnaire, 851 (71.9%) completed the post-questionnaire. 54% were seen in the outpatient department before the procedure. Participants reported that the indication was explained in 85%, 65% said they received information on risks, 94% received information on sedation, 23% judged their colonoscopy to be more uncomfortable than expected. Twenty-one percent of patients said they left hospital not knowing how they would get results, although 87% remembered having the endoscopic findings discussed with them. The authors concluded that effective pre- and post-procedure communication were key.

  - An adult prospective survey of endoscopy patients to identify system improvements that were then implemented. The survey, which was administered a day after endoscopy, was performed before \((N = 71)\) and after \((N = 60)\) process improvements identified by the initial survey. Information provision and staff communication skills were identified for optimization. Education of endoscopy staff significantly improved the quality of information provided before and after the procedure. More patients in the “after” group than the “before” group reported that they, or the person collecting them, remembered the doctor explaining the findings (89 vs. 100 %, \(p = 0.007\)) and the intended follow-up (73 vs. 90 %, \(p = 0.015\)). At the close of the audit cycle, 95% of patients reported a high level of satisfaction with their overall endoscopy journey. The pre-audit satisfaction level was not reported.

  - This is an adult-focused systematic review examining literature on quality that is relevant to patients who require colonoscopy or endoscopy services. The authors found 4 studies which reported that discussion of the results with the endoscopist influenced patient satisfaction.\(^1\) In one study, discussing the results with the endoscopist following the colonoscopy was associated with greater willingness to return for colonoscopy.\(^2\)

**Articles excluded:**

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
In the one pediatric study by Jacobs et al. only 19 (40.4%) of 47 families had a follow-up visit or call after the procedure. Of the 19, 18 (94.7%) remember having a discussion about the pathology results. The authors comment that not having the pathology results in hand did not appear to be a prominent source of concern among families; however, whether this was asked explicitly was not stated. Additionally, in most cases, the endoscopist had come out following the procedure and discussed the gross anatomy findings. The outcome of the other 28 patients who did not receive a follow-up visit or call is not reported. There is very serious risk of bias with regard to patient selection bias, recall and indirectness. The study does not specifically address provision of pathology and management information.

There were 3 adult studies. De Jong et al. conducted a prospective audit of 1187 patient’s experience with colonoscopy. While 1187 patients completed the pre-questionnaire only 851 (71.9%) completed the post-questionnaire, therefore introducing bias into the study. Twenty-one percent of patients said they left hospital not knowing how they would get results, although 87% remembered having the endoscopic findings discussed with them. Discussion of pathology findings was not directly assessed. Spodik et al. carried out a prospective, randomized, single-center, investigator-blinded study with 115 randomized. Only 83 completed the study protocol. Participants were randomized to receive either discharge instructions only or discharge instructions and a copy of the endoscopy report at the time of discharge from the endoscopy suite. Receiving the report reduced post-procedure anxiety ($P = 0.001$) and increased recall of findings and recommendations. After controlling for the type of procedure, age, sex, and race, the intervention group was found to have higher satisfaction scores than the standard group by an average of 3 points, but this was not statistically significant ($P = 0.100$). Older patients were more likely to receive the report ($P = 0.037$) and older patients had significantly lower satisfaction scores by 6 points ($P = 0.004$). Recall bias is an issue as patients were asked to recall findings and recommendations. Toomey et al. conducted a prospective survey of adult endoscopy patients to identify system improvements that were then implemented. The survey, which was administered a day after endoscopy, was performed before (N = 71) and after (N = 60) process improvements identified by the initial survey. Information provision and staff communication skills were identified for optimization. Education of endoscopy staff significantly improved the quality of information provided before and after the procedure. More patients in the “after” group than the “before” group reported that they, or the person collecting them, remembered the doctor explaining the findings (89 vs. 100%, $p = 0.007$) and the intended follow-up (73 vs. 90%, $p = 0.015$). At the close of the audit cycle, 95% of patients reported a high level of satisfaction with their overall endoscopy journey. The pre-audit satisfaction level was not reported.

One adult-focused systematic review examining literature on quality relevant to patients who require colonoscopy or endoscopy services found 4 studies which reported that discussion of the results with the endoscopist influenced patient satisfaction. In one study, discussing the results with the endoscopist following the colonoscopy was associated with greater willingness to return for colonoscopy.

Due to the type of studies being observational, the evidence starts off as low quality. In the pediatric paper participant numbers are low, reporting is inconsistent and there is bias at all stages including selection, reporting, detection and attrition which drops the quality down to very low. Additionally, the adult papers only provide indirect evidence.
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating</th>
<th>List reasons for downgrading or upgrading evidence</th>
<th>Quality of the evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1) Very serious (-2)</td>
<td>In the pediatric paper participant numbers are low, reporting is inconsistent and there is bias at all stages including selection, reporting, detection and attrition which drops the quality down to very low.</td>
<td></td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>Serious (-1) Very serious (-2)</td>
<td>2 adult papers provide indirect evidence.</td>
<td></td>
</tr>
<tr>
<td>Imprecision</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication Bias</td>
<td>Not assessed</td>
<td>Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
</tr>
<tr>
<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td></td>
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</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large (+1) Very large (+2)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Overall quality of the evidence (please circle/check-off):

- ☐ ☐ ☐ ☐ High
- ☐ ☐ ☐ ☐ Moderate
- ☐ ☐ ☐ ☑ Low
- ☐ ☐ ☐ ☐ Very low

REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 41**: Pathology findings should be reviewed with patients and/or caregivers in a timely fashion. This process must be documented.
  - **Indicator 40**: Rate with which pathology findings are reviewed with the patient and/or caregiver.

