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## International Consensus on Quality Standards and Indicators for Pediatric Endoscopy: A Report from the PEnQuIN --Manuscript Draft--

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<b>Abstract:</b>	<p><b>Introduction:</b>  Pediatric-specific quality standards for endoscopy are needed to define best practices, while measurement of associated indicators is critical to guide quality improvement. The international Pediatric Endoscopy Quality Improvement Network (PEnQuIN) working group was assembled to develop and define quality standards and indicators for pediatric gastrointestinal endoscopic procedures through a rigorous guideline consensus process.</p> <p><b>Methods:</b>  The Appraisal of Guidelines for REsearch and Evaluation (AGREE II) instrument guided PEnQuIN members, recruited from 31 centers of various practice types representing 11 countries, in generating and refining proposed quality standards and indicators. Consensus was sought via an iterative online Delphi process, and finalized at an in-person conference. Quality of evidence and strength of recommendations were rated according to the GRADE (Grading of Recommendation Assessment, Development, and Evaluation) approach.</p> <p><b>Results:</b>  Forty-nine quality standards and 47 indicators reached consensus, encompassing pediatric endoscopy facilities, procedures, endoscopists and the patient experience. The evidence base for PEnQuIN standards and indicators was largely adult-based and observational, and downgraded for indirectness, imprecision and study limitations to very low quality, resulting in conditional recommendations for most standards (45/49).</p> <p><b>Conclusions:</b>  The PEnQuIN guideline development process establishes international agreement on clinically meaningful metrics that can be used to promote safety and quality in endoscopic care for children. Through PEnQuIN, pediatric endoscopists and endoscopy services now have a framework for auditing, providing feedback and, ultimately, benchmarking performance. Expansion of evidence and prospective validation of PEnQuIN standards and indicators as predictors of clinically relevant outcomes and high quality pediatric endoscopic care is now a research priority.</p>
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## **Overview of the Pediatric Endoscopy Quality Improvement Network (PEnQuIN) Quality Standards and Indicators for Pediatric Endoscopy: A Joint NASPGHAN/ESPGHAN Guideline**

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**ABBREVIATIONS**

- American College of Gastroenterology: ACG
- American Society for Gastrointestinal Endoscopy: ASGE
- Appraisal of Guidelines for REsearch and Evaluation: AGREE
- Canadian Association of Gastroenterology: CAG
- European Society for Paediatric Gastroenterology Hepatology and Nutrition: ESPGHAN
- European Society of Gastrointestinal Endoscopy: ESGE
- GI Quality Improvement Consortium: GIQuIC
- Global Rating Scale: GRS
- Grading of Recommendation Assessment, Development, and Evaluation: GRADE
- North American Society for Pediatric Gastroenterology, Hepatology and Nutrition: NASPGHAN
- Patient/population, intervention, control/comparator and outcome: PICO
- Pediatric Endoscopy Quality Improvement Network: PEnQuIN

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

## **ABSTRACT**

### **Introduction:**

Pediatric-specific quality standards for endoscopy are needed to define best practices, while measurement of associated indicators is critical to guide quality improvement. The international Pediatric Endoscopy Quality Improvement Network (PEnQuIN) working group was assembled to develop and define quality standards and indicators for pediatric gastrointestinal endoscopic procedures through a rigorous guideline consensus process.

### **Methods:**

The Appraisal of Guidelines for REsearch and Evaluation (AGREE II) instrument guided PEnQuIN members, recruited from 31 centers of various practice types representing 11 countries, in generating and refining proposed quality standards and indicators. Consensus was sought via an iterative online Delphi process, and finalized at an in-person conference. Quality of evidence and strength of recommendations were rated according to the GRADE (Grading of Recommendation Assessment, Development, and Evaluation) approach.

### **Results:**

Forty-nine quality standards and 47 indicators reached consensus, encompassing pediatric endoscopy facilities, procedures, endoscopists and the patient experience. The evidence base for

PEnQuIN standards and indicators was largely adult-based and observational, and downgraded for indirectness, imprecision and study limitations to very low quality, resulting in conditional recommendations for most standards (45/49).

**Conclusions:**

The PEnQuIN guideline development process establishes international agreement on clinically meaningful metrics that can be used to promote safety and quality in endoscopic care for children. Through PEnQuIN, pediatric endoscopists and endoscopy services now have a framework for auditing, providing feedback and, ultimately, benchmarking performance. Expansion of evidence and prospective validation of PEnQuIN standards and indicators as predictors of clinically relevant outcomes and high quality pediatric endoscopic care is now a research priority.

**KEY WORDS:**

- Quality Assurance, Health Care
- Practice Guidelines as Topic/\*standards
- Pediatric Gastroenterology/\*standards
- Endoscopy, Gastrointestinal/\*standards
- Key Performance Indicators

## INTRODUCTION

Measuring the quality of endoscopic care is an increasingly expected standard component of performing gastrointestinal endoscopy in children.<sup>1,2</sup> Quality of care has been defined as the “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”<sup>3</sup> With regard to endoscopy, quality of care is multifaceted and encompasses technical skill, as well as elements related to the healthcare system, facilities, workforce, training, clinical quality, and patient and caregiver experience.<sup>4-7</sup> Although the pediatric endoscopy community has long endeavored to consistently provide the best possible patient care, it is currently underequipped to achieve this goal, in large part because pediatric-specific quality standards and indicators are lacking. In response, the international Pediatric Endoscopy Quality Improvement Network (PEnQuIN), jointly supported by the North American Society of Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) and the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), was initiated to fill this gap.

