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Quality improvement in pediatric inflammatory bowel disease: Moving forward to improve outcomes

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Abstract

In recent years, pediatric health care has embraced the concept of quality improvement to improve patient outcomes. As quality improvement efforts are implemented, network collaboration (where multiple centers and practices implement standardized programs) is a popular option. In a collaborative network, improvement in the conduct of structural, process and outcome quality measures can lead to improvements in overall health, and benchmarks can be used to assess and compare progress. In this review article, we provided an overview of the quality improvement movement and the role of quality indicators in this movement. We reviewed current quality improvement efforts in pediatric inflammatory bowel disease

(IBD), as well as other pediatric chronic illnesses. We discussed the need to standardize the development of quality indicators used in quality improvement networks to assess medical care, and the validation techniques which can be used to ensure that process indicators result in improved outcomes of clinical significance. We aimed to assess current quality improvement efforts in pediatric IBD and other diseases, such as childhood asthma, childhood arthritis, and neonatal health. By doing so, we hope to learn from their successes and failures and to move the field forward for future improvements in the care provided to children with IBD.

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Core tip: This review article provides an overview of the quality improvement movement and the role of quality indicators. Active quality improvement efforts in pediatric inflammatory bowel disease are discussed, and the need for standardizing the development of quality indicators across all fields of healthcare is emphasized. This article also discusses the importance of incorporating validation techniques when developing and selecting quality indicators. Examples of quality improvement efforts in other areas of pediatric chronic illnesses are presented, with important lessons highlighted to guide future quality improvement initiatives.

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INTRODUCTION

The inflammatory bowel disease (IBD) are a group of chronic gastrointestinal diseases caused by inflammation of the gastrointestinal tract and resulting in malabsorption of nutrients, failure to thrive, abdominal pain, and extraintestinal manifestations^[1]. They consist of two main subtypes: Crohn's disease (CD) and ulcerative colitis (UC), and patients who do not fall into either subtype are deemed IBD type unclassified (IBD-U)^[1]. Adult and pediatric onsets of IBD differ in some regards, with one of them being in regards to the degree of psychosocial burden. Quality of life is significantly affected, with children being frequently affected by psychosocial issues as a result of stunted growth, weight gain from drug therapy and the inability to feel confident around peers due to associated bowel issues^[2].

Incidence and prevalence of pediatric IBD have been increasing worldwide. A recent systematic review with the aim of describing international trends for pediatric IBD rates found that 60% and 20% of relevant publications reported statistically significant increases in CD and UC incidence, respectively^[3]. The findings represented data from 32 countries, thereby providing evidence that pediatric IBD has become a global disease affecting a multitude of countries^[3]. Several developed countries had released reports characterizing incidence rates within their pediatric population. In Ontario, Canada, there was a 5% and 7.6% increase per year in incidence for children aged 0-4 years and 5-9 years, respectively^[4]. Similar increases have been demonstrated in Spain and Northern California, United States^[5,6].

With increasing incidence and prevalence comes greater economic burden, both on the healthcare system and on patients' families. Based on 2003-2004 data, the direct healthcare costs of IBD in the United States was \$3.1 billion for CD and \$2.1 billion for UC^[7]. Children had the highest cost of direct medical care, and lengths of hospital stay were also high, with an average of 8.1 d for CD patients who were ≥ 5 years of age^[8]. While the average pediatric patient with IBD costs significantly more in direct medical costs than the average adult, a high degree of variability in care and outcomes has been noted in the literature^[7]. A study from the United States demonstrated variation in care provided to children in a network of pediatric IBD centers, including a large degree of variation in use of immunosuppressive medications at diagnosis^[9]. Similarly, we have previously described variation in surgical outcomes in Canadian children based on family income, despite a universal access healthcare environment^[10]. In addition, we described a high degree of variability in medication prescription rates in children with IBD from three countries^[11]. This variation in care may be unwarranted, and indicate room for improvement in the quality of care^[12]. The description of unwarranted variation in care has therefore spurred quality improvement efforts in pediatric IBD^[13].

