

**Pediatric Endoscopy Quality Improvement Network (PEenQuIN) Quality Standards and Indicators for Pediatric Endoscopy Facilities: A Joint NASPGHAN/ESPGHAN Guideline**

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## **ABBREVIATIONS**

- 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
- Global Rating Scale: GRS
- Grading of Recommendation Assessment, Development, and Evaluation: GRADE
- North American Society for Pediatric Gastroenterology, Hepatology and Nutrition: NASPGHAN
- Paediatric Global Rating Scale: P-GRS
- Patient/population, intervention, control/comparator and outcome: PICO
- Pediatric Endoscopy Quality Improvement Network: PEnQuIN
- Surgical Safety Checklist: SSC
- United Kingdom: UK
- World Health Organization: WHO

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## ABSTRACT

**Introduction:** There is increasing international recognition of the impact of variability in endoscopy facilities on procedural quality and outcomes. There is also growing precedent for assessing the quality of endoscopy facilities at regional and national levels by using standardized rating scales to identify opportunities for improvement.

**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 facilities where endoscopic care is provided to children. Consensus was reached via an iterative online Delphi process and subsequent in-person meeting. 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 27 standards for facilities supporting pediatric endoscopy, as well 10 indicators that can be used to identify high quality endoscopic care in children. These standards were subcategorized into 3 subdomains: Quality of Clinical Operations (15 standards, 5 indicators); Patient and Caregiver Experience (9 standards, 5 indicators); and Workforce (3 standards).

**Discussion:** The rigorous PEnQuIN process successfully yielded standards and indicators that can be used to universally guide and measure high quality facilities for procedures around the world where endoscopy is performed in children. It also underscores the current paucity of evidence for pediatric endoscopic care processes, and the need for research into this clinical area.

**KEYWORDS:**

- Quality Assurance, Healthcare
- Practice Guidelines as Topic/\*standards
- Pediatric Gastroenterology/\*standards
- Endoscopy, Gastrointestinal/\*standards
- Patient Care/standards

## INTRODUCTION

High quality endoscopic procedures in children require facilities that are specifically designed to assure best practice in pediatric populations.<sup>1-3</sup> Generally speaking, there is a paucity of evidence to define best endoscopic practices for both children and adults, although a number of endoscopic societies have developed guidelines for the latter.<sup>4-9</sup> To ensure optimal performance of pediatric gastrointestinal procedures, facilities that support endoscopy services in children require evidence- and consensus-based standards and indicators that focus on safety and efficacy. Internationally, there are many different regulatory policies that pertain to endoscopy facilities that must also be followed to ensure local compliance. Facilities that support endoscopy services for children must also have processes in place for outcomes assessment, as well as continual quality improvement activities.<sup>10,11</sup> Finally, pediatric endoscopy should only occur in facilities that can ensure a child- and family-centered approach to care, with personnel that have been specifically trained for this purpose.<sup>2</sup>

Across the world, pediatric endoscopy is currently performed in a wide variety of settings, including general operating rooms, multi-purpose procedure rooms, dedicated endoscopy suites and stand-alone surgical centers.<sup>1,12</sup> In some pediatric practice models, procedures take place in rooms, units or suites that have been specifically dedicated for their purpose.<sup>13</sup> In others, pediatric endoscopy services may be co-located in environments that care for adult patients undergoing gastrointestinal procedures. In many pediatric care models, peri-procedural services, including scheduling and pathology, may involve independent clinical operations and personnel. As such, pediatric endoscopy facilities should not be defined by physical location alone, but instead by all personnel, equipment and operations involved in the provision of pediatric endoscopy services.<sup>7</sup>

While facilities that provide combined adult/pediatric care can be beneficial from an efficiency standpoint, they should also provide a child- and family-centered environment and be staffed by personnel that are competent to provide care to children of different ages. This principle must also apply when pediatric endoscopy is performed in facilities that support the broader practice of multi-specialty ambulatory (i.e., day surgery) procedures. Although multi-purpose centralization of pre- and postprocedural care may offer institutional benefits, it is critical that all facilities that provide endoscopy services for children are specifically designed to provide optimal endoscopic procedural performance and patient care that is safe, effective, timely and efficient.<sup>2</sup> In short, it is important that all high quality facilities for pediatric endoscopy adhere to well-defined standards, regardless of procedural location, environment, patient population(s) served and organizational model.

Notably, there has been international recognition of the impact of variability in endoscopy facilities on procedural quality and outcomes.<sup>14-16</sup> In particular, the United Kingdom (UK) has established a national program to assure high quality endoscopy by assessing and rating procedural facilities in a transparent manner using a Global Rating Scale (GRS).<sup>9</sup> The GRS was originally developed over 15 years ago to rate all endoscopy service centers in the UK involved in performing colon cancer screening in adults. Over time, the GRS has been validated for a broad range of endoscopy services, and adopted to varying degrees as a

measure of facility quality in numerous other countries.<sup>14-16</sup> Most recently, pilot work in England has adapted the GRS for pediatric endoscopy (P-GRS) with the goal of improving the quality of care for children in the UK within their nationally established framework. It is now incumbent upon the greater international pediatric gastroenterology community to rigorously and comprehensively evaluate quality metrics published in the GRS, the P-GRS and all other published quality assurance instruments, with the goal of developing consensus around standards and indicators that should be used to assess endoscopy facilities serving children around the world.

A principal aim of the Pediatric Endoscopy Quality Improvement Network (PEnQuIN) has been to outline international standards for all *facilities*, as a key *domain* of pediatric endoscopy, as well as indicators that can be used to measure their quality (**Table 1**). Three specific subdomains of facility quality that align with the GRS are outlined: (1) Quality of Clinical Operations; (2) Quality of Patient and Caregiver Experience; and (3) Workforce. 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 will be useful in the following ways: (1) To assess the quality of existing facilities where pediatric endoscopy is performed; (2) To serve as a basis for quality improvement activities at the pediatric endoscopy facility level; and (3) To provide guidance for institutions seeking to redesign existing or build new facilities for gastrointestinal procedures in children.

## 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<sup>17</sup>, was used to structure the development of the PEnQuIN standards and indicators. Proposed quality standards and indicators were derived from three sources: (1) a systematic literature review of Medline, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL); (2) a hand-search of lists of references from published adult consensus statements<sup>4,8,18,19</sup>; and (3) 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).<sup>20,21</sup> 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').<sup>22</sup> Consensus among the PEnQuIN working group was subsequently achieved via an iterative online Delphi process followed by an in-person consensus conference, with consensus defined as  $\geq 80\%$  agreement. 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.<sup>23</sup> 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.<sup>23</sup> Afterward, the quality standards and indicators reaching consensus were mapped to their relevant domain: (1) Facilities; (2) Procedures; or (3) Endoscopists and Endoscopists in Training.