Thousands of children undergo endoscopic procedures annually in Europe and North America to diagnose and manage digestive diseases.<sup>8</sup> Internationally, the definition of childhood varies, but generally includes infancy through adolescence.<sup>9,10</sup> There is evidence to suggest that high quality endoscopic care results in improved health outcomes, better patient and caregiver experiences and fewer repeat procedures<sup>11</sup>; however, available evidence also demonstrates significant variation in the practice of pediatric endoscopy.<sup>8,12,13</sup> For example, multi-center outcomes data has demonstrated variable terminal ileal intubation rates during ileocolonoscopy across providers, with greater than 30% of procedures lacking documentation of this maneuver,<sup>12</sup> and

may represent an opportunity for quality improvement.<sup>8,12,13</sup> The same outcomes repository has shown routine diagnostic pediatric lower endoscopy times to vary considerably (mean time 32.6 minutes  $\pm$  14.2 minutes, range 5-120 minutes),<sup>12</sup> again suggesting opportunity for individual provider improvement on this metric.<sup>14</sup> Maintaining and enhancing the quality and safety of pediatric endoscopic services requires a continual process that defines and measures indicators of pediatric endoscopic care to identify gaps in care, inform plans for improvement, and implement changes based on the measures. This improvement process also entails analyzing the effects of changes and acting on what is learned to systematically advance the quality of endoscopic care that is delivered to children.<sup>6,15</sup>

### **Quality Standards and Indicators**

Endoscopy services and providers benefit from measurable targets for quality improvement.<sup>7,16</sup> As such, the road to quality improvement begins with an effort to define minimum expected *quality standards* which provide a framework for quality assurance and improvement that aids both endoscopy facilities and endoscopists in assessing the quality of service they provide (**Table 1**). *Quality indicators*, which are measurable and auditable key performance indicators against which practice can be compared, are also required to support quality improvement activities designed to enhance patient outcomes, maximize patient safety, and optimize efficiency. Quality indicators may relate to organizational structures (healthcare environment), healthcare processes (delivery of care) or outcomes (results of care provided), and should be clinically relevant, evidence-based and amenable to both measurement and improvement.<sup>17,18</sup> Some standards and indicators may be procedure-specific while others may be generic to all pediatric endoscopic procedures.<sup>17</sup>

*[insert Table 1]*

## **The Road to Quality**

Knowledge that quality improvement is central to enhancing outcomes is important but not sufficient to ensure high quality care. Evidence-based guidelines are required that define quality standards and indicators. These must be carefully constructed with the goal of enabling providers and services to identify suboptimal performance, monitor key outcomes and address specific deficits to ensure provision of high quality patient- and family-centered care. Performance standards and indicators should be carefully selected such that they identify and assess all important aspects across the entire continuum of pediatric endoscopy service delivery and, when taken together, provide a comprehensive snapshot of service quality.<sup>18</sup>

Minimum targets (minimally acceptable thresholds of performance) and aspirational targets (desirable levels of performance) for quality indicators are also required to provide benchmarks against which performance can be measured. Even if there is insufficient evidence to recommend a specific target, it is important to monitor indicators for quality assurance purposes. Ideally, indicators can also be used to incentivize engagement in continuous quality improvement activities that yield results as they outline clear criteria for performance assessment.

At a local level, service and provider performance must be measured, summarized, and fed back (i.e., via audit and feedback) to improve performance and self-monitoring and, ultimately, to enhance patient care. By providing objective data, audit and feedback can be employed to

highlight discrepancies between current and target performance, while also promoting action and behavior change to improve suboptimal performance.<sup>19</sup> Across centers, computerized endoscopy reporting systems and centralized data repositories are required to enable data comparison in a way that supports wide-scale pediatric endoscopy quality improvement efforts.<sup>20–22</sup>

### **Quality and Pediatric Endoscopy**

To date, defining meaningful, realistic, practical and objective consensus- and evidence-based standards and indicators for endoscopy has been a complex enterprise, requiring national and societal commitment and support.<sup>4,23–31</sup> However, given the unique indications, pathophysiology and risk profile involved in pediatric endoscopy, there has been concern that principles derived from an adult perspective are not directly generalizable to the specific needs of children and their families.<sup>32</sup> Additionally, there has been limited literature examining the applicability of adult endoscopic quality and safety indicators (e.g., withdrawal time) to pediatric endoscopy practice and their impact on clinically relevant outcomes.<sup>1,6,32</sup> In turn, it is important that adult standards and indicators are evaluated in terms of their relevance to pediatric endoscopy, and that standards and indicators unique to pediatric endoscopy are identified.

To date, the introduction of colorectal cancer screening programs has fostered an effort to accurately define and measure quality indicators across the spectrum of endoscopic care to help improve care.<sup>27,33</sup> The American Society for Gastrointestinal Endoscopy (ASGE) and American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy recently published a comprehensive list of measurable quality indicators for various endoscopic procedures derived from current evidence and expert consensus.<sup>23–27</sup> Additionally, the ASGE has developed the

Endoscopy Unit Recognition Program and the GI Quality Improvement Consortium (GIQuIC) benchmarking registry, with the aim of promoting improvement by empowering staff to create safe, high quality endoscopy units.<sup>2,34,35</sup> In the United Kingdom, an accreditation process for endoscopy units was developed in response to a 2004 prospective multicenter audit of colonoscopy services that revealed significant deficiencies in the quality of colonoscopy services at that time.<sup>36</sup> Since then, minimal quality standards for the delivery of endoscopy have been established<sup>28,29</sup> and the endoscopy Global Rating Scale (GRS), a web-based, patient-centered quality improvement tool for endoscopy units, has been developed for national use.<sup>37,38</sup> More recently, an adapted GRS has been successfully piloted in pediatric units in the United Kingdom.<sup>7</sup> In Canada, the Canadian Association of Gastroenterology (CAG) has published consensus guidelines on safety and quality in endoscopy which include a comprehensive set of clearly defined, evidence-based measures to support continuous quality improvement in endoscopy across Canada.<sup>4</sup> Subsequently, the CAG adapted the British GRS to develop a similar web-based, patient-centered tool for endoscopy facilities to assess and improve the quality of service they offer. The European Society of Gastrointestinal Endoscopy (ESGE) has also recently defined performance measures for gastrointestinal endoscopy.<sup>30,31</sup>

To address the need to develop and define a set of quality standards and indicators tailored to pediatric endoscopic practice, we assembled an international working group on quality in pediatric endoscopy, PEnQuIN. This paper explains the rationale behind the PEnQuIN initiative and describes the rigorous international guideline development process we utilized. It also introduces a series of 4 accompanying clinical practice statements in this supplemental issue that provide in-depth details on important domains of quality, including facilities, endoscopists and

procedures, as well as elements of procedural documentation that should be mandatory to ensure high quality pediatric endoscopy.

