# Pediatric Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline

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# ABSTRACT

Introduction: High-quality pediatric gastrointestinal procedures are performed when clinically indicated and defined by their successful performance by skilled providers in a safe, comfortable, child-oriented, and expeditious manner. The process of pediatric endoscopy begins when a plan to perform the procedure is first made and ends when all appropriate patient follow-up has occurred. Procedure-related standards and indicators developed to date for endoscopy in adults emphasize cancer screening and are thus unsuitable for pediatric medicine.

Methods: With support from the North American and European Societies of Pediatric Gastroenterology Hepatology and Nutrition (NASPGHAN and ESPGHAN), an international working group of the Pediatric Endoscopy Quality Improvement Network (PEnQuIN) used the methodological strategy of the Appraisal of Guidelines for REsearch and Evaluation (AGREE) II instrument to develop standards and indicators relevant for assessing the quality of endoscopic procedures. Consensus was sought via an iterative online Delphi process and finalized at an in-person conference. The quality of evidence and strength of recommendations were rated according to the GRADE (Grading of Recommendation Assessment, Development, and Evaluation) approach.

Results: The PEnQuIN working group achieved consensus on 14 standards for pediatric endoscopic procedures, as well as 30 indicators that can be used to identify high-quality procedures. These were subcategorized into three subdomains: Preprocedural (3 standards, 7 indicators), Intraprocedural (8 standards, 18 indicators), and Postprocedural (3 standards, 5 indicators). A minimum target for the key indicator, "rate of adequate bowel preparation," was set at >80%.

Discussion: It is recommended that all facilities and individual providers performing pediatric endoscopy worldwide initiate and engage with the procedure-related standards and indicators developed by PEnQuIN to identify gaps in quality and drive improvement.

Key Words: healthcare, patient care/standards, patient safety, pediatric gastroenterology/\*standards, performance measures, quality assurance

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ediatric gastrointestinal endoscopic procedures-including upper endoscopy, ileocolonoscopy, colonoscopy, and sigmoidoscopy—are routinely performed around the world, largely for diagnosis, but also for the treatment of digestive disorders in children. At the procedural level, endoscopy can be assessed in terms of its quality in accordance with the six domains put forward by the Institute of Medicine, with high-quality defined as procedures that are safe, effective, patient-centered, efficient, timely and equitably performed (1). According to the American Society of Gastrointestinal Endoscopy (ASGE), high-quality procedures are indicated; involve recognition or exclusion of correct and relevant diagnoses; provide therapy when appropriate; and involve strategies to maximally mitigate risk (2). Ideally, pediatric endoscopic procedures are successfully performed, only and whenever clinically indicated, in all children regardless of country of origin, sex, race, ethnicity, insurance status, or socioeconomic status, by skilled providers in a manner that is safe, comfortable, and expeditious.

The process of pediatric endoscopy should be viewed as a continuum of care that begins with appropriate recognition by a provider that a particular procedure is indicated (3-5). When performed for diagnostic purposes, the procedure is complete when all information gleaned from its performance (eg, mucosal inspection, diameters of a stricture, biopsy results) and its implications for care are communicated to the patient and/or their caregivers (6). For patients undergoing interventions during endoscopy, the procedure should be considered complete when postprocedural patient monitoring is no longer necessary, and/or further immediate interventions are not required. For both types of procedures, a full assessment of the quality of endoscopy generally occurs after a patient has recovered and left the facility where their procedure was performed (7). Standards and indicators for high-quality endoscopy should be established for all phases of the process, including before, during and after procedural performance.

Although in certain jurisdictions there may be regulatory requirements for endoscopic procedures in children, these are

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variable and inconsistent and may not reflect best practices for pediatric endoscopy. To date, clinically relevant quality standards and indicators that measure those standards have been less welldefined for pediatric endoscopic procedures, as compared with those that are performed in adult populations (4,7,8). With regard to colonoscopy, in particular, there are a number of well-established evidence-based quality standards and indicators that can be measured as they relate to colon cancer surveillance, including cecal intubation and adenoma detection rates (9–13). These standards and indicators do not apply in pediatrics, as colonoscopy is not typically performed for preventive medicine purposes and instead lower endoscopy in children generally requires ileal intubation to

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ensure diagnostic accuracy and optimal management (14). Similarly, thresholds for tissue sampling during pediatric procedures, in which congenital, developmental, autoimmune, allergic or other inflammatory processes are commonly under investigation, may differ from those in adult populations, where biopsies may be more targeted towards cancer detection (5).

A principal aim of the Pediatric Endoscopy Quality Improvement Network (PEnQuIN) has been to outline international standards for gastrointestinal *procedures* performed in children, as a key *domain* of pediatric endoscopy, as well as indicators that can be used to measure their quality (Table 1). Three specific phases of pediatric endoscopic procedures are outlined as subdomains:

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## TABLE 1. Quality-related terminology

	Term	Definition
PEDATRIC ENDOSCOPY CUALITY IMPROVEMENT NETWORK	Domain	• Broad area of pediatric endoscopic care.
	Quality standard	<ul> <li>Recommendation on high-quality practice for a specific aspect of pediatric endoscopic care.</li> <li>Quality standards may reflect priority areas for quality improvement and may be related to quality indicators.</li> </ul>
	Quality indicator	<ul> <li>A measure of the process, performance, or outcome of pediatric endoscopic service delivery used in determining the quality of care.</li> <li>Can highlight potential targets for quality improvement.</li> <li>Other terms for a quality indicator include performance measure, quality measure, key performance indicator, clinical quality measure, etc.</li> </ul>

Preprocedure; Intraprocedure; and Postprocedure. The PEnQuIN process was sponsored by both the North American and European Societies of Pediatric Gastroenterology Hepatology and Nutrition (NASPGHAN and ESPGHAN). Its primary assumptions are that all standards and indicators identified through rigorous evidence review and consensus can be useful in the following ways: to assess the quality of an endoscopic procedure; to serve as a basis for quality improvement activities at an individual endoscopist, group of endoscopists or facility level; and to provide guidance for individual providers, a group of providers, and/or their facilities seeking to assess procedural quality and identify areas for improvement.