Standards related to endoscopy facilities are presented within this document along with related indicators and their definitions (e.g., 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)). Using the previously established GRS, we then mapped the facility-related standards to the GRS framework.<sup>9</sup> Detailed methodology is outlined within the PEnQuIN overview document.<sup>24</sup>

## **RESULTS**

The PEnQuIN working group achieved consensus for a total of 27 standards related to endoscopy facilities, with 10 related indicators that can be used to measure the quality of endoscopy services as means for continuous quality improvement at the facility level. Consensus was not reached, and no recommendations were made, for an additional standard (*Supplemental Appendix 1*, <http://links.lww.com/MPG/C462>). Using the GRS as a framework, the PEnQuIN process found that all standards that achieved consensus could be mapped to one of 3 subdomains, with associated indicators: Quality of Clinical Operations (15 standards, 5 indicators); Quality of Patient and Caregiver Experience (9 standards, 5 indicators); and Workforce (3 standards). A fourth domain included in the GRS, entitled “Training,” was determined to be outside the scope of this document, which applies to all facilities, regardless of the presence or absence of trainees. Standards and indicators that relate to training are included in an independent PEnQuIN consensus guideline that addresses endoscopist considerations, including training.<sup>25</sup>

Each standard that reached consensus for inclusion in this PEnQuIN guideline on facility 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 facility 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.

### **FACILITY SUBDOMAIN 1: QUALITY OF CLINICAL OPERATIONS**

Quality of pediatric endoscopy must be assured before a procedure is performed, during its performance, as well as after the child has recovered from the procedure and left the facility. Despite wide variation in settings, best practices for endoscopy in children across all facilities can be standardized in accordance with available evidence and expert consensus, which in turn may inform regulatory policies. Operational processes required to perform pediatric endoscopy must occur before, during and after procedures, with appropriate technical and personnel resources. In addition, pediatric endoscopy facilities must incorporate mechanisms

for local oversight and formal review of endoscopic processes across the continuum of care. It is also critical that performance reports for both the facility and all associated personnel, including endoscopists, be generated and reviewed on a regular basis, with the goal of identifying opportunities for improvement.

The following achieved consensus within the PEnQuIN working group as minimum standards of high quality clinical operations in pediatric endoscopy facilities, as measured by their 5 associated indicators (**Table 2**).

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

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

**Key evidence:** Although several important consensus statements and review papers have addressed the importance of a pediatric approach to designing and operating endoscopy facilities,<sup>1,10,12</sup> there is little direct evidence to support this standard. Pitetti et al performed a cross-sectional prospective observational study over three years, examining the impact of implementing the 2001 Joint Commission Sedation Guidelines at their pediatric hospital and demonstrated improved documentation across sedated procedures in children, including endoscopic procedures, along with less variation in care and fewer adverse events at the facility level.<sup>26</sup> Similarly, Sheu et al found that participation in the American Board of Pediatrics' Maintenance of Certification Part IV activities that emphasized standardized documentation practices during pediatric endoscopy led to improved completeness of endoscopy reporting, improved colonoscopy preparation and fewer adverse events.<sup>11</sup> Adult studies in European countries have shown that adherence to national guidelines for sedation and cancer screening can improve endoscopic care.<sup>27,28</sup> There is no direct evidence that the performance of pediatric procedures in locally or nationally accredited facilities is associated with better outcomes.

**Standard 2: Endoscopy facilities where pediatric procedures are performed should have a process in place for ensuring timely performance of elective pediatric endoscopic procedures, based on procedure indications and patient characteristics, that is in line with guidelines, when available.**

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 58.4%; agree, 33.3%; uncertain, 8.3%

**Key evidence:** There is no evidence that procedures performed in a "timely manner" result in better outcomes in children undergoing endoscopy. This is mainly because the studies necessary to determine this have not been conducted and the definition of what constitutes an appropriate time frame has not been established for children. Avoidable morbidity occurring due to the lack of a diagnosis that would have been made had endoscopy occurred earlier is a reasonable definition of "untimely," which can be used to guide discussion on what constitutes "timely" endoscopy. This is reasonable as an assumption, and it is the opinion of this expert group, but it remains unsubstantiated by formal studies in the literature.

One single-center pediatric retrospective observational study comparing endoscopy occurring under general anesthesia versus sedation revealed a significantly longer time to procedure for patients with an anesthesia provider present (64 days) compared to patients who underwent procedural sedation provided by the endoscopist (22 days). However, there was no difference between the two groups with regard to the number of emergency room visits or hospital admissions, both pre- and post-endoscopy.<sup>29</sup> A national audit in Canada in the adult setting revealed that there is variability in meeting targets for wait times across centers; however, the impact of wait times on disease morbidity was not examined.<sup>30</sup>

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

**GRADE:** Conditional recommendation, very low quality evidence. Vote: strongly agree, 54.2%; agree, 41.7%; disagree, 4.1%

**Key evidence:** Consensus exists for the proposition that all pediatric endoscopy facilities should have specific processes in place that ensure all children who require urgent endoscopy after-hours and on weekends have procedural access. Although the PEnQuIN working group recognized that some facilities may not act as a site for urgent and/or after-hours procedures in children, the consensus was that all endoscopy services for children should have processes in place to communicate (e.g., via website, automated message) where patients who require emergent procedures can receive them. There is limited direct evidence that after-hours and emergency access to endoscopy improves clinical outcomes of pediatric patients, for example by reducing morbidity, mortality or length of stay. Russell et al investigated whether implementation of an algorithm to provide rapid access to endoscopy after button battery ingestion in children reduced morbidity.<sup>31</sup> Time to endoscopy was reduced from 183 minutes (n=4) to 33 minutes (n=7). Furthermore, a tracheoesophageal fistula was diagnosed in the pre-intervention group, while no patients in the post-intervention group experienced injury from the ingestion.

There is some limited, indirect evidence that adult patients may benefit from high quality endoscopy during evening and weekend hours. In a letter to the editor, Davies et al reported that instituting a rotating list of providers facilitated urgent endoscopy on weekends among adult patients, and reduced length of stay by 23 inpatient days across 58 patients requiring access to weekend procedures during the study period.<sup>32</sup> Of course, there is likely wide variation in how hospitals and larger hospital systems ensure after-hours access. For example, practitioners may need to utilize general surgical settings, as opposed to dedicated endoscopy facilities. Survey data suggests this can limit access to a trained workforce, including endoscopy nurses.<sup>33</sup> In certain scenarios or locales, it may be appropriate to designate regional referral centers for urgent endoscopy, and for outlying facilities to develop effective systems for rapid transfer of appropriate patients.