In addition, with increasing burden of pediatric IBD,

the issue of quality of care becomes more important. Improved quality of care should lead to improved outcomes, and therefore lower long-term burden as well as medical and psychosocial benefits. While the motivation for improving processes involved in providing high quality medical care is clear, such quality improvement efforts should be based in evidence and undergo validation to ensure efficient resource allocation.

Recognizing the disparities present in modern-day healthcare systems, the Institute of Medicine released two reports highlighting current issues affecting quality^[14,15]. Both reports have argued that quality of care is sub-optimal across all aspects of health regardless of disease type, and have proposed that healthcare systems be reformed to prevent mis-use of healthcare services^[16]. As a result of these reports, many providers, including pediatric IBD specialists, have worked with quality improvement experts to improve the quality of care for their patients by implementing quality improvement programs. We have reviewed current published quality improvement efforts in pediatric IBD, and the evidence that they have improved outcomes. In addition, we have examined evidence from quality improvement work in other fields to inform future pediatric IBD efforts and improved their likelihood of success.

WHAT IS QUALITY IMPROVEMENT?

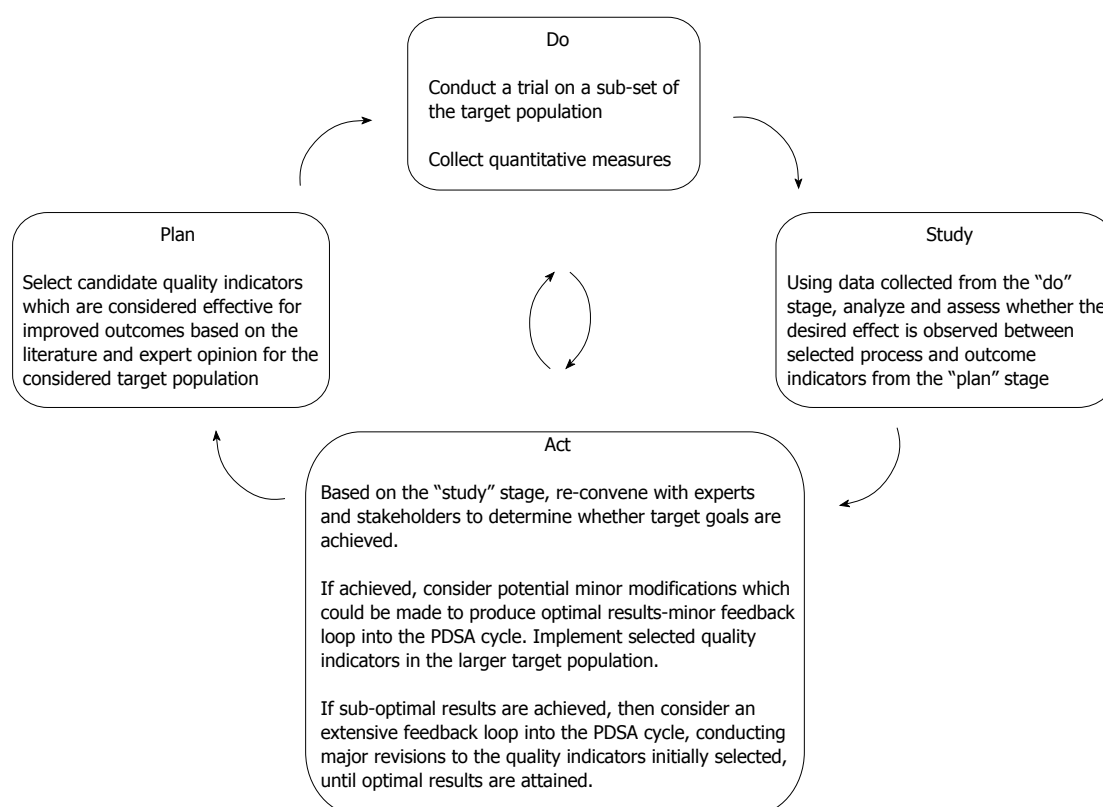
Quality improvement in medicine is defined as the effort to change care using an evidence-based approach in order to make tangible positive changes to the delivery healthcare^[17]. With origins stemming from the field of industry and production, quality improvement efforts have slowly been introduced into the field of healthcare delivery over the past few decades. Definitions used to describe common quality improvement terms can be found in Table 1.