# **METHODS**

With approval from NASPGHAN and ESPGHAN, a rigorous multi-step guideline development process, guided by the Appraisal of Guidelines for REsearch and Evaluation (AGREE) II instrument (15), was used to structure the development of the PEnQuIN standards and indicators. Proposed quality standards and indicators were derived from three sources: a systematic literature review of Medline, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL); a hand-search of lists of references from published adult consensus statements (2,10,12,16); and a survey of PEnQuIN working group members. Titles and abstracts from 4505 records were reviewed and 54 potential quality standards and 62 indicators were generated from the three aforementioned sources. The Population, Intervention, Comparator, Outcome (PICO) approach was used to frame questions relevant to each potential quality standard and corresponding indicator(s) (17,18). Evidence was mapped to each standard and corresponding indicator(s) and the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) system was then used to assess the quality of evidence ("very low," "low," "moderate," or "high") (19). Consensus among the PEnQuIN working group was subsequently achieved via an iterative online Delphi process followed by an in-person consensus conference. The GRADE approach was then utilized to determine the strength of recommendation as "strong" (recommended) versus "conditional" (suggested) for each quality standard that reached consensus (20). As per GRADE methodology, a "strong" recommendation was defined as a broadly applicable standard that can be adopted across endoscopists and endoscopy services despite variability in practice, whereas a "conditional" recommendation was defined as suggesting that implementation

may vary. The choice to implement a "conditional" standard should take into account patient values and preferences, available resources and the setting of implementation (20).

Additionally, working group members voted on minimum targets (minimally acceptable thresholds of performance) for applicable indicators at the in-person conference. At each stage of the process, consensus was defined as  $\geq 80\%$  agreement. Afterward, the quality standards and indicators reaching consensus were mapped to their relevant domain: facilities; procedures; or endoscopists and endoscopists in training.

Standards related to pediatric endoscopic procedures are presented within this document along with related indicators and their definitions (eg, binary [yes/no], rate [numerator representing actual performance numbers and denominator representing the number of opportunities for correct performance in a given setting or timeframe]). Detailed methodology is outlined within the PEn-QuIN overview document (21).

# RESULTS

The PEnQuIN working group achieved consensus for a total of 14 standards related to endoscopic procedures in children, with 30 related indicators that can be used to measure the quality of procedures and provide a means for continuous quality improvement at the level of an individual provider, a group of providers or a facility. Consensus was not reached, and no recommendations were made, for an additional one standard and eight indicators (Appendix 1, Supplemental Digital Content, *http://links.lww.com/MPG/C461*). All standards that achieved consensus can be mapped to one of three subdomains, with associated indicators: Preprocedure (3 standards, 7 indicators); Intraprocedure (8 standards, 18 indicators); and Postprocedure (3 standards, 5 indicators). In addition, a minimum target for defining high-quality pediatric procedures was set by consensus for one key indicator related to lower endoscopy in children:

1. an unadjusted rate of adequate bowel preparation:  $\geq 80\%$  (Indicator 28).

Each of the standards that reached consensus for inclusion in this PEnQuIN guideline on procedure quality is presented below, with the strength of recommendation and quality of supporting evidence (according to the GRADE approach), a short discussion of the evidence considered and the voting results. Indicators related to each standard are listed in accompanying tables, organized by the subdomains of procedure quality. The PEnQuIN working group assumed the likely use of electronic endoscopy reporting systems for facilitating data retrieval for specific indicators but did not mandate this or specify any particular system.

# **Procedures Subdomain 1: Preprocedure**

High-quality pediatric endoscopy involves performing specific procedures for appropriate indications, with the goal of optimally diagnosing and/or managing digestive disorders in children (3,4,7,8). Clear communication with patients and/or their caregivers around the rationale for proceeding with endoscopy is required, as is a comprehensive discussion of potential risks and benefits to the patient that may come from its performance. Upholding Preprocedure standards of endoscopy generally relies on individual providers but can be assured in a transparent manner at an endoscopist, group practice or facility level. Additionally, pediatric endoscopic procedures should include clinical assessment of patient risk, and a comprehensive, patient-centered informed consent/assent process that clearly engages children and/or their caregivers. This also includes assessment of any patient comorbidities, including type 1 diabetes, obesity, airway compromise, coaimmune deficiencies, cardiac gulopathies, disease and neurodevelopmental and psychiatric conditions (22). There should also be patient-centered, preprocedural planning to ensure a patient remains comfortable and safe throughout the entire process of the procedure. It is reasonable to assume that these standards and indicators should be universally applied and can be upheld, regardless of endoscopy service resources, practice size or the procedure being performed.

The following achieved consensus within the PEnQuIN working group as minimum Preprocedure quality standards, as measured by their seven associated indicators (Table 2).

#### Standard 28: Pediatric endoscopic procedures are performed for an appropriate, clearly documented indication, consistent with current evidence-based guidelines, when available.

**GRADE:** Conditional recommendation, low-quality evidence. Vote: strongly agree, 70.8%; agree, 25.0%; uncertain, 4.2%

Key evidence: Despite consensus that pediatric endoscopy should be performed for appropriate indications, as determined by available guidelines, there is limited evidence to suggest that this improves outcomes. Three pediatric and two adult guidelines list appropriate indications for endoscopy, but are mainly opinionbased (3,5,13,23,24), which further complicates efforts to support this standard. To date, three retrospective observational studies in pediatrics and five prospective adult studies have sought to address whether performance of endoscopy for approved vs non-approved indications differs in terms of clinically relevant outcomes. One single-center study of endoscopy in children reported "change in management due to endoscopic findings" in 45% of cases, with an overall positive diagnostic yield of 39.2%, when both upper endoscopy and ileocolonoscopy were performed in accordance with recommended guidelines (25). Another single-center study suggested that "appropriate" endoscopy led to a greater yield (26), and a third determined recurrent abdominal pain to be an inappropriate indication for endoscopy in that it was associated with lower diagnostic yield (27). Five 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 performance of procedures for indications judged to be inappropriate (28-32).