**Standard 4: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *preprocedure* policies that ensure best practice in pediatric care.**

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 58.3%; agree, 41.7%

**Key evidence:** Examples of preprocedure policies include antibiotic prophylaxis guidelines, antithrombotic agent guidelines, surveillance schedules, diabetes mellitus management guidelines, sedation/anesthetic risk assessment guidelines, allergy or drug sensitivity guidelines and procedural pause.<sup>4</sup> Although adhering to and monitoring compliance with preprocedure protocols are likely sensible means of mitigating procedural risks<sup>34</sup>, particularly infection, bleeding and sedation, there are limited data for this and few pediatric-specific studies. In terms of antibiotic prophylaxis, a Cochrane systematic review concluded that its use in adults with cirrhosis and upper gastrointestinal bleeding was beneficial.<sup>35</sup> Another Cochrane systematic review found a significant reduction in the incidence of peristomal infection with prophylactic antibiotics after percutaneous endoscopic gastrostomy placement in adults.<sup>36</sup> In terms of understanding the impact of antithrombotic agents, Hui et al performed a large, seminal study of polypectomy that found anti-coagulant agents (particularly warfarin), but not anti-platelet agents, were associated with an increased risk of bleeding.<sup>37</sup> One pediatric study by Hoffman et al, a prospective abstraction of 960 procedural records, found 4.2% of patients to have sedation-related adverse events (hypotension, bradycardia, hypoxemia); these were significantly reduced when American Academy of Pediatrics or American Society of Anesthesiologists structured assessments were used to determine the best type of sedation to employ.<sup>38</sup> There is no pediatric or adult evidence to determine whether facilities that closely monitor adherence to preprocedure fasting guidelines have improved outcomes.

**Standard 5: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *intraprocedural* policies that ensure best practice in pediatric care .**

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 54.2%; agree, 37.5%; disagree, 8.3%

**Key evidence:** Examples of intraprocedure policies include photo/video documentation of terminal ileal intubation, patient monitoring and evaluation of bowel preparation quality.<sup>4</sup> There is no direct pediatric evidence that links adherence to intraprocedural policies and patient outcomes, including policies that call for photo-documentation of procedural landmarks, documentation of patient physiologic monitoring or documentation of bowel preparation quality. There are several adult guidelines that support photo or video documentation of key anatomical landmarks to corroborate complete examination,<sup>4-6,39-42</sup> and two that link photo documentation to improved outcomes, such as polyp detection rates<sup>43</sup> and upper gastrointestinal neoplasm detection rates.<sup>44</sup> No pediatric or adult studies have shown that documentation of intraprocedural patient physiologic monitoring improves outcomes. Similarly, pediatric evidence for benefits from routine evaluation and documentation of bowel preparation is limited. A retrospective study in children<sup>45</sup> and a prospective, multi-center registry<sup>46</sup> both found that documentation of poor bowel preparation is associated with a reduced likelihood of terminal ileal intubation. However, bowel preparations in these studies were not uniform and the quality of preparation was variably reported. Nevertheless,

these findings parallel those of several adult studies that have linked inadequate bowel preparation to significantly lower cecal intubation rates.<sup>47-52</sup> Although one study of adults undergoing colonoscopy showed no significant association between bowel preparation scores and adenoma detection,<sup>53</sup> another systematic review demonstrated higher Boston Bowel Preparation Scale scores to be associated with higher polyp detection rates and more complete procedures.<sup>54</sup> No pediatric studies have linked bowel preparation quality to diagnostic yield.

**Standard 6: Endoscopy facilities where pediatric procedures are performed should implement and monitor adherence to *postprocedural* policies that ensure best practice around the discharge of pediatric patients after endoscopic procedures.**

GRADE: Conditional recommendation, no evidence. Vote: strongly agree, 47.8%; agree, 47.8%; uncertain, 4.4%

**Key evidence:** Examples of postprocedural policies include assessment of readiness for discharge and follow-up of pathology results.<sup>4</sup> There is limited evidence in either pediatric or adult patients that implementation and adherence to postprocedural policies or best practices around discharge of pediatric patients after endoscopic procedures, are associated with improved outcomes. Nevertheless, consensus dictates that upon discharge written details of the procedure should be provided to patients and their families, as well as any physician who may become involved in plans for postprocedural care. Among adults, Spodik et al demonstrated that provision of a procedure report at the time of discharge reduced patients' postprocedure anxiety, improved their recall of findings and recommendations and improved adherence to recommendations.<sup>55</sup> Canadian Association of Gastroenterology (CAG) consensus guidelines recommend that adult endoscopy facilities provide specific information in a discharge report, including plans for follow-up that have been or will be made, as well as contact information for the medical team.<sup>4</sup>

**Standard 7: Endoscopy facilities where pediatric procedures are performed should follow institution or facility policies regarding implementation of preprocedural and postprocedural safety and quality checklists.**

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 37.5%; agree, 58.3%; uncertain: 4.2%

**Key evidence:** Examples of safety and quality checklists include time-out protocols and readiness for discharge assessment tools. The World Health Organization (WHO) developed the Surgical Safety Checklist (SSC) in 2008 to improve patient safety, increase interprofessional communication and reduce medical errors.<sup>56</sup> Following international implementation of the SSC, several studies and meta-analyses have demonstrated improvements in morbidity and mortality<sup>57-61</sup> and a decrease in medical insurance claims,<sup>62</sup> although concerns for added work burden pervade. Currently, there is no direct evidence that implementing endoscopy checklists leads to improvements in patient outcomes related to the performance of endoscopic procedures in either adults or children. Effectiveness of the SSC in surgical settings may vary with adherence to protocols.<sup>61</sup> Embedding checklists into operating rooms has been shown to increase compliance with the time-out process,<sup>60</sup> while

implementing workflows that monitor adherence may improve SSC completion rates.<sup>63</sup> A more recent study by Zingiryan et al showed improvement in communication but no change in surgical outcomes following implementation of a SSC after a 2-year longitudinal follow-up.<sup>64</sup> Data are needed on the effectiveness of a SSC for endoscopic procedures, including those performed in children.