## **METHODS**

### **The PEnQuIN Initiative**

The PEnQuIN was established in 2017 with Co-Chairs from NASPGHAN (CMW and JRL) and ESPGHAN (MAT). Its overarching aims are:

1. To improve the quality of pediatric endoscopy, as well as the delivery of patient- and family-centered endoscopic care;
2. To support endoscopy facilities where pediatric procedures are performed, as well as endoscopists and endoscopists in training who perform procedures on pediatric patients, to achieve high quality care.

PEnQuIN members consist of an international group of 33 endoscopists representing 31 centers across 11 countries. Working group members were identified as key stakeholders from NASPGHAN and ESPGHAN and were specifically selected based on *a priori* criteria developed by the PEnQuIN co-chairs to represent various geographic regions and practice types, including both academic and community practitioners, and practice settings. Particular attention was also made to assuring adequate representation from both therapeutic and diagnostically-focused endoscopists and included various perspectives (e.g., an adult endoscopist who performs some pediatric endoscopy). Working group membership was reviewed as part of the NASPGHAN and

ESPGHAN societal guideline approval processes to ensure diverse and appropriate representation.

As a first step, the PEnQuIN working group sought to develop and define a set of quality standards and indicators tailored to pediatric endoscopic practice. An overview of this process is outlined below, and detailed results are reported in the accompanying articles in this supplement.

As a second principal initiative, we sought to achieve consensus on standardized reporting elements for endoscopic procedures performed on pediatric patients. The methodology and resulting reporting elements are also outlined in an additional manuscript in this supplement.

### **Process to Develop Quality Standards and Indicators for Pediatric Endoscopy**

A rigorous multistep guideline development process, based on the Appraisal of Guidelines, REsearch and Evaluation II (AGREE) tool<sup>39</sup>, was used to structure the development of the PEnQuIN standards and indicators. AGREE II is an internationally accepted framework for guideline development that guides and assesses scientific rigor and transparency throughout the process.<sup>39</sup> An overview of the multistep guideline development process used by PEnQuIN is outlined in **Table 2**.

*[insert Table 2]*

### ***Sources and Searches***

An initial set of proposed pediatric endoscopy quality standards and indicators were derived from 3 sources: (1) a librarian-assisted systematic literature search; (2) a hand-search of

reference lists from published adult consensus statements (CAG<sup>4</sup>, ASGE<sup>24</sup>, British Society of Gastroenterology<sup>28</sup> and ESGE<sup>18</sup>); and (3) a survey of PEnQuIN members conducted in May 2018. Literature searches were performed in Medline, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) for (a) all relevant records from 2015 through to July 24, 2018 and (b) pediatric-focused records from 1990 through to July 24, 2018. Key search terms included endoscopy and quality. The detailed search strategy, which was developed by a reference and instruction librarian in collaboration with the PEnQuIN Co-Chairs, is available in *Supplemental Appendix 1*. We included both adult and pediatric studies given the paucity of pediatric data. Only human studies published in English were considered. All citations were exported into EndNote<sup>®</sup> (Philadelphia, Pennsylvania) and duplicates removed. The citations were divided among three reviewers (CMW, JRL and MAT) who independently performed a title and abstract screen to identify potentially relevant citations. The three authors then met on several occasions to review the full-text publications, categorize them by topic and link them to the proposed quality standards and indicators.

### ***Review and Grading of Evidence***

Proposed quality standards and their related indicators were divided amongst pairs of PEnQuIN working group members. Each pair developed a list of questions relevant to the standard (and corresponding indicator(s)) using the PICO format, which comprises the patient/population, intervention, control/comparator and outcome.<sup>40,41</sup> PICO-format questions were reviewed by the PEnQuIN Chairs (CMW, JRL and MAT) until they were precisely defined.

The quality of evidence for each quality standard (and corresponding indicator(s)) was then evaluated using the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) approach, including assessment of the risk of bias, indirectness, inconsistency, imprecision and other considerations (including publication bias).<sup>42</sup> The quality of evidence for each standard was classified as high, moderate, low or very low as described in GRADE methodology (**Table 3**),<sup>42,43</sup> of as ‘no evidence’ when no relevant studies were found. This process was completed independently by 2 PEnQuIN members using a standardized template. Any disagreements were resolved through review by two additional authors (CMW and JRL).

*[insert Table 3]*

### ***Consensus Process***

Prior to the face-to-face meeting, the proposed standards and indicators were revised iteratively using a modified Delphi process<sup>44-46</sup> that was conducted using the online platform SurveyMonkey® (San Mateo, California). All PEnQuIN working group members were asked to vote anonymously on their level of agreement with each proposed standard and indicator on a 5-point scale (with 1, 2, 3, 4 and 5 indicating ‘strongly disagree’, ‘disagree’, ‘uncertain’, ‘agree’ and ‘strongly agree’, respectively). The GRADE evaluations of the evidence base for each standard and indicator was appended electronically (i.e., hyperlinked) to each statement along with a folder containing all relevant full-text references. Additionally, working group members were invited to provide comments and suggested revisions to the proposed standards and indicators. The standards and indicators were revised, based on comments from panelists and any

additional evidence identified, through 2 separate Delphi rounds conducted in May 2018 and October 2018.

Subsequently, standards and indicators were finalized at an in-person consensus conference on October 28, 2018, held in conjunction with the 2018 NASPGHAN Annual Meeting. The GRADE evaluations of the evidence for the individual standards and indicators were reviewed, and the phrasing of specific statements was discussed prior to finalization. Participants then voted on their level of agreement using the aforementioned 5-point scale. Standards and indicators were considered to reach consensus if  $\geq 80\%$  of participants rated them as 4 ('agree') or 5 ('strongly agree'). If  $\geq 80\%$  agreement was not reached, the standard or indicator was discarded. Additionally, each indicator reaching consensus was reviewed and a decision was made as to whether it was possible to set a minimum target at the current time. Participants then voted on minimum targets for each identified indicator, with  $\geq 80\%$  agreement being defined as consensus agreement.