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.

**GRADE:** Strong recommendation, moderate-quality evidence. Vote: strongly agree, 79.2%; agree, 16.7%; uncertain, 4.1%

Key evidence: Informed consent/assent in pediatrics should be conducted in a manner consistent with local law. If a child is unable to provide consent for themselves, it is recommended, if possible, that they participate in a developmentally appropriate decision-making process to provide assent (a child's affirmative agreement). There is moderately strong evidence that patients are more satisfied and report better patient experience when they receive information in a timely manner before elective endoscopic procedures (33,34). Surveys suggest that the vast majority of patients and caregivers prefer that informed consent be obtained before the date of service (33,35,36). Prompts to improve patient/ caregiver likelihood of reading an information leaflet and the consent form may increase patient satisfaction with the endoscopic procedure (37), while patient comprehension of a procedure may be enhanced by direct verbal communication with the proceduralist (33,38). Several randomized controlled trials in pediatrics provide evidence that the use of standardized videos as part of the informed consent process improves overall comprehension of endoscopy, as well as patient understanding of procedural risks and any alternatives to performing the procedure (39,40). These trials also suggest that documentation of the informed consent process is often inadequate, and alternatives to performing endoscopy are rarely discussed as part of the consent process (39,41).

Standard 30: For all endoscopic procedures, the sedation/ anesthetic plan should be documented along with a standardized measure of patient complexity.

**GRADE:** Conditional recommendation, low-quality evidence. Vote: strongly agree, 62.5%; agree, 33.3%; uncertain, 4.2%

Key evidence: There is limited evidence to support the consensus that a sedation/anesthetic plan should be documented along with a standardized measure of patient complexity before pediatric endoscopy to improve procedural outcomes. Generally speaking, a number of studies around the world have shown that planning to perform sedation for gastrointestinal endoscopy is associated with improved procedure quality, patient satisfaction and patient safety (42-45). To date, the most commonly accepted approach to grading patient complexity reflects guidelines from the American Society of Anesthesiologists (ASA) around patient physical status (46). Taking into account a patient's age and developmental status when choosing a sedation regimen has also been suggested to improve procedural success (47,48). Several studies have found that the smallest and youngest pediatric patients with the highest ASA classifications are at the greatest risk for adverse events during endoscopic procedures (49-52). Despite limited direct evidence that a lack of documentation of ASA status before pediatric endoscopy adversely affects outcomes (14), two large hospital-based studies that looked at sedation practices in children, including during endoscopic procedures, found that documenting sedation plan and ASA status led to fewer adverse events (53,54).

# **Procedures Subdomain 2: Intraprocedure**

Endoscopy in children is fundamental to the diagnosis and optimal management of a number of digestive diseases in children

#### TABLE 2. Indicators related to the "Preprocedure" subdomain

Indicator 17: Rate with which the endoscopy report documents the indication for the procedure

- Numerator: Number of procedure reports for pediatric endoscopies that clearly document the indication for the procedure
- Denominator: All pediatric endoscopies performed
- **Calculation:** Proportion (%)
- Associated PEnQuIN Standards: S28

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

- Numerator: Number of pediatric endoscopies that are performed for an indication that is in accordance with current evidence-based guidelines and/or published standards, when available
- Denominator: All pediatric endoscopies performed
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S28
- Indicator 19: Rate with which informed consent/assent is obtained
  - Numerator: Number of pediatric endoscopies for which informed consent/assent is obtained and this process is documented

• Denominator: All pediatric patients undergoing endoscopies

• Calculation: Proportion (%)

#### Associated PEnQuIN Standards: S29

Indicator 2<sup>†</sup>: Rate with which a preprocedure history and directed physical examination is performed

- Numerator: Number of pediatric endoscopies occurring in an endoscopy facility where preprocedure history and directed physical examination are performed and this is documented
- Denominator: All pediatric endoscopies occurring in an endoscopy facility
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S4

Indicator 20: Rate with which the sedation/anesthetic plan is documented

- Numerator: Number of pediatric endoscopies that document the sedation/anesthetic plan
- Denominator: All pediatric endoscopies performed that involve sedation/anesthetic
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S30

Indicator 21: Rate with which the sedation/anesthetic plan is documented

- Numerator: Number of pediatric endoscopies that document ASA status
- Denominator: All pediatric endoscopies performed that involve sedation/anesthetic
- Calculation: Proportion (%)

• Associated PEnQuIN Standards: S30

- Indicator 3<sup>†</sup>: Rate of appropriate prophylactic antibiotic administration in accordance with accepted guidelines
  - Numerator: Number of pediatric endoscopies where prophylactic antibiotics are administered in accordance with currently accepted guidelines
  - Denominator: All pediatric endoscopies occurring at an endoscopy facility/group/provider level where prophylactic antibiotics are *indicated* in
  - accordance currently accepted guidelines • Calculation: Proportion (%)
  - Associated PEnQuIN Standards: S4

ASA = American Society of Anesthesiologists; PEnQuIN = Pediatric Endoscopy Quality Improvement Network.<sup>†</sup>Procedure-related indicators linked to facility standards.

and should be performed completely and efficiently to maximize its value (ie, ensure the highest possible diagnostic yield) while minimizing risks and costs related to maneuvers and unnecessarily prolonged procedure times. Children must also be assured of being safe and comfortable for the duration of a procedure, which may require sedation. It is important that complete inspection with direct visualization of the mucosa be assured, as this is the lynchpin of both accurate diagnoses and successful maneuvers. For lower gastrointestinal procedures, in particular, complete inspection may rely on optimal bowel cleansing. Appropriate tissue sampling is also essential to inform diagnosis. Finally, the procedure should be accurately and completely documented in the medical record in a timely manner, as the procedure report represents the foundation upon which optimal patient care after endoscopy can be assured.

The following achieved consensus within the PEnQuIN working group as minimum Intraprocedural quality standards, as measured by their 18 associated indicators (Table 3).

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.