**PICO Question:**
Does timely review of pathology results with patients/families improve patient/family experience and understanding of pathology results?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Discussion of pathology with patients/families in a timely fashion with no delays
- **Control/Comparator**: Patients/families who have not had pathology discussed with them and/or there is a delay
- **Outcome**:
  - Understanding of results
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 1 pediatric, 1 adult
  - A pediatric, retrospective questionnaire study involving a phone call by one investigator 2-3 weeks after a procedure. Questions answered based on recall. It was clear that prompt communication and explanation was a good thing judging by the qualitative information reported and some of the patient replies which were also reported verbatim. Of the patients in the study, only 19 had been seen in outpatient department or phoned with results by the time of the phone call. The outcome of the other 28 patients was not reported and there was no indication as to the average reporting time of pathology in their hospital. Of the 19, 18 (94.7%) remember having a discussion about the pathology results. The authors comment that not having the pathology results in hand did not appear to be a prominent source of concern among families; however, whether this was asked explicitly was not stated. Additionally, in most cases, the endoscopist had come out following the procedure and discussed the gross anatomy findings.
  - An adult, prospective audit of 1187 patient’s experience with colonoscopy. 1187 patients completed the pre-questionnaire; 851 (71.9%) completed the post-questionnaire. Twenty-one percent of patients said they left hospital not knowing how
they would get results, although 87% remembered having the endoscopic findings discussed with them. Discussion of pathology findings was not directly assessed.

**Articles excluded:**

**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
In the one pediatric study by Jacob et al. only 19 (40.4%) of 47 families had a follow-up visit or call after the procedure. Of the 19, 18 (94.7%) remember having a discussion about the pathology results. The authors comment that not having the pathology results in hand did not appear to be a prominent source of concern among families; however, whether this was asked explicitly was not stated. Additionally, in most cases, the endoscopist had come out following the procedure and discussed the gross anatomy findings. The outcome of the other 28 patients who did not receive a follow-up visit or call is not reported. There is very serious risk of bias with regard to patient selection bias, recall and indirectness. The study does not specifically address provision of pathology and management information.

There was one adult study by De Jong et al. who conducted a prospective audit of 1187 patient’s experience with colonoscopy. While 1187 patients completed the pre-questionnaire only 851 (71.9%) completed the post-questionnaire, therefore introducing bias into the study. Twenty-one percent of patients said they left hospital not knowing how they would get results, although 87% remembered having the endoscopic findings discussed with them. Discussion of pathology findings was not directly assessed.

Due to the type of studies being observational, the evidence starts off as low quality. In the pediatric paper, participant numbers are low, reporting is inconsistent and there is bias at all stages including selection, reporting, detection and attrition, which drops the quality down to very low. Additionally, the adult paper only provides indirect evidence and did not directly assess discussion of pathology results.

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias</strong></td>
<td>No × Serious (-1) × Very serious (-2)</td>
<td>□ In the pediatric paper, participant numbers are low, reporting is inconsistent and there is bias at all stages including selection, reporting, detection and attrition, which drops the quality down to very low.</td>
<td>□ High</td>
</tr>
<tr>
<td>(study limitations)</td>
<td></td>
<td></td>
<td>□ Moderate</td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inconsistency of results</strong></td>
<td>No × Serious (-1) × Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Indirectness of evidence</strong></td>
<td>No × Serious (-1)</td>
<td>□ 2 adult papers provide indirect evidence.</td>
<td></td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the)</td>
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</tbody>
</table>
### PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th></th>
<th>Very serious (-2)</th>
<th>Serious (-1)</th>
<th>Very serious (-2)</th>
<th>Low</th>
<th>Very Low</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interventions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Imprecision</strong></td>
<td>No</td>
<td>Serious (-1)</td>
<td>Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Publication Bias</strong></td>
<td>Not assessed</td>
<td>Unlikely</td>
<td>Likely (-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Likely (-1)</td>
<td>Very likely (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Large effect</strong></td>
<td>No</td>
<td>Large (+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very large (+2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Effects of all plausible confounding</strong></td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose-response gradient</strong></td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

- **Overall quality of the evidence (please circle/check-off):**
  - High
  - Moderate
  - Low
  - Very low

### REFERENCES

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):

- **Standard 42**: All endoscopists engaged, directly or indirectly, in endoscopy service delivery to pediatric patients should be trained and certified as having competence to perform specified routine and/or emergency pediatric endoscopic procedures according to appropriate standards.
  - **Indicator 41**: Rate with which pediatric endoscopies are performed by trained and credentialed endoscopists.

**PICO Question:**
Should endoscopists performing procedures on pediatric patients be required to be trained and certified as having competence to perform specified routine and/or emergency pediatric endoscopic procedures according to appropriate standards?

- **Population/Patient**: Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention**: Endoscopists trained and certified as having competency to perform pediatric procedures
- **Control/Comparator**: Endoscopists not trained and certified as having competence to perform pediatric procedures
- **Outcome(s)**:
  - Cecal intubation rate
  - Terminal ileal intubation rate
  - Need for assistance
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 1 pediatric, 4 adult

Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

The only pediatric-related study is a retrospective review by Suzuki et al. which examined 256 pediatric colonoscopy procedures performed by adult gastroenterologists in Japan. Adult endoscopists were able to achieve a 98.4% terminal ileal intubation rate, with a mean intubation time of 6.2 +/- 3.5 min, a diagnostic yield of 60.5%, and had no complications. However, performance was not compared against pediatric endoscopists and details regarding training and credentialing of the adult gastroenterologists was not specified.

In the adult literature, there are a few studies which have examined the relationship between physicians’ specialty and colonoscopy-related outcomes. Bielawaska et al. performed a multivariate analysis of risk factors for early perforations (n=192) in 1,144,900 adult colonoscopies using the Clinical Outcomes Research Initiative National Endoscopic Database. Colonoscopies performed by surgeons and endoscopists of unknown specialty had higher rates of perforation than those performed by gastroenterologists (odds ratio, 2.00; 95% confidence interval (CI), 1.30–3.08). Bressler, et al. analyzed data from the Canadian Institute for Health Information, the Ontario Health Insurance Program, and Ontario Cancer Registry for all patients (>20 years of age) with a new diagnosis colorectal cancer (CRC) who had a colonoscopy within 3 years before their diagnosis. Patients with a new or missed colorectal cancer (defined as having a colonoscopy to the site of the CRC within 3 years before their diagnosis date) were more likely to have the index procedure done by an internist or a family physician, as compared with a surgeon or gastroenterologist (p < 0.001). Similarly, Singh et al. analyzed 388 early/missed colorectal cancers (CRC detected 6-36 months after a colonoscopy) identified from the Manitoba Cancer Registry for independent risk factors associated with early/missed CRCs. Patients with early/missed CRC were more likely to have their index colonoscopy performed by a family physician as compared with a gastroenterologist (OR 1.59, 95% CI: 1.01 – 2.47). There was no difference between surgeons, internists and gastroenterologists. In all of the aforementioned studies, details of the training and credentialing processes of endoscopists was lacking.