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

GRADE: Conditional recommendation, no evidence. Vote: strongly agree, 37.5%; agree, 50.0%; uncertain: 12.5%

**Key evidence:** There is currently no published evidence that the timeliness or completeness of procedure reporting has an impact on patient clinical outcomes associated with gastrointestinal procedures in children. Nevertheless, in line with published quality standards for gastroenterologists who perform endoscopy in adult patients, the committee agreed that high quality pediatric endoscopy should include complete procedural summaries that are entered into the patient record in a timely manner. In one prospective study, adult patients who were provided an endoscopy report immediately after a procedure had decreased postprocedure anxiety and better recall of procedural findings.<sup>55</sup> The same study found no demonstrable impact of immediately providing endoscopy reports on patient satisfaction. Currently, several guidelines for endoscopy report completeness exist,<sup>4,19,65,66</sup> whereas what represents ‘timely’ entry has not been determined. A full discussion of the importance of high-quality procedure reporting to pediatric care can be found in the related PEnQuIN guideline on endoscopy reporting elements.<sup>67</sup>

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

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 91.7%; agree, 8.3%

**Key evidence:** Although there is strong consensus that reprocessing of endoscopic equipment must be performed appropriately, there is no direct evidence that this positively impacts the outcomes of children undergoing endoscopic procedures. Nevertheless, given the potential serious consequences of infectious contamination,<sup>68–70</sup> it seems prudent to recommend standard, best practices for endoscopic equipment cleaning, as well as for equipment tracing that can allow identification of exposed patients and early intervention, if required.

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

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 87.5%; agree, 12.5%

**Key evidence:** There is limited, indirect evidence that standardizing processes for handling, labelling and processing of tissue specimens obtained during pediatric endoscopy can improve clinical outcomes, although the recommended practice of confirming specimen labels is incorporated within the WHO's SSC.<sup>56</sup> Nevertheless, the PEnQuIN working group strongly agreed that inappropriate handling or mislabeling of tissue specimens can impact clinical outcomes through misinterpretation and/or misclassification of disease. One study of tissue specimens obtained from adult patients found that standardizing biopsy processing to ensure that specimens are embedded perpendicularly, with the mucosal surface facing upwards on the slide, improved diagnostic yield, as measured by the diagnostic confidence of the histopathologists, from 46% to 60%.<sup>71</sup>

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

GRADE: Conditional recommendation, no evidence. Vote: strongly agree, 56.5%; agree, 34.8%, uncertain: 8.7%

**Key evidence:** There are no studies addressing this question, therefore no conclusions can be drawn about whether undergoing pediatric endoscopy in a facility that has a process in place to document, monitor and report results of tissue sample handling leads to improved outcomes. One European adult position paper on quality standards in upper endoscopy authored in collaboration between gastroenterologists and surgeons suggests that this should be aspired to.<sup>41</sup>

**Standard 12: Endoscopy facilities where pediatric procedures are performed should monitor their rate of serious adverse events from pediatric endoscopic procedures and anesthesia using a reliable system and report the results to the appropriate institutional or facility oversight committee.**

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 87.5%; agree, 12.5%

**Key evidence:** Immediate and late adverse events associated with endoscopy and/or anesthesia have been variably defined, and are generally recognized to involve at least one or more of the following clinical outcomes: non-completion of a planned procedure, admission to hospital, prolongation of existing hospital stay, additional procedure(s) or subsequent medical consultation.<sup>72</sup> The adverse event literature has outlined standardized nomenclature and consensus definitions for adverse events and their severity in adult endoscopy patients.<sup>34,72-75</sup> Comparatively, there is limited literature that characterizes adverse events related to endoscopy in children<sup>76,77</sup>, and no agreed upon lexicon for the reporting of pediatric endoscopy adverse events, which has hampered multicenter data collection and analysis.<sup>75</sup>

Although there is relatively strong consensus that all endoscopy facilities should track and appropriately report adverse event rates related to the performance of gastrointestinal endoscopy in children, there is only limited, indirect evidence that this practice can improve clinical outcomes. Furthermore, expected adverse event rates for most procedures in adults and in children have been imprecisely calculated, and are considered to be very low.<sup>77,78</sup> The

paucity of events may complicate calculations to determine observed over expected event rates, and may lend an impracticality to a recommendation that reporting occur on a regular basis.<sup>79,80</sup> In adults, national registries that track event rates across centers have improved the potential to identify outliers, as well as opportunities to mitigate patient risks associated with endoscopic procedures.<sup>78-92</sup> There is consensus that pediatric endoscopy facilities would benefit from the development of similar large registries to which adverse event rates could be reported.

**Standard 13: Endoscopy facilities where pediatric procedures are performed should maintain a comprehensive quality improvement program incorporating formal, standardized review of performance reports at both facility and endoscopist levels.**

GRADE: Conditional recommendation, low quality evidence. Vote: strongly agree, 58.3%; agree, 29.2%, uncertain: 12.5%

**Key evidence:** Although there is good consensus for regularly conducting and monitoring formal, standardized reviews of pediatric endoscopy services at the facility and endoscopist level (e.g., wait times, adverse event rates and terminal ileal intubation rates), there is no evidence that this practice improves patient outcomes. Guidelines from CAG and others have similarly accepted low GRADE evidence for such a standard in stating that formal review of reports, with regular monitoring, are needed in endoscopy facilities to maintain quality of endoscopy procedures in adult patients.<sup>4,8,14</sup> Pediatric data are limited to a few abstracts that have studied candidate quality indicators for upper endoscopy<sup>93</sup> and ileocolonoscopy<sup>93,94</sup>; these data suggest that conducting reviews of quality metrics in pediatric endoscopy facilities may provide a means for assessing and benchmarking performance quality of endoscopic procedures in children.

**Standard 14: Endoscopy facilities where pediatric procedures are performed should have an internal oversight committee/team with representation from pediatric specialists to monitor adherence to best practice guidelines, implement changes and communicate closely with clinical and business operational leadership.**

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 25.0%; agree, 58.3%; uncertain, 12.5%; disagree, 4.2%

**Key evidence:** Although there is consensus that endoscopy facilities where pediatric procedures are performed should each have an internal oversight committee/team to monitor adherence to best practice guidelines, there is no direct evidence to support this standard either in pediatric or in adult literature. There is also limited evidence across procedural fields in general to suggest that participation in recognized quality assurance programs may improve outcomes. Pertaining to endoscopy, a prospective randomized study of Polish colonoscopists, whose endoscopy group leaders were randomized to attend or not attend a national program to improve adenoma detection rates, suggested that monitoring and reporting quality indicators in facilities where endoscopy is performed in adults could lead to collective improvement.<sup>95</sup> In a UK study, regular audits of colonoscopy quality have been shown to improve procedural performance.<sup>96</sup> In this study, two audit cycles were completed between 1999 and 2002. Changes to practice were based on results of the audits and also



considered the opinions of relevant staff. The colonoscopy completion rate improved after the audit cycles from 60% initially to a final adjusted completion rate of 94%.