**GRADE:** Conditional recommendation, low-quality evidence. Vote: strongly agree, 75.0%; agree, 20.8%; uncertain, 4.2%

**Key evidence:** There is moderately strong evidence that appropriate sedation practices should be employed during pediatric endoscopy to maintain patient safety, whereas evidence that sedation can improve clinical outcomes by increasing patient cooperation and comfort is less direct. Best sedation practices for endoscopy are generally considered to involve both the administration of sedatives and patient monitoring (55). There are two observational studies that show that monitoring children undergoing endoscopic procedures with pulse oximetry and electrocardiogram is associated with improved patient outcomes (56,57), and one randomized controlled trial suggests additional monitoring with capnography can further improve patient safety (58). Evidence linking documentation of sedation with better outcomes is less precise, but there are two general studies in children that include endoscopic procedures and show that standardized documentation is associated with fewer

#### TABLE 3. Indicators related to the "Intraprocedure" subdomain

Indicator 4<sup>†</sup>: Rate with which a preprocedural team pause is conducted

- Numerator: Number of pediatric endoscopies for which a preprocedural team pause (time-out) is conducted and this is documented
- Denominator: All pediatric endoscopies occurring at an endoscopy facility/group/provider level
- Calculation: Proportion (%)

#### Associated PEnQuIN Standards: S4

Indicator 22: Rate with which patient monitoring during sedation/anesthesia is performed

- Numerator: Number of pediatric endoscopies in which patient monitoring during sedation/anesthetic is performed and this is documented
- Denominator: All pediatric endoscopies performed that involve sedation/anesthetic
- Calculation: Proportion (%)

#### Associated PEnQuIN Standards: S31

Indicator 23: Rate with which the dose and route of administration of all medications used during the procedure are documented

- Numerator: Number of pediatric endoscopies in which the dose and route of administration of all medications used during the procedure are documented
- Denominator: All pediatric endoscopies in which medications are administered
- Calculation: Proportion (%)

#### • Associated PEnQuIN Standards: S31

Indicator 24: Rate with which intraoperative patient comfort is documented

- Numerator: Number of pediatric endoscopies with non-anesthesiologist administered sedation where a standardized tool is used to document patient comfort
- Denominator: All pediatric endoscopies performed with non-anesthesiologist administered sedation
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S31

Indicator 25: Rate with which reversal agents are used

- Numerator: Number of pediatric endoscopies in which the use of a reversal agent (eg, naloxone, flumazenil) is documented
- Denominator: All pediatric endoscopies performed that involve sedation/anesthetic
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S31

Indicator 26: Rate with which the procedure is interrupted and/or prematurely terminated due to a sedation/anesthesia-related issue

- Numerator: Number of pediatric endoscopies in which procedure interruption and/or premature termination due to a sedation/anesthetic-related issue is documented
- Denominator: All pediatric endoscopies performed that involve sedation/anesthetic
- Calculation: Proportion (%)

#### • Associated PEnQuIN Standards: S31

Indicator 27: Procedure time

- Construct: Median procedure time from first insertion until final removal of endoscope. This should be calculated by procedure type (eg, upper endoscopy, ileocolonoscopy)
- Calculation: Median (range) time in minutes
- Associated PEnQuIN Standards: S32

#### Indicator 28: Rate of adequate bowel preparation

- Numerator: Number of pediatric endoscopies with adequate bowel preparation. This should be assessed formally, using a tool with strong validity evidence (eg, Ottawa Scale (79), Boston Bowel Preparation Scale (77,78), Aronchick Scale (80)) or, at a minimum, using standardized language with clear definitions (eg, excellent, good or fair)
- Denominator: All pediatric endoscopies for which bowel preparation is required
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S33
- **Minimum target:** ≥80% (unadjusted)
- Indicator 29: Rate with which the endoscopy report documents the quality of the bowel preparation
  - Numerator: Number of procedure reports for pediatric endoscopies that document the quality of the bowel preparation. The documentation should reflect formal assessment using a tool with strong validity evidence (eg, Ottawa Scale (79), Boston Bowel Preparation Scale (77,78), Aronchick Scale (80)) or, at a minimum, using standardized language with clear definitions (eg, excellent, good or fair).
  - Denominator: All pediatric endoscopies performed for which bowel preparation is required
  - Calculation: Proportion (%)
  - Associated PEnQuIN Standards: S33

Indicator 30: Rate of procedure completeness as defined by inspection of all relevant areas, acquisition of appropriate biopsies and successful completion of interventions

- Numerator: Number of cases in which completeness of the procedure (inspection of all relevant areas, acquisition of appropriate biopsies and successful completion of interventions) is documented
- Denominator: All pediatric endoscopies performed
- Calculation: Proportion (%)

#### Associated PEnQuIN Standards: S34

Indicator 31: Rate with which endoscopic interventions are performed or eschewed, appropriately

- Numerator: Number of pediatric endoscopies in which interventions are performed appropriately (in accordance with the indication and findings) and documented *plus* the number of pediatric endoscopies in which interventions are not performed for appropriate reasons that are documented
- Denominator: All pediatric endoscopies performed

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#### TABLE 3. (Continue)

• Calculation: Proportion (%)

## • Associated PEnQuIN Standards: S34

Indicator 32: Rate of endoscopic intervention completion

- Numerator: Number of pediatric endoscopies in which interventions (eg, polypectomy) are performed to completion
- Denominator: All pediatric endoscopies in which interventions are performed
- Calculation: Proportion (%)

#### Associated PEnQuIN Standards: S34

Indicator 33: Rate with which biopsies are obtained or eschewed, appropriately

- Numerator: Number of pediatric endoscopies in which biopsies are obtained appropriately, in accordance with currently accepted guidelines (eg, number of duodenal biopsies in a patient with suspected celiac) *plus* the number of pediatric endoscopies in which biopsies are not obtained for appropriate reasons that are documented
- Denominator: All pediatric endoscopies performed
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S36

**Indicator**  $7^{\dagger}$ : Rate of *documented* intraprocedural adverse events

- Numerator: Number of intraprocedural adverse events that are *documented* for a procedure/facility/group/provider
- Denominator: All intraprocedural adverse events occurring at a procedure/facility/group/provider level
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S12

Indicator 34: Rate with which the endoscopy report documents findings

Numerator: Number of procedure reports for pediatric endoscopies that document findings. Both written and photo documentation is preferable. If no
findings, this should be documented in writing.