Bhangu et al. conducted a prospective review of 10,026 colonoscopies performed at a hospital in the United Kingdom and found that endoscopists accredited for bowel cancer screening colonoscopy as part of the National Health Service Bowel Cancer Screening Programme (BCSP) had a higher adenoma detection rate (OR 1.26, 95% CI: 1.10-1.46, P<0.001) as compared with those who were not credentialed. In the same cohort, surgeons (general or colorectal) had better adenoma detection rates (OR 1.27, 95% CI: 1.14-1.41, P<0.001) and polyp detection rates (OR 1.48, 95% CI: 1.36-1.61, P<0.001) but lower cecal intubation rates (OR 0.72, 95% CI: 0.63 – 0.83, P<0.001) as compared with physicians (general or gastroenterologists).
Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td>Serious (-1)&lt;br&gt;Very serious (-2)</td>
<td></td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of results)</td>
<td>No</td>
<td>Serious (-1)&lt;br&gt;Very serious (-2)</td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence (Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No</td>
<td>Serious (-1)&lt;br&gt;Very serious (-2)</td>
<td>Mainly adult studies that deal with outcomes not relevant to pediatric endoscopy (e.g., adenoma detection rate)</td>
</tr>
<tr>
<td>Imprecision (Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No</td>
<td>Serious (-1)&lt;br&gt;Very serious (-2)</td>
<td></td>
</tr>
<tr>
<td>Publication Bias (Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed</td>
<td>Unlikely&lt;br&gt;Likely (-1)&lt;br&gt;Very likely (-2)</td>
<td></td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>Large (+1)&lt;br&gt;Very large (+2)</td>
<td></td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
<tr>
<td>Dose-response gradient</td>
<td>No</td>
<td>Yes (+1)</td>
<td></td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- **High**
- **Moderate**
- **Low**
- **Very Low**

**Quality of the evidence (1 per outcome):**

- **High**
- **Moderate**
- **Low**
- **Very Low**
REFERENCES


PEnQuIN GRADE reporting template

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s)**
- **Standard 43**: Endoscopists who perform procedures on pediatric patients should be granted privileges to perform specified pediatric procedures based on a formal assessment of their competence consistent with appropriate standards, when available.
  - **Indicator 42**: Rate with which the competence of practicing pediatric endoscopists is assessed.

**PICO Question:**
What is the most appropriate frequency with which the competence of credentialed endoscopists performing routine and/or emergency endoscopic procedures on pediatric patients is assessed?

- **Population/Patient**: Credentialed endoscopists performing routine and/or emergency endoscopic procedures on pediatric patients
- **Intervention**: Minimum assessment frequency of credentialed endoscopists
- **Control/Comparator**: Lower than “I”
- **Outcome(s):**
  - Cecal intubation rate
  - Terminal ileal intubation rate
  - Need for assistance
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Articles excluded:**
**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
Once an endoscopist is licensed, assessment measures can be used by practicing endoscopists to ensure ongoing provision of high-quality endoscopy services, to promote improvements in care delivery, and ultimately, to enhance health-care outcomes. In the adult literature, some studies have shown a correlation between annual endoscopy volume and/or lifelong endoscopy volume and measures of endoscopic competence, such as adenoma detection rate; however, this relationship is not consistent. There is no direct evidence which assesses the frequency with which credentialed endoscopists should be assessed.

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Conclusion:**
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn regarding the most appropriate frequency with which the competence of credentialed endoscopists performing pediatric diagnostic upper endoscopy and/or colonoscopy should be assessed.

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s)**
- **Standard 44:** The privileges of endoscopists who perform procedures on pediatric patients should be subject to formal, regular, scheduled review to ensure that renewal is based on documented competence to perform specified pediatric procedures consistent with appropriate current standards, when available.

**PICO Question:**
Does formal, regular, scheduled review of documented competence of individual physicians by facilities permitting endoscopic procedures on pediatric patients improve endoscopy quality?

- **Population/Patient:** Pediatric patients undergoing routine and/or emergency endoscopic procedures
- **Intervention:** Having the procedure performed in a facility that has a scheduled review of documented competence of individual physicians
- **Control/Comparator:** Having the procedure performed in a facility that has no scheduled review of documented competence of individual physicians
- **Outcome:**
  - Diagnostic yield
  - Terminal ileal intubation rate
  - Cecal intubation rate
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:**
- None

**Relevant guidelines:**

**Articles excluded:**
STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.

STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

Conclusion:
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn as to whether endoscopy quality is improved in facilities which have formal, regular, scheduled review of documented competence of individual physicians improves endoscopy quality.
**STEP 1: Create a PICO question(s) for your standard/indicator**

**Standard(s)/Indicator(s)**
- **Standard 45**: Endoscopists who perform procedures on pediatric patients should regularly review their endoscopic practice and outcome data with the aim of continuous professional development.
  - **Indicator 43**: Number of procedures performed annually.

**PICO Question:**
Does collecting, maintaining and providing information on quality indicators for each individual endoscopist performing procedures on children improve outcomes?