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

GRADE: Conditional recommendation, no evidence. Vote: strongly agree, 41.7%; agree, 58.3%

**Key evidence:** Gaps persist in the establishment of pediatric endoscopy quality guidelines as well as the collection of data necessary to provide evidence for the impact of such guidelines on procedural outcomes. Endoscopy safety and quality guidelines have been established with adult gastroenterology associations and national systems for quality improvement, although evidence to support their benefits in terms of patient outcomes remains limited.<sup>4,97</sup> Other quality improvement programs, such as the American College of Surgeons' National Surgical Quality Improvement Program, have been associated with improved safety and quality outcomes, including mortality, morbidity and infections across a range of academic-, community- and private practice-based settings.<sup>98</sup> Nevertheless, there is strong consensus that the development and implementation of pediatric-specific endoscopy guidelines to improve endoscopy quality and safety outcomes should be pursued.

#### **FACILITY SUBDOMAIN 2: QUALITY OF PATIENT AND CAREGIVER EXPERIENCE**

Providing high quality care for children undergoing endoscopy invariably involves ensuring high quality communication and experiences for their caregivers as well. From a patient- and caregiver-centered care perspective, high quality endoscopic procedures begin with a seamless, timely scheduling process that includes clear instructions for procedure preparation. Children and their caregivers should be assured of high quality processes on the day of the procedure that are efficient, but are also designed to maintain patient safety and comfort during preprocedure operations, the procedure itself, as well as after the procedure, during a recovery phase. Upon discharge from the procedural encounter, high quality endoscopic care ensures that processes are in place should there be concerns raised by patients, caregivers or providers for late adverse events. In addition, all patients, caregivers, referring physicians and germane members of a patient's healthcare team, should receive effective and timely counseling regarding all procedural findings, including pathology. The PEnQuIN working group achieved consensus on the following standards for assuring high quality care of patients undergoing pediatric endoscopy, as well as their caregivers, as measured by the 5 associated indicators (**Table 3**).

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

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 50.0%; agree, 33.3%; uncertain, 16.7%

**Key evidence:** To improve the patient and caregiver experience, pediatric endoscopy units should utilize patient-centered processes for routine, diagnostic, therapeutic and emergency

procedures that are specifically geared toward the care of children and their families. There is weak evidence that patient-centered processes of care can effectively improve the patient and/or family experience. This matter has been only indirectly addressed through prospective studies of adult patient satisfaction, which have identified the following determinants: endoscopy unit environment, staff attitude, patient comfort, clarity of communication with the endoscopist and patient wait times.<sup>16,99,100</sup>

**Standard 17: Patients and/or caregivers should receive appropriate information about the endoscopic procedure before the procedure date.**

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

**Key evidence:** Although there was consensus that patients should receive preprocedure information, there is very little direct evidence that this standard improves endoscopy outcomes in children.<sup>101-103</sup> Survey studies of both pediatric and adult patients/caregivers suggest that those who receive standardized patient information handouts have more preprocedure knowledge of potential adverse events and feel more prepared.<sup>101,104</sup> Standardized informational handouts may also improve patient knowledge of and satisfaction with the procedural experience, and may reduce preprocedure anxiety as well as intraprocedural distress.<sup>102,105</sup> However, these studies also reveal some complexity to the impact of providing patients with standardized preprocedure information. Among children, preprocedure knowledge of endoscopy was associated with greater anticipatory anxiety, but less intraprocedural distress and more favorable attitudes toward undergoing repeat procedures.<sup>102,103</sup> Studies in adults demonstrate mixed results of presenting preprocedure information, particularly via video, with regard to anxiety reduction.<sup>106-110</sup> Procedural outcomes may also be affected, as suggested by one study that showed higher colonoscopy completion rates in patients who received preprocedure information.<sup>105</sup>

**Standard 18: Endoscopy facilities where pediatric procedures are performed should have a clear and well-defined process for communicating instructions that ensure effective, age-appropriate and patient- and family-centered bowel preparation.**

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

**Key evidence:** There is consensus that adequate bowel preparation is critical to the performance of successful pediatric ileocolonoscopy, and that endoscopy facilities should ensure best practices for communicating bowel preparation instructions to children and their families. Although various patient education interventions have shown variability in effectiveness for improving the quality of bowel preparation, the overall quality of evidence for this in pediatrics is low, due to small sample sizes, significant trial design heterogeneity and the different educational interventions studied. Maxwell et al<sup>111</sup> measured bowel preparation quality and found no significant benefit of using an educational cartoon over the standard instructions. Brief et al<sup>112</sup> demonstrated better quality preparations in pediatric patients who received their instructions via a smartphone application compared to standard written instructions. Studies of adult patients have also demonstrated superiority of

smartphone apps to deliver prep instructions and education.<sup>113,114</sup> Interactive social media,<sup>115</sup> educational videos<sup>116</sup> and text reminders<sup>117</sup> have also demonstrated efficacy in small trials of adult patients undergoing colonoscopy, and may even improve cecal intubation rates.<sup>105,115</sup>

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

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 58.3%; agree, 37.5%; disagree, 4.2%

**Key evidence:** To enhance the patient and caregiver experience, pediatric endoscopy units should utilize patient-centered processes for preoperative and recovery phases of care that are geared towards pediatric patients and their families. Examples include availability of child life experts, a dedicated place for caregivers to wait during procedure, and parental presence at induction. As mentioned, evidence that patient-centered processes of care can effectively improve the patient and/or family experience is weak and has only been indirectly addressed in prospective studies of adult patient satisfaction.<sup>16,99,100</sup>

**Standard 20: Endoscopy facilities where pediatric procedures are performed should ensure availability of pediatric-specific monitoring and resuscitation equipment.**

GRADE: Strong recommendation, moderate quality evidence. Vote: strongly agree, 100%

**Key evidence:** There is direct pediatric evidence that electronically monitoring both healthy and medically complex infants and children undergoing sedated gastrointestinal endoscopy with pediatric-specific continuous pulse oximetry and electrocardiogram equipment leads to increased detection of dangerous vital signs in children and improves their safety.<sup>118,119</sup> Other examples of equipment that may need to be pediatric-specific in their design include endotracheal tubes, masks and blood pressure cuffs. There is also rigorous randomized controlled evidence showing that the addition of capnography to the electronic monitoring of infants and children undergoing sedated endoscopy decreases apnea and disordered respiration, as well as hypoxemia.<sup>120</sup> Although the evidence is less direct, it is important to recognize supportive studies in adult patients undergoing routine and advanced endoscopic procedures that have similarly found the use of capnography to reduce apnea, disordered respiration, hypoxemia and arrhythmias.<sup>121,122</sup>