- Denominator: All pediatric endoscopies performed
- Calculation: Proportion (%)

#### • Associated PEnQuIN Standards: S37

Indicator 35: Rate with which the endoscopy report documentation is complete

- Numerator: Number of procedure reports for pediatric endoscopies for which documentation is complete (all recommended reporting elements included)
   Denominator: All pediatric endoscopies performed
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S37

Indicator 36: Rate with which the endoscopy report documentation is finalized

- Numerator: Number of procedure reports for pediatric endoscopies for which documentation is finalized (ie, signed and entered into the medical record)
   Denominator: All pediatric endoscopies performed
- Calculation: Proportion (%)

#### • Associated PEnQuIN Standards: S37

Indicator 37: Rate with which endoscopy report documentation is finalized in a timely manner

- Numerator: Number of procedure report for pediatric endoscopies for which documentation is finalized (ie, signed and entered into the medical record)
  within a specified timeframe, per institutional/regulatory policies
- Denominator: All pediatric endoscopies performed

• Calculation: Proportion (%)

Associated PEnQuIN Standards: S37

 $\label{eq:pensitive} \begin{array}{l} \mbox{PEnQuIN} = \mbox{Pediatric Endoscopy Quality Improvement Network.} \\ \begin{tabular}{l} \mbox{^{\dagger}Procedure-related indicators linked to facility standards.} \end{array}$ 

adverse events (53,54). Among adult patients, several endoscopic studies suggest that using standardized documentation leads to improved patient outcomes, including fewer adverse events (43,52,59).

There are a number of comparative studies of sedation regimens in pediatric endoscopy that link patient cooperation and comfort with sedation practice (48,60,61), although these are limited by practical issues around outcomes measurement. Indeed, such measures generally rely on observation, which can be biased (62). It has been suggested that tracking the number of pediatric procedures that are interrupted and/or prematurely terminated due to a reported sedation/anesthetic-related issue may be of use, although such reports may also be subject to observer bias (63).

Finally, although there are several measures of patient cooperation, comfort and safety in children with strong validity evidence (64,65), none have been examined within the context of

pediatric endoscopy. There are several standardized scores for measuring patient comfort in adult endoscopy (62,66), and at least one has linked improved patient comfort with greater patient satisfaction (67). Nevertheless, none of these studies provide direct evidence that ensuring and documenting patient comfort during sedated pediatric endoscopic procedures improves patient outcomes.

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

**GRADE:** Conditional recommendation, very low-quality evidence. Vote: strongly agree, 37.5%; agree, 45.8%; uncertain, 16.7%

**Key evidence:** There is strong consensus that pediatric endoscopic procedures should be performed efficiently, with the goal of optimizing patient quality and safety while minimizing sedation/anesthesia time and exposure to endoscopic maneuvers; however, there is a paucity of reasonable quality indicators for endoscopic efficiency in children, and direct evidence for this standard in pediatrics is extremely limited. There are many different factors that contribute to procedure time, including those related to the procedure, equipment and sedation/anesthesia. Colonoscopy efficiency in adult patients can be measured by the time from rectal insertion to cecal intubation and is typically analyzed by adenoma or polyp detection rates. In contrast, ileocolonoscopy represents the preponderance of lower endoscopy procedures in children and requires additional time points of cecal intubation and terminal ileum intubation.

Adult studies of colonoscopy have correlated longer procedure times, including longer withdrawal times, with higher polyp detection rates; (68,69) these studies and others are based on a premise that brief procedure times in adults may be associated with low diagnostic yield. Longer procedure times in adults may also reflect added time for therapeutic maneuvers, such as polypectomy, and may be associated with procedure completeness (ie, performance of a polypectomy as indicated). There is one study in pediatrics that also shows longer procedure times for children undergoing colonoscopies with polypectomies (14).

Nevertheless, the discussion of procedure time in pediatrics evokes altogether different issues. Beyond time required for therapeutic interventions, procedure times in children have been assumed to be prolonged due to inadequate colonoscopy preparation, inexpert insertion technique as well as time spent performing biopsies during withdrawal per pediatric standards of practice (5). Furthermore, most children require ileocolonoscopy for completeness of their procedures. Pasquarella et al (70) reported that lower procedure time in children was significantly associated with higher ileal intubation rates, while longer procedure time was significantly associated with incomplete ileocolonoscopy. The overarching concern in pediatrics that prolonged endoscopy times may be a marker of low quality procedures is an important target for future qualityrelated research.

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.

**GRADE:** Conditional recommendation, low quality evidence. Vote: strongly agree, 56.5%; agree, 43.5%

Key evidence: There was strong consensus that a complete pediatric colonoscopy should include ileal intubation and a small body of direct pediatric evidence that adequacy of bowel prep affects ileal intubation rates. In a single-center retrospective review of 652 pediatric patients, poor quality bowel preparation was inversely related to successful ileal intubation (71). In addition, a prospective multi-center study of 21,807 pediatric colonoscopies, for which prep quality was reported in 44% of cases, found that poor bowel preparation was significantly associated with a lower rate of ileal intubation, compared to bowel preparation described as "excellent," "good," or "fair" (14). These studies are limited by heterogeneous means of assessing bowel preparation, as there are no validated scales to rate pediatric bowel prep (72). To date, the most commonly reported method has been the use of standardized language such as "excellent," "good," "fair," or "poor"; ideally with clear, predetermined definitions for such terms. Nevertheless, pediatric evidence to date is consistent with several large adult studies that have demonstrated that the rate of cecal intubation is strongly associated with the adequacy of bowel prep (14,71-77). A number of standardized tools have been shown to have strong validity evidence in the context of adult colonoscopy, including the Boston Bowel Preparation scale (adequate:  $\geq 6$ ) (78,79), Ottawa

Bowel Preparation scale (adequate:  $\leq$ 7) (80), or Aronchick Scale (adequate: "excellent," "good," or "fair") (81); however, their application to pediatrics has not been systematically evaluated.