- **Population/Patient**: Endoscopists performing endoscopic procedures on children
- **Intervention**: Endoscopists who receive/collect and review information on their endoscopy-related quality indicators
- **Control/Comparator**: Endoscopists who do not receive/collect and review information on their endoscopy-related quality indicators
- **Outcome**: Change in quality indicator(s) (e.g., ileal intubation rate, cecal intubation rate) over time

**STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.**

**Studies included:**


**Relevant guidelines:**


**Articles excluded:**

### Summary of Evidence:
Only one study by Abdul-Baki et al.\(^1\) evaluated public disclosure of endoscopists’ quality metrics. It was an adult study, observational, with small numbers and, therefore, it was assessed to be of low to very low quality. Additionally, it did not evaluate any negative effects.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study type (Starting Quality)</th>
<th>Results</th>
<th>Risk of bias</th>
<th>Inconsistency of Results</th>
<th>Indirectness of Evidence</th>
<th>Imprecision</th>
<th>Large Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdul-Baki et al.(^1)</td>
<td>Observational (Low)</td>
<td>Public reporting increased ADR</td>
<td>Selection bias: More screening colonoscopies post reporting&lt;br&gt;Selection bias: Time before and time after were not equal&lt;br&gt;Selection bias: More screening colonoscopies post reporting</td>
<td>Adult study&lt;br&gt;Outcome: Adenoma detection rate</td>
<td></td>
<td></td>
<td>ADR 45% higher in public report period with large # of data points</td>
</tr>
<tr>
<td>Barclay et al.(^2)</td>
<td>Observational (Low)</td>
<td>Advanced neoplasia improved but not ADR</td>
<td>Performance bias: Education campaign before 8 min timing</td>
<td>Adult study&lt;br&gt;Outcome: ADR and neoplasia detection rate</td>
<td></td>
<td></td>
<td>Limited number of events per physician</td>
</tr>
<tr>
<td>Corley et al.(^3)</td>
<td>Systematic Review</td>
<td>MD behavior can change but no clear evidence that quality measure changes</td>
<td></td>
<td>Adult study&lt;br&gt;Outcome: ADR</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Deng et al.(^4)</td>
<td>Observational (Low)</td>
<td>The reporting and review of procedure details help to improve quality indicators of colonoscopy</td>
<td></td>
<td>Adult&lt;br&gt;Outcome: ADR (cecal intubation, withdrawal time)</td>
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<td>Number of events per physician &lt; 300</td>
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<tr>
<td>Fraser et al.(^5)</td>
<td>Observational (Low)</td>
<td>Colonoscopy audit may improve performance indicators</td>
<td>Performance bias, as may have improved from multiple other effects besides audit</td>
<td>Adult study&lt;br&gt;Outcome: ADR</td>
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<td>Number of events</td>
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<tr>
<td>Gurudu et al.(^6)</td>
<td>Observational (Low)</td>
<td>Monthly feedback significantly improved colonoscopy quality measures, including ADR, while quarterly feedback did not.</td>
<td>Performance bias, as may have improved from multiple other effects besides audit</td>
<td>Adult study&lt;br&gt;Outcome: ADR</td>
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<tr>
<td>Harewood et al.(^7)</td>
<td>Observational (Low)</td>
<td>Quarterly feedback improves colonoscopy completion rates and shortens insertion times</td>
<td>Performance bias, as may have improved from multiple other effects besides audit</td>
<td>Adult study</td>
<td></td>
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<tr>
<td>Harewood et al.(^8)</td>
<td>Randomized (High)</td>
<td>Monthly feedback improves cecal intubation but not ADR among GI trainees</td>
<td>No difference in ADR</td>
<td>Adult study&lt;br&gt;Outcome: ADR</td>
<td></td>
<td></td>
<td>Number of events (4 trainees)</td>
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<tr>
<td>Imperiali et al.(^9)</td>
<td>Observational (Low)</td>
<td>6 month audits improved cecal intubation, not ADR, but ADR detection more consistent</td>
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<td>Adult study</td>
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<tr>
<td>Kahi et al.(^10)</td>
<td>Observational (Low)</td>
<td>A quarterly report card was associated with improved colonoscopy quality indicators</td>
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<td>Adult study</td>
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<td>Number of events</td>
</tr>
</tbody>
</table>
### Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
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</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
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<tr>
<td>Risk of bias (study limitations)</td>
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<td></td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Very serious (-2)</td>
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<tr>
<td>Inconsistency of results</td>
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</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td>Serious (-1)</td>
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<tr>
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<td>Very serious (-2)</td>
<td></td>
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<tr>
<td>Indirectness of evidence</td>
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<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
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<td>Imprecision</td>
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<td>(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Unlikely</td>
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<td>Likely (-1)</td>
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<td>Large effect</td>
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<td>Large (+1)</td>
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<td>Very large (+2)</td>
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<td>Effects of all plausible confounding</td>
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<td>Yes (+1)</td>
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<td>Dose-response gradient</td>
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</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
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</tbody>
</table>

**Worksheet 1:** Adenoma detection rate

**STEP 4:** Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)
Overall quality of the evidence (please circle/check-off):

- High
- Moderate
- Low

Very low

REFERENCES


STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 46**: Endoscopic practice and outcome data of endoscopists who perform procedures on pediatric patients should be regularly reviewed by the appropriate oversight committee to ensure maintenance of competence.

PICO Question:
Is institutional oversight committee review of practice and outcome data of endoscopists performing endoscopic procedures on pediatric patients associated with better endoscopy quality than individual or endoscopy unit review?
- **Population/Patient**: Endoscopists performing endoscopic procedures on children
- **Intervention**: Oversight committee review of quality indicators
- **Control/Comparator**:
  - Individual review of quality indicators Individual
  - Endoscopy unit review of quality indicators
- **Outcome**: Comparison of quality indicator(s)

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**:
- None, only reviews and guidelines were provided

**Articles excluded**:

STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

**Summary of the Evidence**: There is no available direct or indirect evidence to support this standard or this PICO question for pediatric or for adult GI endoscopic procedures.

STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

**Conclusion**:
No relevant studies were found addressing this PICO question. Therefore, no conclusion can be drawn as to whether institutional oversight committee review of practice and outcome data of endoscopists performing endoscopic procedures on pediatric patients provides better endoscopy quality than individual or endoscopy unit review.
STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):
- **Standard 47:** Endoscopists who perform lower endoscopic procedures on pediatric patients should aim to complete an ileocolonoscopy unless the procedure is being performed for an indication that does not require this.
  - **Indicator 44:** Rate of cecal intubation.
  - **Indicator 45:** Rate of ileal intubation.

**PICO Question:**
Should endoscopists aim to complete a full ileocolonoscopy on pediatric patients undergoing a diagnostic lower endoscopic examination (unless the procedure is being performed for an indication that does not require this)?

- **Population/Patient:** Pediatric patients undergoing a lower endoscopic examination
- **Intervention:** Terminal ileal intubation (photodocumented and/or stated in written report)
- **Control/Comparator:** Procedure completion less than "I"
- **Outcome:**
  - Need for assistance
  - Adverse event rate
  - Missed diagnosis
  - Diagnostic yield

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 5 pediatric, 1 adult and pediatric, 18 adult

**Pediatric**
  - This study details 60 pediatric colonoscopies, a small number, from 1999-2001. It is underpowered for testing differences. Sixty of 1452 colonoscopies performed during the study period were included and were performed by 2 gastroenterologists. 30 were performed using an enteroscope and 30 with a colonoscope. The caecum was reached in 56/60 (93%) and the terminal ileum in 50/60 (83%). Of those scoped the authors stated that 6 (10%) had been diagnosed because of the full colonoscopy. 2 had right sided polyps the other 4 were patients with Crohn disease.
  - A retrospective review of 170 pediatric patients with Crohn who had ileocolonoscopy where the TI was normal endoscopically or who had non-specific inflammation (in 73) and who had cross-sectional enterography (CT enterography (CTE) and MR enterography (MRE) in) within 30 days of their ileocolonoscopy. TI skipping was in 43 (59%) with 20 with histology changes (17 with positive imaging), 14 with imaging only inflammation and 9 with proximal changes, proximal to the extent of ileocolonoscopy. Of 209 patients identified who had had imaging for investigation of Crohn disease, of those the 170 who had had TI visualized were
included. 39 did not have TI visualized. 110 had CTE 99 had MRE. 81% TI intubation. Stricture in 19 at ICV, colonic in 11 and poor prep in 7. Technical problems in 2. So, the paper takes out the 39 who didn't have TI intubated – for our purposes it would have been helpful to know what the proximal changes were, but as 19 had an ICV stricture, this means they got to cecum. Not all had the same imaging modality. There was selection bias and other areas of bias including imprecision, some degree of heterogeneity.

  - Describes a 98% TI intubation rate in pediatrics and the paper discussed the utility of upper endo in addition to ileocolonoscopy (IC) alone. This increases diagnostic rate from 32.6% to 39.2 when upper endo is also performed. The paper highlights that improvement on TI intubation rate is possible within a single unit, but this is clearly a group of above average endoscopists, given their status as an international training center (it is internationally renowned). This was a random sample of patients from a 30-month period. It’s not clear how they were randomized so this would increase the risk of selection bias of course. 6 were then excluded due to insufficient data. 98% TI intubation occurred, 2% unable to due to bowel prep. No strictures or other issues were reported. It rightly discusses the relevance of children having diagnostic scopes when calprotectin is normal and whether this would help decide on the relevance of TI intubation (and one could argue of coping at all). So, although the management changed in 45% of patients with this combination of scopeing, the actual diagnoses are not detailed in the paper. The paper would be even more relevant to the PICO question if the authors were able to review the final diagnoses and if specifically, the TI histology was positive when colonic histology was not diagnostic or unclassified. This notwithstanding, this paper shows that IC is entirely possible, especially in the era of ScopeGuide, which is not addressed in any of the other papers in pediatrics.

  - Retrospective assessment of the PEDS-CORI data and details a 69.4% TI intubation rate, with 15.6% cecal intubation rate, and with 31.5% of patients’ scopes not intended to get to TI, the rate of ileal intubation was detailed as 84% with the rate dependent on indication and 30.6% overall did not include the TI. When it was intended, 16% did not reach the TI. It details outcomes. This paper although helpful doesn’t answer the question as we do not know what cases were missed because of the failure to get to cecum or TI, although it is clear that 16% of cases should have had TI intubation on an intention to access the TI basis. The variation in center and endoscopist characteristic data are very interesting and insightful.

  - Details a single center retrospective review of 652 cases with indication for colonoscopy for query of IBD (378/652, 57.9%) or for re-assessment, rectal bleeding (68/652, 10%), and abdominal pain (68/652, 10%). Extent of procedure was detailed by photos and/or TI biopsy. On page 49 Table 2, reasons for incomplete exam were cited, with anatomy, looping and poor bowel prep cited as main reasons for incomplete assessment when it occurred. Clearly it details a center where there is a high intubation rate. It is not clear that all required TI intubation from the list of indications, and they are honest in saying that their top 5 were consistent with a need for TI intubation (92%) but 53 were not required. Incomplete examinations would have resulted in 9.1% (they state) of IBD diagnoses being missed if right sided intubation had not occurred. This is helpful. There is no information about percentage of cases where an attending had to take over, but
complication rates were low. Looking at diagnostic yield, in 207 of 652 (with all but 53 cases cited as possible IBD) only 91 had Crohn and 116 had UC. Of trainee procedures 425 were successfully TI intubated. Out of 49 unsuccessful intubations, 31 were trainees. It is not clear if those were predominantly trainee procedures or not.

**Pediatric and Adult**

  - This study analyzed cross-sectional images of adult and pediatric patients with Crohn disease obtained by computed tomography enterography (CTE) to determine whether skipping of the distal TI can occur. This is actually a paper that takes in all comers, adults and children over 10. With this in mind it isn’t as valid as some of the other papers already and has the same issues regarding bias. In 153 patients with 67 who had TI tagged as normal, only 48 had histology, 13 of those had abnormal histology. 36 of 67 had abnormal TI on imaging. Sparing of the TI was described due to proximal imaging showing ileal and even more proximal disease.