Participants who voted in both Delphi rounds and attended the in-person meeting ( $n = 24$ ) were eligible to participate in a final round of online voting in February and March 2020, during which they classified each standard as 'conditional' or 'strong.' This aimed to determine the strength of recommendation for each standard that reached consensus, with a vote of  $\geq 80\%$  of participants needed to classify a statement as 'strong' (recommended). If this threshold was not achieved, the standard was considered 'conditional' (suggested). The strength of the recommendation, which reflected the extent to which the PEnQuIN working group was confident that the desirable effects of adherence to the standard outweigh the undesirable effects,

considered 4 key factors: risk-benefit balance, the quality of the evidence, cost and resource allocation and the values and preferences of patients and their families.<sup>47</sup> Therefore, it was possible for a recommendation to be classified as 'strong' despite having low quality evidence or classified as 'conditional' despite there being high quality evidence.<sup>47,48</sup> As per GRADE methodology, a 'strong' recommendation should be considered indicative of a more broadly applicable statement that can be adopted across individuals and institutions despite variability in practice, whereas a 'conditional' recommendation suggests that different choices will be appropriate for different institutions and individuals. Additionally, the strength of a recommendation does not necessarily reflect its priority for implementation.<sup>47,48</sup>

As a separate initiative, the group also engaged in an online iterative Delphi process from January to July 2020 to identify required standard reporting elements for high quality pediatric endoscopy procedure reports. The results of this are outlined in an accompanying manuscript in this supplement.

### ***Role of Funding Sources***

Funding for the consensus meeting was provided by NASPGHAN and ESPGHAN, and NASPGHAN administered all aspects of the in-person meeting. The protocol was approved by both NASPGHAN and ESPGHAN, who agreed to develop a joint societal guideline. The views of the funding bodies did not influence the content of the guideline. In accordance with NASPGHAN and ESPGHAN policy, written disclosures of any potential conflicts of interest for the preceding 24 months were recorded by all PEnQuIN working group members and reviewed in accordance with societal policies. No concerns were identified.

## RESULTS OVERVIEW

The demographics of the 33 PEnQuIN working group members, who represent various practice types from 11 countries across North America and Europe, are outlined in **Table 4**.

*[insert Table 4]*

The literature search yielded 4401 records (2893 after duplicates removed) and an additional 104 records were identified through hand-searching (*Supplementary Appendix 1*). Thirty-nine initial quality standards and 52 indicators were generated from relevant studies, consensus statements and published guidelines regarding quality of endoscopic procedures. An additional 15 standards and 6 indicators were added by the PEnQuIN consensus panel. During the consensus process, 1 indicator was split into 2 distinct indicators, 4 standards and 13 indicators were eliminated, and 2 standards and 2 indicators were combined into a single standard and indicator, respectively (*Supplementary Appendix 2*).

Consensus was achieved across 24 participants eligible for the final round of voting on 49 quality standards and 47 indicators. These relate to the entire process of endoscopy in children, including the following domains:

1. Facilities - encompassing the (i) quality of clinical operations; (ii) quality of the patient and caregiver experience; and (iii) workforce;
2. Procedures;

### 3. Endoscopists and endoscopists in training.

The quality standards and their related indicator(s) that reached consensus are outlined in **Table 5**. Within each associated manuscript, the definition of each indicator, including details on how to calculate it, is included.<sup>17</sup> The GRADE evidence summaries for each can be found in **Supplementary Appendix 3**. The quality of evidence supporting the quality standards was generally of very low quality. Accordingly, 45 of 49 standards were classified as ‘conditional’ recommendations, indicating that the desirable effects of adherence to the standard likely outweigh the undesirable effects; however, each institution needs to consider individual practitioner, patient and institutional circumstances, preferences and values in deciding whether to implement the standard.<sup>47,48</sup> For the 4 standards classified as ‘strong’ recommendations, there was *moderate* evidence for two: Standard 20 (pediatric-specific monitoring and resuscitation equipment) and Standard 29 (informed consent/assent). The other two standards that were classified as ‘strong’ recommendations by the PEnQuIN working group, despite *very low* quality evidence, were determined by the group to be important to follow across individuals and institutions due to their high potential to cause significant patient harm if not adopted (i.e., risk-benefit profile): Standard 21 (age/size/weight appropriate endoscopy equipment) and Standard 48 (appropriate trainee supervision pending achievement of competence).

*[insert Table 5]*

Minimum targets were defined for three key indicators that relate to performance of high quality ileocolonoscopy in children:

- (a) unadjusted rate of adequate bowel preparation:  $\geq 80\%$  (indicator 28);
- (b) unadjusted cecal intubation rate:  $\geq 90\%$  (indicator 44); and
- (c) unadjusted terminal ileal intubation rate:  $\geq 85\%$  (indicator 45).

## **DISCUSSION**

The provision of safe, high quality, patient- and family-centered endoscopic care for children is a basic tenet of all endoscopists, as well as NASPGHAN and ESPGHAN, premier professional societies that strive to support this practice. Central to the goal of performing high quality pediatric endoscopy are meaningful, consensus- and evidence-based pediatric-specific performance *standards* that provide a framework for quality improvement, as well as *indicators* against which practice can be measured. The development of PEnQuIN quality standards and indicators through a rigorous international consensus guideline process has helped to realize this goal. The fruits of the PEnQuIN process are standards and indicators that can be used in a number of different ways to support high quality endoscopic care for children, as outlined in **Table 6**.

*[insert Table 6]*

To facilitate implementation across centers, quality indicators must be clearly defined, and their measurement standardized to permit comparative assessment. Within the accompanying manuscripts, we summarize the key evidence pertaining to each quality standard and describe precise measurement methodology for each quality indicator, with the goal of facilitating their

uptake in clinical practice. However, simply having performance measures available or focusing on data collection without feedback is insufficient to lead to sustained engagement, action and improved health outcomes. Feedback, defined as the provision of a summary of clinical performance (written, electronic or verbal) of health care over a specified period of time, is essential.<sup>49</sup> To this end, the PEnQuIN quality indicators must be adopted, implemented and audited at local levels so that endoscopic services and providers are aware of their performance and how it compares with others. This can serve to identify areas of underperformance, providing opportunity for discussion, intervention, and support.