The plan-do-study-act (PDSA) has been used as a paradigm for quality improvement efforts^[18,19]. With this framework, at the plan stage, quality indicators are developed to measure the quality of care provided. During the do stage, these indicators are implemented into practice and quantitative measures are collected. At the study stage, the statistics gathered in the previous stage are used to evaluate the progress that this action has on healthcare delivery. At the act stage, a feed-back loop is utilized such that quality indicators which have produced sub-optimal results are re-examined and cycled back through the PDSA cycle. Quality indicators which have improved quality of care are also re-examined to ensure that additional modifications cannot be added to ensure optimal care is being provided^[20]. The National Health Services(NHS) in the United Kingdom has recommended that the PDSA be used in trial phase and then implemented fully once outcomes have been satisfied^[20]. A modified PDSA cycle can be found in Figure 1, and is adapted from Langley *et al*^[19].

In general, many efforts for quality improvement have been unsuccessful due to the lack of a trial phase,

Table 1 Definitions of common quality improvement terms^[17,18,22,23]

Term	Definition
Quality improvement	The overall framework used to describe the process of implementing evidence-based interventions to bridge the disparities currently present in various healthcare systems
Quality indicators	A set of measures used to assess the appropriateness and quality of health care. Quality indicators are considered the fundamental building blocks of quality improvement efforts
Structural indicators	Indicators having to do with the structure of the healthcare system (<i>e.g.</i> , staffing, equipment, environment, electronic health records)
Process indicators	Indicators having to do with the process of providing care (<i>e.g.</i> , investigations, treatments, interaction with patients)
Outcome indicators	Indicators having to do with assessing the outcome of patients (<i>e.g.</i> , mortality, morbidity, quality of life, patient satisfaction)

**Figure 1** Modified plan-do-study-act cycle. PDSA: Plan-do-study-act.

and the lack of feed-back and change. Too often, quality indicators are developed and measures are extracted, but the process does not extend further beyond that point^[21].

WHAT ARE QUALITY INDICATORS?

The process of quality improvement of medical care requires markers of adequate and inadequate care. The essential building blocks for quality improvement efforts are the proper identification and implementation of effective quality indicators^[22]. These quality indicators are measurable elements of practice performance for which there is evidence or consensus that they may be applied to assess and improve the quality provided^[23]. The types of quality indicators have been broadly categorized as follows: (1) Structural measures-[indicators to do with the structure of the health system (*e.g.*, staffing, equipment, electronic medical records)]; (2) Process measures-[indicators to do with the process of providing care (*e.g.*,

investigations, treatment, interactions with patients)]; and (3) Outcomes measures-[indicators which assess the outcome of patients (*e.g.*, mortality, morbidity, quality of life, patient satisfaction)]^[18]. While improvement in all categories of indicators is desirable, process measures have garnered the majority of the attention, as they are most easily modified. To serve their intended purpose, process measures should predict facility-level outcomes, predict patient-level outcomes, and specify changes in care that are supported by the scientific evidence while being acceptable to patients and clinical staff^[24].

QUALITY IMPROVEMENT IN PEDIATRIC IBD

Understanding the benefits associated with standardized quality improvement efforts, an initiative called ImproveCareNow (ICN) was implemented amongst several