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.

**GRADE:** Conditional recommendation, no evidence. Vote: strongly agree, 75.0%; agree, 12.5%; uncertain, 12.5%

**Key evidence:** There was a strong consensus that endoscopic investigation for diagnosis and therapy of children with digestive disorders should be performed completely according to an established protocol for the expected condition. Presumably, incomplete examinations expose patients/caregivers to the inconvenience, cost and risk associated with procedures, without providing reliable diagnostic yield or appropriate therapeutic benefit; however, there is no validated definition of what constitutes complete endoscopic procedures in children. Furthermore, there is no direct evidence that pediatric endoscopic procedures performed completely in accordance with procedural indications are associated with better outcomes.

There is limited evidence to suggest that photo/video documentation of important anatomical landmarks can be helpful in determining procedural completeness. In one observational study in adults, higher rates of photo/video documentation were associated with improved cecal intubation rates (82). In two other retrospective investigations, endoscopists who were defined as "more meticulous" at cecal image documentation had higher polyp detection rates (83), whereas ampulla photo-documentation was found to be a predictor of neoplasm detection during upper endoscopic procedures in adult patients (84). A number of adult guidelines have provided recommendations regarding which anatomical landmarks should be photo/video documented, including image documentation of duodenum, gastric fundus via retroflexed view and the gastro-esophageal junction for upper endoscopy; and the cecum/ appendiceal orifice and terminal ileum for ileo-colonoscopy (6.12.13.23.85 - 88).

# Standard 35: Photo/video documentation of all visualized abnormal findings should be obtained.

**GRADE:** Conditional recommendation, very low-quality evidence. Vote: strongly agree, 70.9%; agree, 20.8%; uncertain, 8.3%

**Key evidence:** There was consensus that photo/video documentation of abnormal findings should be included in a pediatric endoscopy report, despite no direct evidence that this improves outcomes in children. Many adult consensus guidelines and position statements have also supported image documentation, despite similarly limited high-quality evidence (6,12,13,23,85–88).

Standard 36: Endoscopic biopsies should be obtained as appropriate for the procedural indication, consistent with current evidence-based guidelines, when available.

**GRADE:** Conditional recommendation, low-quality evidence. Vote: strongly agree, 66.7%; agree, 29.2%; uncertain, 4.1%

**Key evidence:** Despite numerous current pediatric consensus statements that recommend routine tissue sampling even in the absence of visible endoscopic abnormalities in all children undergoing upper endoscopy and ileocolonoscopy to improve the likelihood of detecting disease, if present, the quality of evidence to support this practice is low and indirect (3,5,89–91). Although pediatric studies have been generally retrospective single-center studies, their findings have consistently suggested that performance of both upper gastrointestinal endoscopy and ileocolonoscopy with biopsies increases diagnostic yield during evaluation for suspicion of inflammatory bowel disease, and may be important in disease

differentiation (89,92–98). For example, evidence-based international guidelines related to *Helicobacter pylori* (91), celiac disease (90), eosinophilic esophagitis (99) and inflammatory bowel disease (100) all outline the sites and number of biopsies recommended for pediatric endoscopy.

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.

**GRADE:** Conditional recommendation, very low-quality evidence. Vote: strongly agree, 66.7%; agree, 20.8%; uncertain, 12.5%

**Key evidence:** There is consensus that full documentation of endoscopic procedures in children that includes all clinical and quality measures is important: it encourages mucosal inspection, ensures complete examination, can obviate the need for repeated procedures, improves diagnostic yield and acts as a legal record; however, there is no direct pediatric evidence that demonstrates that such complete documentation, including photodocumentation, is linked to better patient outcomes. As described above, there is evidence that photodocumentation may be linked to procedural quality in the adult context (83,84). Several adult guidelines also support the need for appropriate documentation of endoscopic procedures, including photo/video documentation (6,12,13,23,85–88).

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

**GRADE:** Conditional recommendation, no evidence. Vote: strongly agree, 25.0%; agree, 62.5%; uncertain, 8.3%; disagree, 4.2%

**Key evidence:** Although there was consensus that standardizing disease-related terminology in pediatric endoscopy reports, also commonly referred to as procedure notes, represents an opportunity to improve procedural quality, there is no available direct or indirect evidence that focusing on textual descriptions in documentation can improve outcomes of children undergoing endoscopic procedures (86,101,102). A number of adult studies have documented substantial variation in the use of different standardized disease-related terminology, as well as in the use of scoring systems and/or scales (103–109). To date, no conclusion can be drawn for either pediatric or adult endoscopic care regarding the best way to document abnormal findings, nor what scoring systems or scales should be utilized for pediatric patients undergoing routine and/or emergency endoscopic procedures.

# **Procedures Subdomain 3: Postprocedure**

High-quality endoscopy involves maintaining patient safety and ensuring procedural effectiveness after the scope has been withdrawn and the patient returns to their baseline clinical status. As part of postprocedure care, patients must recover from any sedation and be monitored for any adverse events secondary to performing the procedure that may not have been immediately apparent (ie, before scope removal). When patients are clinically stable for discharge from the procedural facility, they will nevertheless require self-monitoring and/or monitoring by caregivers for late procedure-related adverse events. These have been well reported to occur, albeit on rare occasions; therefore, patients must receive clear instructions on what to monitor for as well as when, where and how to seek further care (4). Finally, high-quality procedures are not complete until tissue sampling analysis has been reviewed in a timely manner directly with the patient, through the lens of planning the next steps in their care.

The following achieved consensus within the PEnQuIN working group as minimum Postprocedural quality standards, as measured by their five associated indicators (Table 4).

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.