There is plenty of evidence regarding the benefits of applying quality standards and indicators to gastrointestinal procedures. In particular, one recent systematic review and meta-analysis showed that endoscopist feedback can lead to improvements in adult-focused colonoscopy quality indicators, particularly for low performers.<sup>50</sup> Additionally, a study of 302 adult endoscopic units across the United Kingdom demonstrated that the implementation of performance measures, along with supportive training, can result in significant improvements in endoscopic quality, with cecal intubation rates improving from 76.9 to 92.3% from 1999 to 2011.<sup>37</sup> These effects may be in part due to the act of monitoring itself, which likely acts as a motivator for behavior change (i.e., Hawthorne effect) and resultant improvements in the quality of patient care.<sup>51</sup>

The PEnQuIN initiative was able to establish minimum targets for a few key variables, including cecal intubation rate, terminal ileal intubation rate and bowel preparation quality. Moving forward, it will be important for longitudinal data to be collected across sites with the goal of gathering aggregate baseline data for pediatric endoscopy to determine appropriate minimum and

aspirational targets for other PEnQuIN quality indicators against which services and providers can measure their performance. Over time, such a database will also have the power to track rare but important outcomes, such as serious adverse events, thereby allowing for a better understanding of practice variation and opportunities for improvement at both the endoscopist and facility levels. Of course, central to this process may be the need for standardized electronic endoscopy reporting systems that can permit meaningful aggregation and comparison of data across sites. It is our hope that the PEnQuIN standards and indicators can lend themselves to a quality dashboard for pediatric endoscopy that can be used to support quality improvement in endoscopy units servicing children around the world. Work by the PEnQuIN working group has already begun in this regard.

### **Implementation Strategy**

For the PEnQuIN guidelines to be useful, it is imperative that they are accompanied by practical recommendations to facilitate implementation across facilities for gastrointestinal procedures in children. We recommend that facilities develop a quality improvement plan informed by the PEnQuIN standards, as well as a mechanism for audit and feedback of endoscopy services and endoscopists' performance using the PEnQuIN quality indicators (**Figure 1**). Institutional needs should dictate which standards and indicators are prioritized for implementation, taking into account urgency for change and potential for impact. A routine, reliable and credible data collection mechanism is critical, as are systems and processes for effective endoscopist feedback and use of data to support continuous quality improvement. For indicators where minimum targets have not yet been established, local data can be utilized to enable longitudinal and cross-sectional comparisons with baseline and/or anonymized data from peers to measure change.<sup>52</sup>

Feedback at the provider level needs to be delivered in a sensitive and timely manner so that endoscopists are aware of their performance and how it compares with their peers and quality targets. Feedback should be personalized, credible, relevant and aimed at fostering growth. It is essential that facilities develop structured processes and a faculty development strategy to ensure that endoscopists who are identified as having lower performance levels are provided with an educational implementation plan and the necessary mentoring and training to help them attain minimum quality targets.<sup>53</sup> Quality improvement activities should also be viewed as supportive rather than punitive.

*[insert Figure 1]*

Implementation requires commitment and support from stakeholders at all levels, including facility management. Facility investment in resources to support quality improvement is crucial, including a computerized endoscopy reporting system to permit automated timely data capture and analysis.<sup>20-22</sup> Additionally, regional, national and international organizations such as NASPGHAN and ESPGHAN have the responsibility to support quality improvement initiatives in pediatric endoscopy. Examples of organizational support include the provision of educational resources to support the upskilling of underperforming endoscopists, as well as the development of a largescale benchmarking program for pediatric endoscopy and accompanying technology infrastructure. This may include centralized data repositories and quality dashboards to enable comparison and standardized reporting of quality indicators across sites to support improvements in care.

## **Generalizability**

We believe the standardized measurement of key endoscopic quality and safety standards and indicators for procedures in children with digestive diseases will be generalizable across the world. We believe there to be a general imperative for enhancing quality improvement activities around pediatric endoscopy, and that the PEnQuIN standards and indicators will ultimately serve to enhance patient outcomes, improve patient safety and optimize efficiency, while also generating data for benchmarking and for the purpose of credentialing and renewal of privileges of all who perform gastrointestinal endoscopic procedures in children. The PEnQuIN working group considers these guidelines to be a starting point. The standards and indicators will evolve over time as new evidence emerges and we gain experience with their practical application.

## **Conclusions**

Pediatric-specific quality standards and indicators for the performance of endoscopic procedures in children can be developed through a rigorous international consensus process. The PEnQuIN quality standards and indicators for the delivery of pediatric endoscopy were based on a systematic approach and rigorous assessment of the literature using the GRADE framework. Consensus was reached for 49 standards and 47 indicators, suggesting that obtaining widespread agreement on clinically meaningful metrics for ensuring safe, high quality, patient- and family-centered endoscopic care is possible. GRADE does not seek to eliminate subjective judgments, and such judgments are an inevitable part of rating evidence and making recommendations ('strong' or 'conditional'), but one merit of the GRADE system is that judgments are made in a systematic and transparent manner. The PEnQuIN standards and indicators provide pediatric endoscopists and endoscopy services with a framework for auditing and improving performance,

providing feedback and, ultimately, benchmarking performance. We anticipate that these guidelines will need to be reviewed and updated in accordance with emerging evidence in 7 to 10 years using rigorous guideline development methodology. Going forward, we as a pediatric endoscopy community need to embrace and prioritize quality assurance to ensure these standards and indicators are implemented and monitored across facilities, thereby improving the quality, safety, efficiency and patient-centeredness of pediatric endoscopic services. Expansion of the evidence base and prospective validation of the PEnQuIN standards and indicators as predictors of clinically relevant outcomes and high quality patient- and family-centered pediatric endoscopic care is now a research priority.