centers in the United States, and is rapidly expanding^[25]. It consists of a network of IBD centers engaged in a well-designed quality improvement program with an overall aim to determine whether measuring and decreasing variability would improve remission rates and other outcomes^[25]. Patient details and center practices are inputted prospectively into a registry, with quality indicator compliance rates fed back to centers on a regular basis. This feedback mechanism forms the basis of well-planned quality improvement efforts, including comparative reports, knowledge sharing activities, and clinical pre-visit planning mechanisms. The participating centers can then use their own results as benchmarks and compare future results as markers of improvement. They can also compare their performance to other participating centers^[26]. Initial results from ICN activities are promising, with improved compliance and remission rates demonstrated in the earliest years of the program. Crandall *et al*^[27] reported improvement in adherence to the selected quality indicators based on prospectively collected data from 6 participating centers. This was associated with a higher proportion of patients with inactive disease by Physician Global Assessment (PGA). However, improvements were relatively modest (13% improvement in remission rates for CD, 11% improvement for UC, based on statistical process control methods). These improvements were associated with a decreased proportion of patients with mild active disease. The proportion of patients with moderate or severely active disease remained stable over time. In addition, improvements in remission rates measured by the more objective short Pediatric Crohn's Disease Activity Index (sPCDAI) were smaller than those measured with PGA^[13,28]. This raises the issue of disease activity measurement in IBD. As evidence grows that clinical remission is insufficient to predict long-term prognosis, the use of measures which correlate strongly with mucosal healing and complete remission becomes especially important^[29].

In another study, Cincinnati Children's Medical Centre, one of the original participating centers in ICN with a long history of quality improvement efforts, published preliminary results of their quality improvement program in a separate report^[30]. As with ICN, a registry was developed, and indicators and outcomes were measured. To assess remission rates, PGA was used, along with patient-reported symptoms. Other variables measured included use of azathioprine and corticosteroids. They also assessed the use of vitamin D supplementations and serum 25-hydroxyvitamin D levels. Process and outcome indicators were chosen based on available guidelines and expert consultation. The institution reported improved remission rates of 59% to 76%, ($P < 0.05$), and a decreased use of repeated steroid courses of 17% to 10%, ($P < 0.05$). Investigators also found significant associations between decreased disease activity and vitamin D supplementations as well as disease activity and serum 25-hydroxyvitamin D levels ($P = 0.02$), although there was no control for confounders such as overall medica-

tion adherence and frequency of clinic visits^[30].

While ICN has become the first large-scale pediatric IBD quality improvement network to demonstrate successful changes in practice, some lessons can be learned from their methods (as well as those of quality improvement efforts in other pediatric patient groups) to further increase the likelihood of success in future quality improvement efforts.

QUALITY INDICATOR DEVELOPMENT AND VALIDATION

The indicators developed by ICN formed the basis of the measurement and feedback system, and therefore were developed with the assumption that improvement in the care provided and outcomes achieved would follow improved compliance with these indicators.

The initial set of indicators developed by ICN were not considered adequate and were revised^[25]. The initial 19 measures initially deemed appropriate for improving pediatric IBD quality were implemented amongst multiple centers. As these measures were being used in routine practice, it became obvious that several quality indicators needed further clarification, and some measures were not appropriate or feasible for inclusion^[25]. Flexibility is therefore required in the development and implementation of a quality improvement network, and the allowance for revision is an important part of the quality improvement process.

A pilot phase, as conducted by ICN is also important to ensure that intervention in the population being studied will produce a desirable effect. While quality indicators in quality improvement efforts are typically derived using RAND appropriateness methodology, which integrates expert opinion and review of the evidence, the literature may not be representative of the centers involved in the network^[24]. For example, a quality improvement network could consist of centers whose patients are mostly from low income neighborhoods. Measurement and control for these confounding factors is paramount. Without a pilot phase, and assessment of confounding, a formal quality improvement network may use imprecise process measures, leading to wasted resources and possibly misleading information^[24]. Following development of a second set of indicators for ICN, various mechanisms were put into place to provide clarification (such as a manual detailing strategies for accurate and complete measurement by participating centers). Of the 19 quality indicators developed, the quality indicators assessed by Crandall *et al*^[25,27], through ICN can be found in Table 2.