  - Retrospective study of a similar group of patients (100 referrals to complete 96 to cecum (not TI)) by a single endoscopist. A high proportion had had previous surgery and indication was for screening for cancer/ surveillance for polyps and around half had tortuosity or redundant colons. Only 20% were for symptoms/ abnormal imaging.

  - From the same group as Gawron et al. but an updated and more recent cohort (2012-15). Looked at failed endoscopy due to anatomy issues, referred to an expert endoscopist who did 175 2nd colonoscopies. Patients were under anesthesia rather than sedation. This was to cecum not TI, detailed as complete. Again, over 50% were for screening or surveillance.

  - Concluded TI intubation was possible in 117/120, abnormal in 24 of 117 (20.5%).

  - Looked at 400 patients: 20 with helpful findings, a further 98 with normal findings, making it very helpful and a total of 118 (29.5%) overall.

  - Detailed TI intubation is possible in 85% and should be a standard. 19% diagnostic yield from looking and biopsying was up to 19% in IBD.

  - 128 colonoscopies, 99 intention to get to TI, 93 intubated, 4 abnormal findings, normal TI pathology helpful in 82 of 95.
  o 300 patients, 257 with diarrhea and 43 with polyps - 44 of 123 patients with TI intubation had disease without colonic involvement. Ileal Bx essential in 15, helpful in 53.

  o 3921 patients, 87.1% intubation of TI. 11 (0.3%) helpful (i.e., low diagnostic yield).

  o Retrospective 6408 patients and 1% had visual changes, with pathology yielding 0.3% abnormality.

• Yoong KKY, Heymann T. It is not worthwhile to perform ileoscopy on all patients. Surg Endosc 2006;20:809–11.
  o Retrospective study 2149 total, TI intubated in 346 (16.1%), 16 had abnormal findings and in half of those it changed management.

  o 297 with normal colonic mucosa were included – normal TI in 200, aphthous ulcers in 97 – ileitis in 5.5% with normal macro findings and 39.2 in those with aphthae seen. Highest rate was in those with known IBD.

  o 945 patients who had undergone colonoscopy then 689 met criteria for chronic bloody diarrhea, and of those 370 had IC – some were biopsied, of those biopsied 19 had abnormal TI histology, 6 had otherwise normal colonic Hx – all Crohn patients had 5 of 7 had ileal and colonic changes, 2 had colon only.

  o Retrospective review of 9785. Normal TI macro in 75.1% patients, highest overall endo findings in those with cancer screening, with known or suspected Crohn patients having highest abnormal ileal Hx- 36.4%. Overall, 5% ileal Bx abnormal but 47.4% with endo abnormal TI had changes on histology. Suggested that if TI normal on macro no need for Bx as yield poor.

  o 156 recruited on intention to get to TI, 149 TI intubation- 11 excluded. Crohn disease diagnosed on basis of scope and histology in 5.8%.

  o Systematic review of many of the papers already looked at – expert commentary says TI intubation in patients with chronic diarrhea, suspected colitic RLQ pain or anemia and where indicated should aspire to intubate to 90%. TI biopsies only indicated where it looks abnormal or where there is a high pretest probability of CD where the TI appears normal at scope; otherwise, negligible value.

  o Examined endoscopies with normal TIs in a series with various exclusions and reviewed 295 of 473. Non-bloody diarrhea 135, 160 non-diarrhea group. 8 of 135 non-bloody diarrhea revealed changes on biopsy. Compared with 5 in the diarrhea group. Further studies required.

- Initial cecum and TI intubation in two groups (90.15% and 75.9%), then selection of patients took place, and we end up with 81 of 764 and then 34/81 macro and 47/81 microscopic findings. 47 of 764 (6.15%) had findings that influenced management. TI histology and intubation improve yield.


- In adults with diarrhea, 1131 cases scoped with 508 TI and abnormal in 26, with TI changes exclusive in 13 (3%). TI biopsy was unhelpful.

**Relevant guidelines:**


**Articles excluded:**


STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)

Summary of the Evidence:
None of the included studies address the PICO question directly. However, there are some studies which provide indirect evidence with regard to the need for ileocolonoscopy. The studies were observational and/or case series and, therefore, of low quality to start. The majority of studies are adult and, therefore, much of the evidence is indirect. Additionally, in the studies where TI intubation was specifically examined, the procedural indication was not outlined and thus it is unclear as to whether TI intubation was required. Many adult papers looked at cancer surveillance/screening. Most papers, adult and pediatric, didn't detail their data well enough to assess the specific PICO question. There was some publication bias and details were inadequate to confidently decide on selection of patients in some studies. Studies using imaging often used variable imaging modalities (CTE and MRE) to document TI findings.

Although some papers had no imprecision, and some papers had small numbers of cases, there was suspicion/evidence of selection bias in others. Therefore, the overall quality of the evidence is low. The pediatric literature clearly shows that a TI intubation rate above 90% is possible;\(^1\,^2\) however, future research is required to evaluate the need for ileal intubation in specific pediatric populations (e.g., inflammatory bowel disease).

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
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</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td></td>
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</tr>
<tr>
<td>Risk of bias (study limitations)</td>
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<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
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<td>High</td>
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<td>Inconsistency of results</td>
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\(^1\)\(^,\)\(^2\)
**PEnQuIN GRADE reporting template**

<table>
<thead>
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<th>beneficial or harmful effect due to the selective publication of studies</th>
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<tr>
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<tr>
<td>Effects of all plausible confounding</td>
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<td>Yes (+1)</td>
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<tr>
<td>Dose-response gradient</td>
<td>No</td>
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</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- High
- Moderate
- Low
- Very low

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

Standard(s)/Indicator(s):

- **Standard 48**: All endoscopists in training who perform procedures on pediatric patients should be supervised with regular performance monitoring and constructive feedback, until they have achieved competence to perform specified routine and/or emergency pediatric procedures according to appropriate current standards.
  - **Indicator 46**: Proportion of endoscopists in training who have achieved competence by the end of their training.