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## **FIGURE LEGEND**

**Figure 1:** Ensuring high quality pediatric endoscopy involves monitoring an entire system, including individual endoscopists in the context of their facilities and a greater endoscopy community. PEnQuIN quality indicators, representing outputs from both procedural processes and outcomes, are fed back to inform iterative ‘Plan, Do, Study, Act’ (PDSA) cycles and ensure continuous quality improvement across all levels. Feedback may target multiple levels of the system, with the specific information requirements of each end-user group being different.

## **TABLE LEGENDS**

**Table 1:** Quality-related terminology

**Table 2:** PEnQuIN quality standards and indicators development process

**Table 3:** Quality of evidence and definitions

**Table 4:** Demographics of PEnQuIN working group members

**Table 5:** PEnQuIN standards and indicators reaching consensus ( $\geq 80\%$  PEnQuIN working group members rating ‘agree’ or ‘strongly agree’)

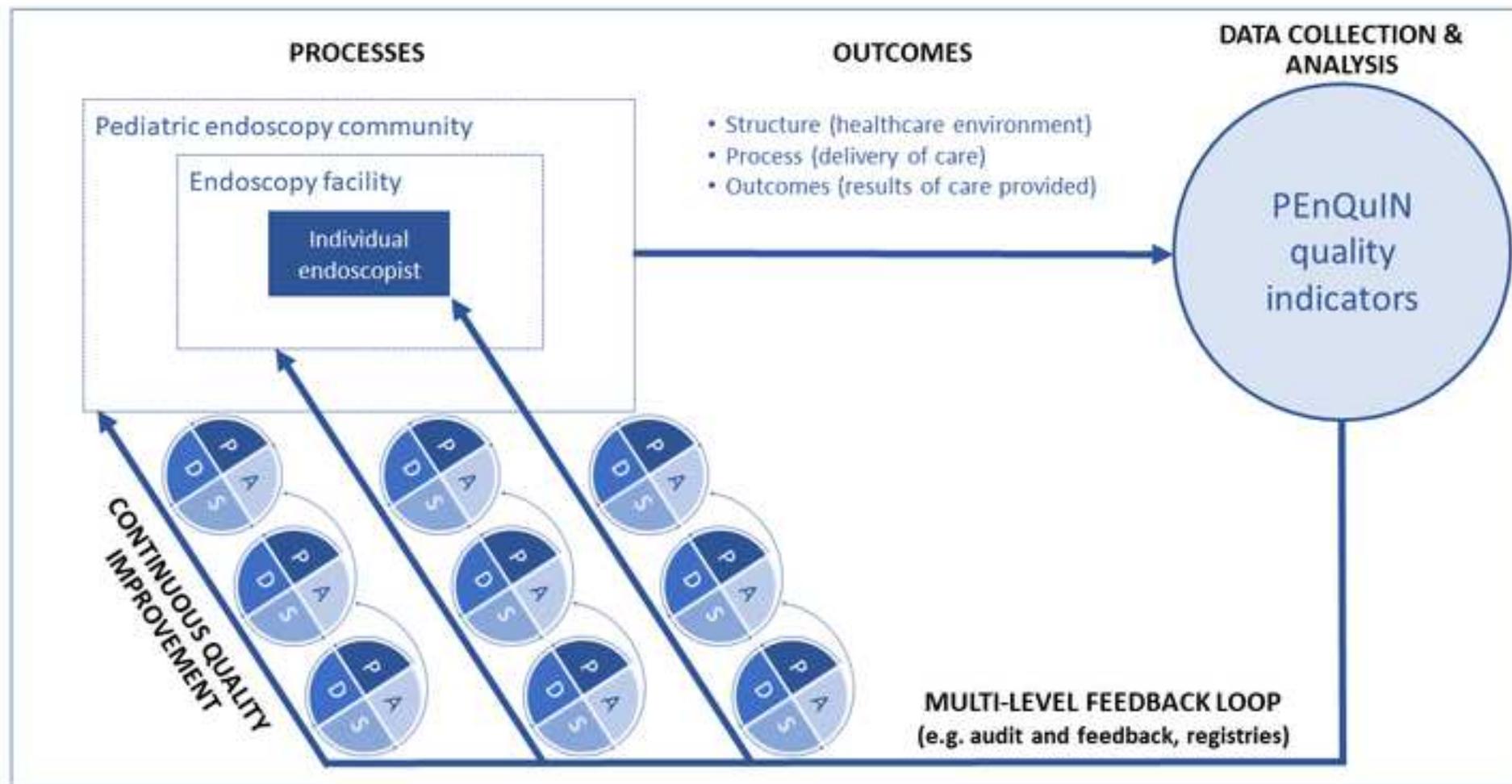
**Table 6:** Potential uses of PEnQuIN quality standards and indicators to support high quality endoscopic care for children

## **SUPPLEMENTAL DIGITAL CONTENT LEGENDS**

**Supplemental Digital Content - Appendix 1 - Figure 1, Tables 1-3:** Search strategy

**Supplemental Digital Content - Appendix 2 - Table 1:** Eliminated standards and indicators

**Supplemental Digital Content - Appendix 3 - GRADE Evidence Summaries**



**Table 1:** Quality-related terminology

	<b>Term</b>	<b>Definition</b>
 <p data-bbox="188 569 456 638"><b>PENQuIN</b> PEDIATRIC ENDOSCOPY QUALITY IMPROVEMENT NETWORK</p>	<b>Domain</b>	<ul style="list-style-type: none"> <li>• Broad area of pediatric endoscopic care.</li> </ul>
	<b>Quality standard</b>	<ul style="list-style-type: none"> <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>
	<b>Quality indicator</b>	<ul style="list-style-type: none"> <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>