**GRADE:** Conditional recommendation, very low-quality evidence. Vote: strongly agree, 75.0%; agree, 25.0%

There was consensus that patients should be provided with written instructions at discharge, despite no direct evidence that this improves outcomes in children. Adverse events related to pediatric endoscopic procedures are rare, with rates similar to those reported for adult procedures (49,110). Although there is limited qualitative evidence that postprocedure planning for children undergoing endoscopy and their families may improve patient experience, and reduce the rate of late adverse events (41), there is no direct evidence for optimal methods of educating patients about potential symptoms which may indicate a procedure-related adverse event.

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.

**GRADE:** Conditional recommendation, very low-quality evidence. Vote: strongly agree, 58.3%; agree, 33.3%; uncertain, 4.2%; disagree, 4.2%

Key evidence: Although there is consensus that being discharged from an endoscopic procedure with written/verbal information regarding endoscopic results, plans for conveying pathology results and follow-up should strengthen patient/caregiver understanding of their treatment plan and enhance overall patient satisfaction, there is very little direct evidence to support this. Moreover, conveying results to patients/caregivers may be difficult to monitor and document, especially in the case of verbalized information. One retrospective pediatric study of recalled information transmitted during postprocedure phone calls was limited by variability in whether or not such calls occurred (41). The investigators called for quality assurance efforts by facilities that use postprocedural calls to transmit information to ensure they occur (41). Among adults, one study compared patient receipt of postprocedure instructions with or without their endoscopy report at the time of discharge and found that the group that also received the endoscopy report as well had less postprocedure anxiety and superior recall of findings and recommendations (111). An adult-focused systematic review concluded that discussion of results with the endoscopist after procedures enhanced patient satisfaction and increased their willingness to return for repeat testing (112).

# Standard 41: Pathology findings should be reviewed with patients and/or caregivers in a timely fashion. This process must be documented.

**GRADE:** Conditional recommendation, very low-quality evidence. Vote: strongly agree, 65.2%; agree, 26.1%; uncertain, 4.4%; strongly disagree, 4.3%

**Key evidence:** There is consensus that pathology findings should be communicated to patients/caregivers in a "timely manner" after the performance of an endoscopic procedure with biopsies, and this should be documented, despite a lack of evidence that this practice improves patient outcomes and patient/caregiver satisfaction. Moreover, "timely manner" has not yet been defined. One retrospective pediatric study determined that only 40% of patients were notified of pathology results at the time of a post-procedural phone survey up to 3 weeks later (41). There is also little known about the timing and communication of pathology findings in adults and how this relates to procedural outcomes. One survey-based study of patients had no knowledge of when they would receive pathology results following their procedure (113). In short, evidentiary support for this standard is very low and additional

**S38** 

#### TABLE 4. Indicators related to the "Postprocedure" subdomain

Indicator 38: Rate with which patients/caregivers receive written postprocedure instructions upon discharge

 Numerator: Number of patients/caregivers who receive written postprocedure instructions upon discharge and communication of these instructions is documented. Instructions should include potential symptoms that may indicate a procedure-related adverse event, along with instructions on what to do should these symptoms develop

• Denominator: All pediatric patients undergoing endoscopies

Calculation: Proportion (%)

Associated PEnQuIN Standards: S39

Indicator 39: Rate with which the plan for pathology follow-up is communicated to patients/caregivers

• Numerator: Number of patients/caregivers who receive a plan for pathology follow-up after a pediatric endoscopy and this plan is documented

- Denominator: All pediatric patients undergoing endoscopies
- Calculation: Proportion (%)

Associated PEnQuIN Standards: S40

Indicator 8<sup>†</sup>: Rate of *documented* immediate postprocedural adverse events

- Numerator: Number of immediate postprocedural adverse events that are documented for a procedure/facility/group/provider
- Denominator: All immediate postprocedural adverse events occurring at a procedure/facility/group/provider level
- Calculation: Proportion (%)

# Associated PEnQuIN Standards: S12

Indicator 9<sup>†</sup>: Rate of *documented* late adverse events

- Numerator: Number of late adverse events, defined as procedure-related adverse events identified after an endoscopy is complete, that are *documented* for a procedure/facility/group/provider
- Denominator: All late adverse events occurring at a procedure/facility/group/provider level
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S12

Indicator 40: Rate with which pathology findings are reviewed with the patient and/or caregiver

- Numerator: Number of patients/caregivers who receive communication about pathology findings after a pediatric endoscopy and this communication is documented
- Denominator: All pediatric patients undergoing endoscopies
- Calculation: Proportion (%)
- Associated PEnQuIN Standards: S41

PEnQuIN = Pediatric Endoscopy Quality Improvement Network. <sup>†</sup>Procedure-related indicators linked to facility standards.

studies to define "timely manner" and correlate this metric with patient outcomes are warranted.

## DISCUSSION

The goal of the PEnQuIN working group in this document was to achieve consensus on a list of key standards that should be applied to all gastrointestinal endoscopic procedures that are performed in children. In addition, the working group defined indicators that can be used to measure the quality of procedures at an individual provider, group of providers or facility level, as appropriate. All standards and indicators that were ascribed to procedural quality can be characterized as process measures that assess performance during the delivery of care (eg, proportion of children with suspected eosinophilic esophagitis who have esophageal biopsies obtained from multiple levels of the esophagus; proportion of patients and their caregivers who receive postprocedure instructions upon discharge). These are different from structural indicators, which measure quality of a healthcare environment (eg, availability of size appropriate equipment) and are delineated by the PEnQuIN working group in a separate document on pediatric endoscopy facilities (114).

As part of the PEnQuIN process, the working group considered that almost all children are referred for endoscopy after clinical assessment by an accredited pediatric gastrointestinal specialist, either in ambulatory settings, (eg, a pediatric gastroenterology clinic) or hospital or urgent care settings (eg, a hospital ward, intensive care setting or emergency department). In other words, there are currently no common processes in either North America or Europe by which non-gastroenterology providers refer children directly and electively via open-access scheduling for endoscopy. as may be the case for adults undergoing colonoscopy for cancer screening preventive healthcare. The PEnQuIN working group agreed that endoscopy in children begins with a determination that a procedure needs to occur and extends through all communications with patients that pertain to the procedure (eg, communication about pathology results), even if they occur after a patient has left the endoscopy facility. As with procedures in adults, some standards and indicators for pediatric endoscopy may be specific to particular endoscopic procedures or gastrointestinal conditions. The performance of gastrointestinal procedures in children de facto requires an endoscopist working in a facility with the equipment, endoscopes and trained personnel required to perform the procedure. As such, quality standards and indicators for pediatric gastrointestinal procedures, which overlap greatly with those relating to facilities and endoscopists, can be assessed for various purposes at the level of an individual provider, a group of providers or a facility.