**PICO Question:**
Should endoscopists performing procedures on pediatric patients be supervised, and their performance monitored regularly (with feedback), until they have achieved competency to perform specified routine and/or emergency pediatric procedures according to appropriate current standards?

- **Population/Patient**: Trainees performing routine and/or emergency pediatric emergency endoscopic procedures on pediatric patients
- **Intervention**: Regular performance monitoring with feedback
- **Control/Comparator**: No regular performance monitoring
- **Outcome**:
  - Achievement of competence
  - Skills improvement documented using an assessment tool with strong validity evidence

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included**: 4 adult


**Articles excluded**:

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**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**

Harewood et al.\textsuperscript{1} conducted a randomized, controlled study aimed to characterize the impact of feedback on colonoscopy performance among gastroenterology trainees within the clinical setting. Four trainees, of similar experience levels (500-600 previously colonoscopies) randomized to receive monthly feedback or no feedback on their colonoscopy performance, including information on their cecal and terminal ileal intubation rates and polyp detection rates and how they compared to the other trainees. The study was conducted over a 4-month period. Following feedback, cecal intubation improved by 10.5% (from 72.9 to 83.4%, \( p = 0.04 \)) in the feedback group and declined by 6.1% (from 78 to 71.9%, \( p = 0.2 \)) in the control group; polyp detection improved by 5.1% (from 12.9 to 18.0%, \( p = 0.2 \)) in the feedback group and by 2.9% (from 16.7 to 19.6%, \( p = 0.5 \)) in the control group.

Three other studies have examined the impact of feedback on endoscopic skills acquisition within the simulated setting. Mahmood et al.\textsuperscript{2} had 26 postgraduate trainees perform 5 consecutive virtual colonoscopies on the same module of a virtual reality simulator. No guidance or feedback was given to candidates before, during, or after each procedure. There was no improvement in performance on the simulator from first attempt to the fifth in the absence of feedback, as measured by completion time, percentage of the mucosa visualized, depth of the instrument inserted, and path length. Kruglikova et al.\textsuperscript{3} randomized 22 novice endoscopic trainees to structured feedback provided by an experienced supervisor or no feedback (control). All participants performed 15 repetitions of a virtual reality simulator task. A simulation-based retention test was performed 4 to 6 weeks after training. Although both groups were able to complete the procedure on the simulator and improved with regard to procedure time and amount of insufflated air, the trainees in the feedback group reached proficiency level on the simulator significantly faster, had fewer perforations (zero in the feedback group versus seven in the control group) and performed significantly better than controls during the delayed retention test with regard to advancement time and percentage of mucosa visualized. Finally, Grover et al.\textsuperscript{4} randomized 33 novice endoscopists competing 8 hours of colonoscopy virtual reality simulation-
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based training to a structured comprehensive curriculum group which received expert feedback or a self-regulated learning group which was provided a list of desired objectives and access to the performance metrics provided by the simulator upon completion of each simulated colonoscopy. The primary outcome was transfer of skills to the clinical setting, which was assessed by blinded raters during 2 patient colonoscopies, performed 4-6 weeks after training, using the Joint Advisory Group Direct Observation of Procedural Skills (JAG DOPS) scale. The curriculum group performed superiorly during their first \((P < 0.001, \eta^2_p = 0.71)\) and second \((P < 0.001, \eta^2_p = 0.57)\) clinical colonoscopies.

Overall, one clinical study\(^1\) and two high-quality simulation-based studies\(^3,4\) showed improved skill acquisition with feedback, while one low-quality simulation-based study showed no skill acquisition in the absence of feedback. \(^2\)

Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias (study limitations)</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inconsistency of results</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Unexplained heterogeneity of results)</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirectness of evidence</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>Serious (-1) Very serious (-2)</td>
<td>No pediatric studies. Three of the four studies were simulation-based.</td>
<td></td>
</tr>
<tr>
<td>Imprecision</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>Serious (-1) Very serious (-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication Bias</td>
<td>Not assessed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Systematic under or overestimate of the underlying beneficial or)</td>
<td>Unlikely Likely (-1) Very likely (-2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>harmful effect due to the selective publication of studies)</th>
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</tr>
</thead>
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</tr>
<tr>
<td></td>
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<td>£</td>
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<tr>
<td></td>
<td>Very large (+2)</td>
<td>£</td>
</tr>
<tr>
<td>Effects of all plausible confounding</td>
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<td>£</td>
</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td>£</td>
</tr>
<tr>
<td>Dose-response gradient</td>
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</tr>
<tr>
<td></td>
<td>Yes (+1)</td>
<td>£</td>
</tr>
</tbody>
</table>

**STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)**

**Overall quality of the evidence (please circle/check-off):**

- ⬤ ⬤ ⬤ ⬤ ⬤ High
- ⬤ ⬤ ⬤ ⬤ Moderate
- ⬤ ⬤ ⬤ ⬤ Low
- ⬤ ⬤ ⬤ ⬤ Very low

**REFERENCES**

STEP 1: Create a PICO question(s) for your standard/indicator

**Standard(s)/Indicator(s):**
- **Standard 49:** Competence assessment tools with strong validity evidence should be used to document progress and proficiency level during endoscopy training.
  - **Indicator 47:** Rate with which the competence of endoscopists in training is assessed longitudinally.

**PICO Question 1:**
What is the most appropriate measurement method to assess competence in performing pediatric endoscopic procedures?

- **Population/Patient:** Endoscopic trainees performing diagnostic upper endoscopy and/or colonoscopy on pediatric patients
- **Intervention:** Competence assessment tools (e.g. GiECAT<sub>kids</sub>) and/or resultant learning curves
- **Control/Comparator:** Minimum number of procedures
- **Outcome(s):**
  - Terminal ileal intubation rate
  - Cecal intubation rate
  - Diagnostic yield
  - Adverse event rate
  - Need for assistance from colleagues
  - Patient experience

STEP 2: List which articles are relevant and should be included. Articles included must be either a randomized control trial, observational study or systematic review.