**Table 2:** PEnQuIN quality standards and indicators development process

- 
- Establishment of PEnQuIN and working group membership
  - Approval of joint societal guideline by NASPGHAN and ESPGHAN Councils
  - Declaration of conflicts of interest by all PEnQuIN members
  - Identification of proposed quality standards and indicators from 3 sources: systematic literature search, published adult consensus guidelines and input from PEnQuIN members
  - Creation of PICO-format questions for each proposed quality standard and corresponding indicator(s), listing all key outcomes
  - Linkage of evidence identified by systematic literature search to each proposed standard and corresponding indicator(s)
  - Evaluation of the quality of evidence for each proposed quality standard (and corresponding indicator(s)) using the GRADE approach
  - Determination of the final quality standards and indicators: consensus achieved through modified Delphi process and in-person consensus meeting
  - Determination of the strength of recommendation for each quality standard and indicator that reached consensus
  - Identification of gaps in knowledge, evidence, education and training. These may inform areas for future research and development
  - Review by NASPGHAN, ESPGHAN as well as other gastroenterology societies and patient representatives\* for comment
- 

ESPGHAN: European Society for Paediatric Gastroenterology, Hepatology and Nutrition; GRADE: Grading of Recommendation Assessment, Development, and Evaluation; NASPGHAN: North American Society for Pediatric Gastroenterology, Hepatology and Nutrition; PEnQuIN: Pediatric Endoscopy Quality Improvement Network; PICO: patient/population, intervention, control/comparator and outcome

\*Manuscripts reviewed by CICRA (Crohn's (and Colitis) in Childhood Research Association) Family Advisory Group

**Table 3:** Quality of evidence and definitions

<b>Level of evidence</b>	<b>Definition</b>
High quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality	Any estimate of effect is very uncertain

\*adapted from reference<sup>41</sup>

**Table 4:** Demographics of PEnQuIN working group members

<b>Characteristic</b>	<b>Category</b>	<b>N (%)</b>
Specialty	Pediatric gastroenterologist	32 (97.0%)
	Adult gastroenterologist	1 (3.0%)
Region	North America	18 (54.6%)
	Europe	15 (45.5%)
Endoscopic practice type (all that apply)	Academic	29 (87.9%)
	Community	5 (15.2%)
Location of endoscopic practice (all that apply)	Hospital setting	33 (100%)
	Out-of-hospital facility	3 (9.1%)
Performs endoscopy in a pediatric-only unit	Yes	24 (72.7%)
	No	9 (27.3%)
Scope of practice (all that apply)	Upper endoscopy	33 (100%)
	Lower endoscopy	33 (100%)
	Therapeutic endoscopy	15 (45.5%)
Supervises endoscopic trainees	Yes	28 (84.9%)
	No	5 (15.2%)

**Table 5:** PEnQuIN standards and indicators reaching consensus ( $\geq 80\%$  PEnQuIN working group members rating ‘agree’ or ‘strongly agree’)

STANDARDS (n = 49)		INDICATORS (n = 47)	
<b>1. FACILITY-RELATED STANDARDS (27 standards, 16 indicators)</b>			
<b>1A. QUALITY OF CLINICAL OPERATIONS</b>			
<b>S1</b>	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.		
<b>S2</b>	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.	<b>I1</b>	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).
<b>S3</b>	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.		
<b>S4</b>	Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to <i>preprocedure</i> policies that ensure best practice in pediatric care.	<b>I2<sup>†</sup></b>	Rate with which a preprocedure history and directed physical examination is performed.
		<b>I3<sup>†</sup></b>	Rate of appropriate prophylactic antibiotic administration in accordance with accepted guidelines.
		<b>I4<sup>†</sup></b>	Rate with which a preprocedural team pause is conducted.
		<b>I5</b>	Rate with which sedation-related fasting guidelines are followed.
<b>S5</b>	Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to <i>intraprocedural</i> policies that ensure best practice in pediatric care.		
<b>S6</b>	Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to <i>postprocedural</i> policies that ensure best practice around the discharge of pediatric patients after endoscopic procedures.		
<b>S7</b>	Endoscopy facilities where pediatric procedures are performed should follow institution or facility policies regarding implementation of preprocedural and postprocedural safety and quality checklists.		
<b>S8</b>	Endoscopy facilities where pediatric procedures are performed should implement policies to monitor and ensure the timeliness and completeness of procedure reporting.		
<b>S9</b>	Endoscopy facilities where pediatric procedures are performed should implement policies to monitor and ensure appropriate reprocessing and traceability of all endoscopic equipment.		
<b>S10</b>	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.		
<b>S11</b>	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.	<b>I6</b>	Rate of mishandled, mislabeled, or misprocessed tissue specimens.
<b>S12</b>	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.	<b>I7<sup>†</sup></b>	Rate of documented intraprocedural adverse events.
		<b>I8<sup>†</sup></b>	Rate of documented immediate postprocedural adverse events.
		<b>I9<sup>†</sup></b>	Rate of documented late adverse events.
		<b>I10</b>	Rate of adverse events.
<b>S13</b>	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.	<b>I11</b>	Participation by an endoscopy facility in a recognized quality assurance program.

S14	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.		
S15	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.		

### 1B. QUALITY OF PATIENT AND CAREGIVER EXPERIENCE

S16	Endoscopy facilities where pediatric procedures are performed should ensure that the services they provide are patient- and family-centered.		
S17	Patients and/or caregivers should receive appropriate information about the endoscopic procedure before the procedure date.	I12	Rate of patients/caregivers who receive procedure-related instructions prior to the date of endoscopy.
S18	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.	I13	Rate with which patients receive adequate instructions on bowel preparation.
S19	Endoscopy facilities where pediatric procedures are performed should have pediatric-specific, patient- and family-centered processes for preoperative and recovery phases of care.		
S20**	Endoscopy facilities where pediatric procedures are performed should ensure availability of pediatric-specific monitoring and resuscitation equipment.		
S21**	Endoscopy facilities where pediatric procedures are performed should ensure availability of endoscopy equipment that is age/size/weight appropriate.		
S22	Pediatric patients are discharged postprocedure according to predetermined standard discharge criteria, with clear documentation of readiness for discharge.	I14	Rate of discharge from an endoscopy facility in accordance with predetermined standard discharge criteria.
S23	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.		
S24	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.	I15	Quality of the patient and caregiver experience.
		I16	Rate with which patient and caregiver experience data are formally obtained.

### 1C. WORKFORCE

S25	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.		
S26	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.		
S27	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.		