While acknowledging this overlap between domains, the PEnQuIN working group also felt that it was possible to enucleate those standards and indicators that relate to the procedure specifically. All procedure standards and indicators outlined in this document do not require specific facility structures, team members or workflows to be in place, and should be universally upheld by all endoscopists for all procedures, regardless of individual skill. Although the working group acknowledged that clinical performance and feasibility of obtaining data to determine indicators may vary significantly, they also felt that indicators that can be ascribed to high-quality procedures should be measurable regardless of practice type or volume. The assessment of these quality indicators for pediatric endoscopic procedures may then be useful to help ensure all children receive high-quality procedures, by allowing an endoscopist and/or their employer, practice or the facility in which they practice to identify opportunities for improving performance.

During the PEnQuIN in-person conference, "rate of adequate bowel preparation" (Indicator 28) was identified to be a priority indicator related to lower endoscopy, and a minimum unadjusted target of  $\geq$ 80% was set by consensus. This indicator reflects the critical importance of bowel preparation for optimal diagnostic evaluation during lower procedures in children, as well as for therapeutic intervention (4,115). Pediatric studies have shown an association between poor preparation and procedure incompletion (14,71), while adult studies have shown that poor preparation is associated with incomplete procedures (45,76), as well as prolonged procedure time (116,117), greater patient discomfort (117) and reduced yield (77,118-120). Additionally, suboptimal bowel preparation can result in additional costs, resource waste and inconvenience related to procedures that must be repeated (121). Although minimum targets for bowel preparation have been identified for adult patients (10,13,122,123), the PEnQuIN group recognized that bowel preparation in children is particularly challenging due to palatability, tolerance and a lack of standardized regimens (124,125); however, they also pointed to numerous consensus statements on the topic regarding best practice, as well as highly associated risks of inadequate bowel preparation, including missed diagnoses, procedural risks and increased costs (12,13,25,115,126). In turn, the group felt that an unadjusted minimum target of 80% adequate preparation was reasonable and allowed for the reality that some children may be very difficult to prepare for endoscopy. A standardized tool, such as the Boston Bowel Preparation scale (adequate:  $\geq 6$ ) (78,79), Ottawa Bowel Preparation scale (adequate:  $\leq$ 7) (80) or Aronchick Scale (adequate: "excellent," "good," or "fair") (81) should ideally be used to assess bowel preparation quality, and this has been shown to be feasible in routine practice (127,128). Low performers on this metric (ie, adequate bowel preparation rates below 80%), at the individual provider, group of providers or facility levels, should be encouraged to engage in quality improvement activities to correct deficiencies.

All standards and indicators outlined in this document are intended to guide and measure the quality of endoscopic procedures in children across all phases of their performance. Certainly, there are many members of a clinical team who may have contact with a patient at different phases of the procedure (ie, preprocedure, intraprocedure and postprocedure). In addition, the quality of procedures may be influenced by many factors related to the facilities in which they are performed. In demarcating those standards and indicators that are specifically related to procedures, the PEnQuIN working group agreed that each in this domain can be universally upheld by an individual provider, a group of providers as well as the facilities in which they perform pediatric gastrointestinal procedures, regardless of procedural volume, personnel or resources.

In addition, the PEnQuIN working group achieved excellent consensus for each standard and indicator included in this document as valuable and relevant to all endoscopy procedures that are performed in children. In other words, every child should only undergo gastrointestinal procedures for appropriate indications, after adequate preparation and with informed consent/assent as well as a plan to ensure their safety and comfort. During every pediatric gastrointestinal procedure, maximal evidence-based efforts should be universally made to ensure the efficient performance of a procedure in its entirety with documentation that clearly lays out its diagnostic and/or therapeutic yield in the medical record. After procedures, all children who have undergone endoscopy should be monitored until they are safe for discharge from endoscopic care, with a clear plan for follow-up, even if that is only required on an as-needed basis (eg, following foreign body removal from an otherwise healthy child).

These expectations can and should apply to large tertiary care centers with many providers in academic, hospital-based settings with endoscopists-in-training. Although it is possible that trainee endoscopists may have an impact on procedure-related quality indicators, the working group nevertheless felt that no child should be penalized in terms of the quality of their healthcare because they receive endoscopy services in a teaching hospital. Likewise, the procedure-related standards and indicators in this document pertain to community-based practices, even those featuring independent pediatric endoscopists performing ambulatory elective procedures in multi-purpose ambulatory surgical centers, with nursing and technical support from endoscopy personnel who are independently employed.

Ideally, the standards and indicators laid out in this document contribute to optimal procedural outcomes and provide a basis for defining the quality of pediatric endoscopic procedures, as well as for assuring consumer transparency. In terms of the former, the rigor of the PEnQuIN process confirmed a dearth of evidence for almost every aspect of endoscopic procedures that are assumed to define their quality. In turn, this PEnQuIN document provides a basis for future research in measuring procedural quality, particularly with an eye to patient outcomes. The PEnQuIN working group does not endorse measurement of procedural quality for punitive purposes, rather the goal is identifying opportunities for continually and universally improving the quality of pediatric endoscopy. PEnQuIN is also committed to developing multi-center registries incorporating these quality metrics that can be used for feedback, benchmarking and to promote improvement.

In conclusion, the PEnQuIN working group believes that the worldwide consensus they achieved throughout this process is a testament to how important these standards and indicators are to ensuring that pediatric endoscopy is done well. We are now calling upon pediatric gastroenterologists as a community, as well as all who provide endoscopy services for children, to commit to their universal implementation without delay.

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