Beyond single trials, there are also systematic reviews and meta-analyses (including one with pediatric evidence)<sup>123</sup> that show that adding capnography into the electronic monitoring of sedation for gastrointestinal endoscopy reduces not only moderate and severe hypoxemia, but also other morbidity (e.g., cardiovascular events) and mortality.<sup>123,124</sup> Overall, there is a preponderance of evidence that generally speaks to electronic monitoring as an important means of detecting physiologic changes in patients undergoing sedation for gastrointestinal procedures, and for prompting interventions to prevent adverse events. Although less direct, it is reasonable to assume that monitoring devices should be sized for pediatric patients to achieve best efficacy.

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

GRADE: Strong recommendation, very low quality evidence. Vote: strongly agree, 91.7%; agree, 8.3%

**Key evidence:** The availability of age, size and weight appropriate endoscopes and related equipment is generally considered of critical importance in performing endoscopy. Nonetheless, only indirect evidence exists on the importance of pediatric-specific equipment. Upper endoscopy and ileocolonoscopy have been well described in populations of children and small infants (i.e., <10 kilograms) who require smaller sized equipment to allow procedural performance while maintaining patient safety.<sup>125,126</sup> Normal anatomic, as well as congenital or acquired anatomic variation in children, may also be relevant when considering appropriate equipment. NASPGHAN, ESPGHAN as well as the American and European Societies for Gastrointestinal Endoscopy (ASGE and ESGE) all suggest using size- and weight-specific equipment in the performance of pediatric endoscopy.<sup>2,3,34</sup> Additional considerations of pediatric endoscopic equipment may be posed by the channel size of appropriately sized endoscopes, which may limit choice of accessories that can be passed for use during procedures. With improvements in technology, more pediatric appropriate equipment may lead to improvements in procedural feasibility and quality. Use of high definition endoscopes may also be important in pediatrics, but direct evidence for this is also lacking. In one prospective study in adults, the generational age of a colonoscope was a significant factor in improved adenoma detection rate.<sup>127</sup>

**Standard 22: Pediatric patients are discharged postprocedure according to predetermined standard discharge criteria, with clear documentation of readiness for discharge.**

GRADE: Conditional recommendation, No evidence. Vote: strongly agree, 29.2%; agree, 58.3%; uncertain, 12.5%

**Key evidence:** Although there is consensus that pediatric patients should be discharged using standardized discharge criteria (e.g., Aldrete score<sup>128</sup>, Observer's Assessment of Alertness/Sedation Scale<sup>129</sup>, Dartmouth Operative Conditions Scale<sup>130</sup>, Pediatric Sedation State Scale<sup>131</sup>) and that facility processes should ensure clear documentation of a patient's readiness for discharge, there is no evidence among pediatric patients that this practice improves clinical outcomes. Guidelines for adults<sup>132</sup> recommend that after completion of endoscopic procedures, patients should be observed for adverse effects from instrumentation and sedation, if administered. The length of the follow-up observation is dependent on the perceived risk to the patient. Patients may be discharged from the endoscopy unit or postprocedure recovery area once vital signs are stable, and the patient has reached an appropriate level of consciousness. Despite the appearance of appropriate recovery, it is well recognized that patients may have a prolonged period of amnesia and/or impaired judgment, as well as impaired cognitive and motor reflexes, after sedation. Quality indicators that apply to adult units should be considered for pediatric endoscopy units; in particular, each unit should have a written policy describing the criteria patients must meet before being discharged from the unit.<sup>39</sup> In addition, it should be clearly documented that the patient has achieved these criteria prior to discharge.

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

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 56.5%; agree, 39.1%, disagree, 4.4%

**Key evidence:** There are no studies which demonstrate that policies that call for timely communication of follow-up instructions and pathology reports are beneficial to patient outcomes. Instead, several studies show that communication after procedures is variable in terms of whether it occurs, how it occurs and what information is communicated. One small, retrospective single-institution pediatric study reported communication of postprocedure pathology results and treatment plans to be suboptimal, with only 40% of families notified of these details during a postprocedure phone call.<sup>101</sup> Future studies may need to account for the complexity of pediatric facilities, which may span multiple locations.

Among adult patients, Spodik et al found that receipt of discharge instructions along with a copy of the procedure report can reduce postprocedure anxiety.<sup>55</sup> Yet, De Jonge et al, who conducted a large, pre- and postprocedure survey study, found that most adults did not know how they would receive results after screening colonoscopy.<sup>104</sup> Both Spodik and De Jonge discuss the importance of clear communication to patients about postprocedural details, including pathology findings and directions for follow-up. Nevertheless, there remains no direct evidence that this practice improves patient outcomes.

**Standard 24: Endoscopy facilities where pediatric procedures are performed should systematically solicit pediatric patient and/or caregiver feedback, report the results to the service and to the institution's or facility's quality committee and implement appropriate remediation plans in a timely manner.**

GRADE: Conditional recommendation, no evidence. Vote: strongly agree, 20.8; agree, 62.5%; uncertain, 16.7%

**Key evidence:** Although there is consensus that feedback from pediatric patients and their families following procedures should be solicited and used to improve facility processes as an important aspect of patient-centered care, there is no direct or indirect evidence that solicitation of such information improves patient outcomes and/or the quality of pediatric endoscopic procedures.

### **FACILITY SUBDOMAIN 3: WORKFORCE**

At the most basic level, performance of high quality endoscopy requires a competent endoscopist and dedicated personnel who contribute to procedures in myriad ways, including room preparation, processing and reprocessing equipment, patient monitoring, documentation of patient care and provision of technical support during endoscopic maneuvers that require assistance. Local and regional regulations may determine minimum staff requirements across the continuum of a procedure, including in preprocedure areas, in the procedure room and during postprocedural care. Qualified personnel who assist in endoscopy may include fully licensed “registered” nurses, licensed practical nurses, advanced practice providers (i.e.,

nurse practitioners, physician assistants), nursing assistants and technicians. Pediatric endoscopy personnel must also include administrative staff who are trained in the complexities of endoscopy scheduling, as well as the assessment of equipment needs and procurement. As always, across all roles and responsibilities, it is patient safety that remains paramount and should dictate training, staffing and maintenance of competence in the pediatric endoscopy unit. However, high quality facilities for pediatric gastrointestinal procedures should also be staffed by personnel who are able to assure efficiency in clinical operations, while maintaining a patient- and caregiver-centered approach to endoscopic care.