## 2. PROCEDURE-RELATED STANDARDS (14 standards, 24 indicators)

### 2A. PREPROCEDURE

<b>S28</b>	Pediatric endoscopic procedures are performed for an appropriate, clearly documented indication, consistent with current evidence-based guidelines, when available.	<b>I17</b>	Rate with which the endoscopy report documents the indication for the procedure.
		<b>I18</b>	Rate with which endoscopy is performed for an indication that is in accordance with current evidence-based guidelines and/or published standards, when available.
<b>S29**</b>	For a patient and/or caregiver to provide informed consent 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.	<b>I19</b>	Rate with which informed consent is obtained.
<b>S30</b>	For all endoscopic procedures, the sedation/anesthetic plan should be documented along with a standardized measure of patient complexity.	<b>I20</b>	Rate with which the sedation/anesthetic plan is documented.
		<b>I21</b>	Rate with which ASA status is documented.
<b>2B. INTRAPROCEDURE</b>			
<b>S31</b>	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.	<b>I22</b>	Rate with which patient monitoring during sedation/anesthesia is performed.
		<b>I23</b>	Rate with which the dose and route of administration of all medications used during the procedure are documented.
		<b>I24</b>	Rate with which intraoperative patient comfort is documented.
		<b>I25</b>	Rate with which reversal agents are used.
		<b>I26</b>	Rate with which the procedure is interrupted and/or prematurely terminated due to a sedation/anesthesia-related issue.
<b>S32</b>	Pediatric endoscopic procedures should be performed efficiently, within a reasonable procedure time (from first insertion until final removal of endoscope).	<b>I27</b>	Procedure time.
<b>S33</b>	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.	<b>I28</b>	Rate of adequate bowel preparation.
		<b>I29</b>	Rate with which the endoscopy report documents the quality of the bowel preparation.
<b>S34</b>	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.	<b>I30</b>	Rate of procedure completeness as defined by inspection of all relevant areas, acquisition of appropriate biopsies and successful completion of interventions.
		<b>I31</b>	Rate with which endoscopic interventions are performed, or eschewed, appropriately.
		<b>I32</b>	Rate of endoscopic intervention completion.
<b>S35</b>	Photo/video documentation of all visualized abnormal findings should be obtained.		
<b>S36</b>	Endoscopic biopsies should be obtained as appropriate for the procedural indication, consistent with current evidence-based guidelines, when available.	<b>I33</b>	Rate with which biopsies are obtained, or eschewed, appropriately.
<b>S37</b>	Pediatric endoscopic procedures should be reported in a manner that allows for full documentation of all necessary and mandated clinical and quality measures.	<b>I34</b>	Rate with which the endoscopy report documents findings.
		<b>I35</b>	Rate with which the endoscopy report documentation is complete.
		<b>I36</b>	Rate with which the endoscopy report documentation is finalized.
		<b>I37</b>	Rate with which endoscopy report documentation is finalized in a timely manner.
<b>S38</b>	Pediatric endoscopic procedures should be reported using standardized disease-related terminology and/or scales, when available.		
<b>2C. POSTPROCEDURE</b>			
<b>S39</b>	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.	<b>I38</b>	Rate with which patients/caregivers receive written postprocedure instructions upon discharge.
<b>S40</b>	Before discharge, all patients and/or caregivers should be given written and/or verbal information regarding the endoscopy findings, plans for conveying pathology results and follow-up. This process must be documented.	<b>I39</b>	Rate with which the plan for pathology follow-up is communicated to patients/caregivers.

<b>S41</b>	Pathology findings should be reviewed with patients and/or caregivers in a timely fashion. This process must be documented.	<b>I40</b>	Rate with which pathology findings are reviewed with the patient and/or caregiver.
<b>3. ENDOSCOPIST-RELATED STANDARDS (8 standards, 7 indicators)</b>			
<b>3A. PEDIATRIC ENDOSCOPISTS</b>			
<b>S42</b>	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.	<b>I41</b>	Rate with which pediatric endoscopies are performed by trained and credentialed endoscopists.
<b>S43</b>	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.	<b>I42</b>	Rate with which the competence of practicing pediatric endoscopists is assessed.
<b>S44</b>	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.		
<b>S45</b>	Endoscopists who perform procedures on pediatric patients should regularly review their endoscopic practice and outcome data with the aim of continuous professional development.	<b>I43</b>	Number of procedures performed annually.
<b>S46</b>	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.		
<b>S47</b>	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.	<b>I44</b>	Rate of cecal intubation.
		<b>I45</b>	Rate of ileal intubation.
<b>3B. PEDIATRIC ENDOSCOPISTS IN TRAINING</b>			
<b>S48**</b>	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.	<b>I46</b>	Proportion of endoscopists in training who have achieved competence by the end of their training.
<b>S49</b>	Competence assessment tools with strong validity evidence should be used to document progress and proficiency level during endoscopy training.	<b>I47</b>	Rate with which the competence of endoscopists in training is assessed longitudinally.

\*\*Strong Recommendation

†Procedure-related indicators linked to facility standards

**Table 6:** Potential uses of PEnQuIN quality standards and indicators to support high quality endoscopic care for children

- 
- Providing a framework for continuous quality improvement activities
  - Measuring the quality of pediatric endoscopic services
  - Setting priorities for quality improvement
  - Identifying targets for quality improvement
  - Supporting the development of performance dashboards
  - Benchmarking performance against local, national and international data to enable comparison and service improvement (comparison of audit data against aggregate data)<sup>17</sup>
  - Providing a framework for collaborative regional, national and international pediatric endoscopy registries
  - Understanding factors underlying variations in care
  - Evaluating the impact of change both within and across facilities
  - Providing evidence of progress in advancing the field of pediatric endoscopy
  - Providing a framework for accreditation and licensing of facilities and/or individual providers
  - Providing a mechanism for identifying high quality pediatric endoscopic services
  - Public reporting
  - Research
-



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**Supplemental Data File (doc, pdf, etc.)**

1 - JPGN-20-1357 - APPENDICES (2021 01 20) R1.pdf