Both sets of ICN quality indicators were developed using RAND appropriateness methodology. Briefly, experts convene twice, before and after a meeting to rate importance of items derived from existing medical literature^[31]. Median scores are calculated and a final list is developed^[32]. Although reliability, feasibility and validity of indicators using the RAND appropriateness method have been established, improvement in the performance of

Table 2 ImproveCareNow quality indicators assessed in Crandall *et al*^[25,27] (of 19 total indicators developed)

Original set of quality indicators	Modified set of quality indicators	Results of quality improvement
Process: Diagnostic evaluation, disease phenotype, disease severity, body mass index including height and weight are all presented as separate measures under the domain titled: "Initial Diagnostic Evaluation"	Process: Assessing disease phenotype, disease severity, body mass index including height and weight were combined into a single "bundled" domain titled: Model classification	Increase in complete disease classification through the "bundled" measures: CD 38% ^b increase, UC 27% ^b increase
Outcome: Nutritional and growth status (those "at risk" with evaluation plans and those currently experiencing "failure" with treatment plans) are presented as separate domains	Outcome: Nutritional and growth status (those "at risk" and those currently experiencing "failure") are combined into the same domain, with no reference to further intervention plans based on the assessed status	Nutritional status: No changes in BMI z-scores for CD, however there was a 0.11 decrease in BMI z-score for UC ($P = 0.01$) Growth status did not change for CD and UC
Process: Treatment measures listed consist of measuring TPMT levels to ensure appropriate doses of thiopurine are prescribed	Process: Several other treatment quality indicators were included under the domain titled Treatment Measures which were not included in the original set such as anti-TNF therapy, skin test, screening for tuberculosis, appropriate infliximab and methotrexate dosage, among several others Outcome: Remission as an outcome measure was added (overall remission, prednisone free remission and sustained remission) The absence of prescribing prednisone was also an added outcome measure	Improved compliance with TPMT status assessment before prescribing thiopurines: CD 20% ^b increase, UC 23% increase Improvement in appropriate dose: CD 8% ^b increase, UC 41% ^b increase Only those with mild disease had significant changes to disease activity for CD and UC Remission rate (sPCDAI) increased 4% ($P < 0.0001$) Proportion with inactive disease improved: CD 13%, UC 11% Proportion who were not on prednisone increased by 4% for CD

^b $P < 0.01$. CD: Crohn's disease; UC: Ulcerative colitis; BMI: Body mass index; TPMT: thiopurine methyltransferase; TNF: Tumor necrosis factor; sPCDAI: Short pediatric Crohn's disease activity index.

the selected indicators do not necessarily correlate with improved outcomes^[33].

The typical indicator development process does not include a validation stage to ensure that the effects on outcomes are desirable. An alternative to the RAND appropriateness method incorporating a validation stage was proposed by Harris *et al*^[24] in the context of an alcohol addiction program. First, outcomes were collected and compared from pre- and post-treatment in a large sample of the target population. The goal of this stage was to determine whether implementing an effort to improve the completion of selected quality indicators would improve scores from baseline^[24]. A candidate set of quality indicators were selected from available literature, and association between selected indicators and outcomes were evaluated, using statistical methods and controlling for important confounding variables. As several predictors were tested for effects, true positives were maximized and false positives were minimized to avoid detection of spurious associations^[24]. Finally, those indicators which demonstrated the highest statistical correlation with outcomes were cross-validated with another subset of patients from the target population to determine whether the effect is sustained. Lastly, expert consultation was re-convened and indicators were re-evaluated^[24]. This approach may result in indicators that are more closely correlated with outcomes, thereby maximizing the cost-benefit ratio of implementing a formal quality improvement network.

Ideally process measures which indicate quality should be associated with both facility-level and patient-outcomes^[24]. Outcomes chosen by ICN as important

measures of success include remission rates (as measured by both PGA and PCDAI), nutritional status [measured by body mass index (BMI) z-score], linear growth velocity, and steroid-free treatment rates^[27]. Some of the indicators chosen would not directly correlate with these outcomes. For example, thiopurine methyltransferase (TPMT) genotype status would dictate safety of use of azathioprine or 6-mercaptopurine and risk of adverse events, but may not directly affect remission or growth velocity. In addition, completion of TPMT genotype is restricted to certain regions with some centers preferring TPMT phenotypic expression testing, and others preferring to monitor complete blood count and/or serum azathioprine metabolite levels. Therefore, TPMT genotype measurement may predict avoidance of serious adverse events, but may not be associated with either patient-level or facility-level outcomes^[34].