The following achieved consensus within the PEnQuIN working group as minimum standards regarding personnel who staff high quality pediatric endoscopy facilities:

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

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

**Key evidence:** Although consensus dictates that clinical outcomes of endoscopy in children will be positively affected if patients and their caregivers are cared for by adequate numbers of well-trained staff<sup>133</sup> using of appropriate equipment,<sup>1,12</sup> there is no pediatric evidence for this standard, and adult evidence is indirect and imprecise. Shah et al performed a population-based comparison of adult gastrointestinal procedure facilities in Canada in 2007 and found that procedures performed in adult patients in private offices, which at that time were exempt from sedation, endoscopic disinfection and credentialing regulations, were more likely to be incomplete, as compared with procedures performed in academic or community-based hospitals.<sup>134</sup> Evidence that quality and number of staff present affect procedural outcomes is similarly indirect. Dellon et al performed a multi-center retrospective study that determined that procedures in adult patients that were performed with nurses with at least 6 months endoscopy experience, as well as procedures performed with at least 2 nurses, were associated with higher polyp detection rates.<sup>135</sup>

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

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

**Key evidence:** There is consensus that participation by endoscopy staff in educational programs should be a facility priority despite no direct evidence of impact on pediatric procedural outcomes. A single pediatric study suggests that interdisciplinary staff participation in simulation-based training of crisis resource management skills was perceived to be beneficial for improving outcomes by staff members of all experience levels.<sup>136</sup> In the adult context, educational programs for staff involved in the performance of endoscopic procedures are more widely available, cover multiple procedural domains (e.g., technical

skills, non-technical skills, cognitive skills) and have been shown in a number of studies to affect clinical outcomes.<sup>14,95,127,137-139</sup>

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

GRADE: Conditional recommendation, very low quality evidence. Vote: strongly agree, 54.2%; agree, 29.2%; uncertain, 12.5%; disagree, 4.1%

**Key evidence:** There is consensus that endoscopy personnel, including nurses, technicians and anesthesiologists, should be specially trained and certified to perform both routine and emergency procedures in children. In a similar vein, training through a hospital or a gastrointestinal society is recommended for both nurses and technicians working with adult patients.<sup>140</sup> Although there is no direct pediatric evidence that training and certification improves patient outcomes, one study of nursing experience with adult endoscopic procedures found a positive relationship between experience level and rate of polyp detection in adults undergoing screening colonoscopy.<sup>135</sup> Requirements for anesthesiologists and their delegates who care for children undergoing gastrointestinal procedures may depend upon the type of anesthesia being administered (e.g., moderate sedation or general anesthesia).<sup>1</sup>

## **DISCUSSION**

The goal of the PEnQuIN working group in developing this document was to achieve consensus on a list of key standards that should be upheld in all facilities around the world where endoscopy is performed in children, in accordance with the best evidence and clinical outcomes. Each indicator that was identified can be continuously measured at a facility, group practice and individual provider level, as appropriate. The standards and indicators outlined in this document are intended to guide and measure endoscopic care processes, and to ensure that high quality procedures are occurring. Although consensus was achieved, it must be recognized that most PEnQuIN standards are ‘conditional’ recommendations, indicating that they are likely to be associated with desirable outcomes but are not mandatory. Instead, the PEnQuIN standards should be prioritized for implementation by endoscopists and endoscopy services, taking into account patient values and preferences, and considering the resources available as well as the setting in which the standards will be implemented.<sup>23</sup> Ideally, the PEnQuIN standards provide a guide for the development of endoscopy services, regional and national pediatric endoscopy facility accreditation, and for assuring consumer transparency. The PEnQuIN working group does not endorse auditing facilities, groups/practices or providers for punitive purposes, rather the goal should be to identify opportunities for continually improving the quality of pediatric endoscopy universally. PEnQuIN is also committed to developing multi-center registries incorporating these quality metrics that can be used for feedback, benchmarking and to promote improvement.

Generally speaking, there was excellent agreement among PEnQuIN working group members that each standard and indicator included in this document is valuable and relevant to all settings where endoscopy procedures in children are performed, and that each contributes to

optimal outcomes of pediatric endoscopy. Nevertheless, few standards achieved one hundred percent agreement. This was perhaps not surprising because the rigorous PEnQuIN process used to develop and evaluate each standard underscored the paucity of evidence for almost every aspect of patient care that is assumed to form the foundation of high quality pediatric endoscopy facilities. In turn, this PEnQuIN document provides a framework and basis for future research in endoscopy facilities, with the goal of ensuring that best practices in endoscopic care of children are evidence-based. An ongoing endeavor to develop evidence for all PEnQuIN standards and indicators will increase their value for pediatric endoscopists, as well as for children with digestive disorders who undergo procedures. As a next step, the PEnQuIN working group is committed to engaging our colleagues and achieving consensus on endoscopy research priorities that will expand the evidence base for these guidelines.

The working group acknowledged that there is great variation in practice models and workflows, which may impact how certain standards are implemented and upheld. Indeed, pediatric endoscopy may occur in facilities that take responsibility for all phases of clinical care. However, in other practice models, pediatric gastroenterologists may contract with hospitals or ambulatory surgical centers to provide certain services. Additionally, some facilities may provide after-hours and/or emergency care while others may defer those services to other centers or other specialties (e.g., pediatric surgeons, otolaryngologists, adult gastroenterologists). The PEnQuIN working group sought to broadly define a pediatric endoscopy facility as encompassing all aspects of endoscopy services and the many personnel involved in their provision. For those facilities that do not provide certain endoscopy services, there should be forethought and formal discussion as to where and how children can receive care. Regardless of care model, role clarity, clear communication and documentation are vital between all members of the multidisciplinary care team to ensure that all pediatric endoscopy facility standards are upheld, and their indicators tracked.

By design, the PEnQuIN working group focused on feasibility when evaluating each standard and indicator and took care to avoid prescribing any standards that might mandate expenditures on capital equipment or staff. For example, the PEnQuIN framework for assessing the quality of facilities, which highlights the need for documentation, includes a method by which each indicator can be obtained through manual data extraction from the medical chart. Although the PEnQuIN working group acknowledged that use of electronic reporting systems may not be universal, it also recognized that use of such systems is preferable. We also believe that electronic reporting systems are more likely to be conducive to regular report generation of quality indicators and thereby more apt to support continuous improvement activities in facilities where gastrointestinal procedures in children are performed. Over time, it is our hope that quality-related tools and dashboards are developed for electronic health record systems to facilitate implementation of the PEnQuIN standards and indicators.