**Studies included:** 4 pediatric, 17 adult

**Pediatric studies:**

**Adult studies:**


Relevant guidelines:


Articles excluded:


**STEP 3: Assess the quality of the evidence for each PICO question (i.e. the outcome)**

**Summary of the Evidence:**
With regard to pediatric studies, the first pediatric-specific competency assessment tool devised was the GiECAT\textsubscript{kids} for pediatric colonoscopy.\textsuperscript{1} Validity evidence was reported in one high quality observational study.\textsuperscript{2} The tool was found to have high inter-rater reliability (ICC = 0.79-0.89) and strong evidence of test-retest validity (ICC = 0.84-0.94), discriminative validity (ability to discriminate between novice, intermediate and experience endoscopists, $P < 0.001$) and concurrent validity (correlation with cecal intubation rate, terminal ileal intubation rate and a global assessment of skills) for use as a formative assessment tool during training.\textsuperscript{2} Analysis of GiECAT\textsubscript{kids} scores versus number of previous colonoscopies revealed that individuals attain competence at variable rates.\textsuperscript{2} A very recent observational study of high quality examined pediatric endoscopists in the United Kingdom reporting into the JETS database and found that formative esophagogastroduodenoscopy (EGD) Direct Observation of Procedure Skills (DOPS) thresholds could be used to indicate readiness for summative assessment for pediatric EGD.\textsuperscript{3} Finally, a cross sectional self-reported survey of pediatric trainees in the European Union trainee alumni showed that those who achieved a terminal ileum (TI) intubation rate of >90% had performed more endoscopies than those with a TI intubation rate of 50-90% or <50% (median 150 versus 38 versus 55) ($p<0.001$). Of the alumni only 61% had achieved the recommended ESPGHAN numbers of 100 EGD and 50 colonoscopies at the end of their training.\textsuperscript{4} There is no pediatric data to advise how frequently to assess competency.

Existing adult GI literature shows a very wide variation in the minimum number of procedures required to achieve competence. Therefore, in general, an absolute minimum number (rather than assessing competency) is not regarded as a useful assessment of training given the variable speed of gaining competence. Recent high quality systematic reviews in adult trainees suggest that trainees need to perform 100 to 280 colonoscopies to achieve a cecal intubation rate of >85–90%.\textsuperscript{5-7} However, the highest quality papers indicate 250, 275 and 280 procedures are required to achieve 90% cecal intubation rates for colonoscopy.\textsuperscript{5,8-10} With regard to EGD, one study demonstrated an 80% success rate of esophageal intubation after 100 procedures,\textsuperscript{11} whereas another study concluded GAGES-UE scores plateaued at 50 procedures.\textsuperscript{12} A more recent high quality study demonstrated that trainees achieve a 95% completion rate in EGD between 187 or 200 procedures when assessed using the moving average methods or the LC-Cusum analysis method, respectively.\textsuperscript{13} In pediatrics, analysis of GiECAT\textsubscript{kids} scores versus number of previous colonoscopies revealed that individuals attain competence at variable rates.\textsuperscript{2} However, there have been no pediatric studies which specifically examine competency standards for pediatric endoscopy.

Two recent systematic reviews have examined validity evidence for available adult colonoscopy competency assessment tools.\textsuperscript{5,14} There are 4 tools with more robust validity evidence: Mayo Colonoscopy Skill Assessment Tool (MCSAT), Gastrointestinal Endoscopy Competency Assessment Tool (GiECAT), the Direct Observation of Procedural Skills (DOPS), and the Global Assessment of Gastrointestinal Endoscopic Skills – Colonoscopy (GAGES-C).

**Worksheet 1: Rating the quality of the evidence for each PICO question (outcome)**

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Rating (Check off one for each criterion)</th>
<th>List reasons for downgrading or upgrading evidence (list all that apply)</th>
<th>Quality of the evidence (1 per outcome)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias (study limitations) (selection bias, performance bias, detection bias, attrition bias, reporting bias, other bias)</td>
<td>No</td>
<td>No Serious (-1) Very serious (-2)</td>
<td>Assessments unblinded in some studies</td>
</tr>
<tr>
<td>Inconsistency of results (Unexplained heterogeneity of)</td>
<td>No</td>
<td>No Serious (-1)</td>
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</tbody>
</table>
## PEnQuIN GRADE reporting template

<table>
<thead>
<tr>
<th>Results</th>
<th>Very serious (-2)</th>
<th>Moderate</th>
<th>Low</th>
<th>Very Low</th>
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</thead>
<tbody>
<tr>
<td><strong>Indirectness of evidence</strong>&lt;br&gt;(Research that doesn’t specifically compare the interventions, populations, or outcomes of interest, for example, adult literature)</td>
<td>No&lt;br&gt;Serious (-1)&lt;br&gt;Very serious (-2)</td>
<td>☐</td>
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<tr>
<td><strong>Imprecision</strong>&lt;br&gt;(Research that includes few patients and few events and thus has a wide confidence interval around the estimate of the effect)</td>
<td>No&lt;br&gt;Serious (-1)&lt;br&gt;Very serious (-2)</td>
<td>☒</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td><strong>Publication Bias</strong>&lt;br&gt;(Systematic under or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies)</td>
<td>Not assessed&lt;br&gt;Unlikely&lt;br&gt;Likely (-1)&lt;br&gt;Very likely (-2)</td>
<td>☒</td>
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<td>☒</td>
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<td><strong>Large effect</strong></td>
<td>No&lt;br&gt;Large (+1)&lt;br&gt;Very large (+2)</td>
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<td><strong>Dose-response gradient</strong></td>
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</table>

### STEP 4: Assess the overall quality of evidence for the standard/indicator (if ≥ 1 PICO question)

<table>
<thead>
<tr>
<th>Overall quality of the evidence (please circle/check-off):</th>
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<tbody>
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</table>

### REFERENCES