In summary, while ICN has successfully demonstrated improved documentation and compliance with select indicators, only modest benefits in patient outcomes have been achieved. Rigorous pilot work, with assessment and validation of correlation between indicators and outcomes could improve success. Elimination of indicators that are unassociated with outcomes would reduce the burden on participating centers and improve the cost benefit balance of a quality improvement network.

LESSONS LEARNED IN OTHER PEDIATRIC QUALITY IMPROVEMENT PROGRAMS

As the idea of quality improvement in health care has

become increasingly significant, several network collaboratives have been created with the overall goal of improving child health. A recent review by Billett *et al*^[35] highlighted five well-established and impactful regional and national pediatric quality improvement networks in the United States. The networks were in the fields of IBD (ICN), childhood asthma care, perinatal care, patient safety, and central line associated blood stream infection prevention in intensive care patients.

Although the review identified five examples of successful collaboratives, there are many other collaboratives in existence which have been able to demonstrate successes in their endeavors as well. The Canadian Neonatal Network (CNN) is a large network which includes upwards of 30 neonatal centers across Canada, with the goal of improving care in intensive care units, and therefore improving neonatal outcomes. Information on patients are collected in a database, which is then subsequently used to inform selection of indicators and to benchmark progress. Quality improvement is a priority of the CNN, as demonstrated by the creation of evidence-based practice for improving quality (EPIQ) cluster randomized controlled trial^[36]. EPIQ aimed to reduce nosocomial infections and bronchopulmonary dysplasia (BPD). Results demonstrated significantly reduced nosocomial infections and BPD in the quality improvement intervention group compared with control centers^[36]. In EPIQ, evidence based literature is used to inform the selection of quality indicators and information collected from the database is used to inform the use of the most appropriate indicators^[37]. Based on the EPIQ trial to assess the association between indicators and outcomes, the collaborative is now confident that these indicators can be used to determine high quality care in all centers involved in the CNN.

Another pediatric collaborative network aimed to improve the quality of care received by children with asthma presenting to emergency departments^[38]. Process and outcome quality indicators were chosen from an existing adult quality initiative, where associations between the selected process indicators and outcomes were observed^[39]. Unfortunately, preliminary results from the pediatric collaborative did not find an association between these process indicators and outcomes, indicating the importance of validation of indicators in the specific patient group to which they will be applied prior to their widespread application^[38].

Another quality improvement network in pediatric asthma based their quality improvement efforts on the chronic care model^[40,41]. Indicators were selected from existing guidelines, a pilot study was conducted to collect data before and after the intervention in cases and controls, and results of the pilot study were used to refine the processes used for quality improvement. After the rigorous initial process, the network was expanded to additional centers. Initial research from this network demonstrated significant improvement in the completion of processes, which resulted in improved outcomes^[41].

IBD practitioners and researchers are certainly not

the only specialists dealing with these issues in chronic inflammatory conditions. No fewer than four sets of quality indicators have been developed for arthritis care^[42-45], including one set for juvenile idiopathic arthritis^[43]. While quality improvement efforts are planned for arthritis care (including by the eumusc.net network), care providers also struggle with issues of measurement and validation^[46].

CONCLUSION

The increased availability of routinely-collected health data (including disease registries, electronic health records, and health administrative data) has resulted in a spotlight on unnecessary variability in the medical care of children with IBD. Quality improvement efforts have therefore never been more relevant, and reduction in negative outcomes in children with chronic diseases such as IBD could save healthcare costs and improve long-term quality of life for patients and families. While quality improvement programs in pediatric IBD are more advanced than those in other pediatric diseases, continually learning from the successes and limitations of networks such as ICN will allow for more rapid improvement in outcomes. The development and validation of quality indicators that are more strongly associated with outcomes will allow for more efficient implementation of quality improvement efforts, thereby reducing costs while improving the quality of life of children with IBD. We are at the beginning of a revolution in health care improvement, and we must therefore continuously learn from and improve upon the methods currently employed by our current quality improvement efforts.

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