The PEnQuIN working group is now calling upon pediatric gastroenterologists as a community to commit to the implementation of these standards for pediatric endoscopy without delay. We do this while recognizing that this may not be possible for many pediatric endoscopy facilities without institutional or facility commitment, or regional guidance. As



such, we anticipate that this document can provide a roadmap for pediatric gastroenterologists to work with their facilities to identify deficiencies in their current processes, along with first steps that may be necessary to ultimately provide high quality pediatric endoscopy services. We believe there is compelling precedence in several countries, including the UK and Canada, through their respective Global Rating Scales, for using standardized assessments of facility quality and collecting feedback on the patient and caregiver experience<sup>141</sup> at a national level to improve endoscopic outcomes. We also believe that the worldwide consensus the PEnQuIN group achieved throughout this process is a testament to how important these standards are to ensure that pediatric endoscopy is done well.

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## TABLE LEGENDS

**Table 1:** Quality-related terminology

	<b>Term</b>	<b>Definition</b>
	<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:** Indicators related to the ‘Quality of Clinical Operations’ subdomain

<p><b>Indicator 1:</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)</p> <ul style="list-style-type: none"> <li><b>Numerator:</b> Number of pediatric endoscopies occurring in an endoscopy facility that are performed within a guideline-specified timeframe</li> <li><b>Denominator:</b> All pediatric endoscopies occurring in an endoscopy facility that are subject to a guideline-specified timeframe</li> <li><b>Calculation:</b> Proportion (%)</li> <li><b>Associated PEnQuIN Standards:</b> S2</li> </ul>
<p><b>Indicator 5:</b> Rate with which sedation-related fasting guidelines are followed</p> <ul style="list-style-type: none"> <li><b>Numerator:</b> Number of sedated pediatric endoscopies occurring in an endoscopy facility where fasting guidelines are followed</li> <li><b>Denominator:</b> All sedated pediatric endoscopies occurring in an endoscopy facility</li> <li><b>Calculation:</b> Proportion (%)</li> <li><b>Associated PEnQuIN Standard:</b> S4</li> </ul>
<p><b>Indicator 6:</b> Rate of mishandled, mislabeled or misprocessed tissue specimens</p> <ul style="list-style-type: none"> <li><b>Numerator:</b> Number of mishandled, mislabeled or misprocessed tissue specimens in an endoscopy facility</li> <li><b>Denominator:</b> All tissue specimens acquired in an endoscopy facility</li> <li><b>Calculation:</b> Proportion (%)</li> <li><b>Associated PEnQuIN Standards:</b> S11</li> </ul>
<p><b>Indicator 10:</b> Rate of adverse events</p> <ul style="list-style-type: none"> <li><b>Numerator:</b> Number of documented intraprocedural, immediate postprocedural and late adverse events in an endoscopy facility</li> <li><b>Denominator:</b> All pediatric endoscopies occurring in an endoscopy facility</li> <li><b>Calculation:</b> Proportion (%)</li> </ul> <p><b>Associated PEnQuIN Standards:</b> S12</p>
<p><b>Indicator 11:</b> Participation by an endoscopy facility in a recognized quality assurance program</p> <ul style="list-style-type: none"> <li><b>Calculation:</b> Binary (yes/no)</li> <li><b>Associated PEnQuIN Standards:</b> S13, S14</li> </ul>

**Table 3:** Indicators related to the ‘Quality of Patient and Caregiver Experience’ subdomain

<p><b>Indicator 12:</b> Rate of patients/caregivers who receive procedure-related instructions prior to the date of endoscopy</p> <ul style="list-style-type: none"> <li>▪ <b>Numerator:</b> Number of patients/caregivers scheduled to undergo pediatric endoscopies who receive procedure-related instructions prior to the date of endoscopy</li> <li>▪ <b>Denominator:</b> All pediatric patients scheduled to undergo endoscopies</li> <li>▪ <b>Calculation:</b> Proportion (%)</li> <li>▪ <b>Associated PEnQuIN Standards:</b> S17</li> </ul>
<p><b>Indicator 13:</b> Rate with which patients receive adequate instructions on bowel preparation</p> <ul style="list-style-type: none"> <li>▪ <b>Numerator:</b> Number of pediatric endoscopies occurring in an endoscopy facility where adequate instructions on bowel preparation were <i>communicated</i> to patients and this is documented</li> <li>▪ <b>Denominator:</b> All pediatric endoscopies occurring in an endoscopy facility where bowel preparation is <i>required</i></li> <li>▪ <b>Calculation:</b> Proportion (%)</li> <li>▪ <b>Associated PEnQuIN Standard:</b> S18</li> </ul>
<p><b>Indicator 14:</b> Rate of discharge from an endoscopy facility in accordance with predetermined standard discharge criteria</p> <ul style="list-style-type: none"> <li>▪ <b>Numerator:</b> Number of pediatric endoscopies for which discharge from an endoscopy facility is performed in accordance with predetermined standard discharge criteria, using a standardized tool, and this is documented</li> <li>▪ <b>Denominator:</b> All pediatric endoscopies occurring in an endoscopy facility</li> <li>▪ <b>Calculation:</b> Proportion (%)</li> </ul> <p><b>Associated PEnQuIN Standard:</b> 22</p>
<p><b>Indicator 15:</b> Quality of the patient and caregiver experience</p> <ul style="list-style-type: none"> <li>▪ <b>Numerator:</b> Number of all patients/caregivers who formally rate the quality of their experience in an endoscopic facility, using a standardized tool, as <i>acceptable</i> in accordance with pre-determined standards</li> <li>▪ <b>Denominator:</b> All patients/caregivers who are asked by an endoscopy facility to formally rate their experience, using a standardized tool</li> <li>▪ <b>Calculation:</b> Proportion (%)</li> <li>▪ <b>Associated PEnQuIN Standards:</b> S24</li> </ul>
<p><b>Indicator 16:</b> Rate with which patient and caregiver experience data are formally obtained</p> <ul style="list-style-type: none"> <li>▪ <b>Numerator:</b> Number of patients/caregivers who provide formal feedback to an endoscopy facility about their experience, using a standardized tool</li> <li>▪ <b>Denominator:</b> All pediatric endoscopies occurring in an endoscopy facility</li> <li>▪ <b>Calculation:</b> Proportion (%)</li> <li>▪ <b>Associated PEnQuIN Standards:</b> S24</li> </ul>