Measuring Quality in Pediatric Endoscopy: *Are we there yet?*

Jenifer R. Lightdale, MD, MPH, FAAP
Division Chief, Gastroenterology
Chief Quality Officer
UMass Memorial
Children's Medical Center
Professor of Pediatrics
University of Massachusetts

Faculty Disclosures

- Mead-Johnson (Speaker Honorarium)
- Perrigo (Medical Advisory Board)
- Norgine (Consulting)
- ASGE (Editorial Honorarium)

Gastrointestinal Endoscopy

- Fundamental to the practice of pediatric gastroenterology
- Tremendous and proven value
  - Diagnosis
  - Treatment

Gastrointestinal Endoscopy

- Benefits are maximized if and when:
  - *Quality of procedure is assured*
  - *Performed optimally*
- Requires consensus around definitions
  - "Quality"
  - "Optimal"
- Involves metrics
  - Accurate
  - Meaningful
  - Practical

Bjorkman, 2006; Rex, 2006; Cotton, 2006; Lieberman, 2007

What is endoscopic quality?

- Difficult to measure *unless* it can be
  - Recognized
  - Defined
- Very likely it should assure *society at large*
  - Recommended and performed when appropriate (indicated)
  - Performed expeditiously, skillfully, successfully, safely and comfortably
  - High value (best quality for least cost)

Bjorkman, 2006; Rex, 2006; Cotton, 2006; Lieberman, 2007

IOM's 6 Domains of Quality

- Effective
- Patient-centered
- Safe
- Efficient
- Timely
- Equitable

Donabedien, JAMA, 1988; Blumenthal, NEJM, 1996; IOM, 2001

Elements of Endoscopic Quality

- Indicated
- Well prepared (informed) patients
- Minimizes risk
- Sedation plan
- Correct equipment
- Procedurally complete
- Reasonable duration
- Diagnostic
- Identifies abnormalities
- Appropriate tissue sampling
- Therapeutic (as appropriate)
- Maintains safety
- Ensures recovery
- Communication re: follow-up
- Pathology
- Accurate documentation/billing
- High value
- Positive patient feedback (satisfaction)

GiECAT$_{KIDS}$

- Gastrointestinal Endoscopy Competency Assessment Tool for pediatric colonoscopy (GiECAT$_{KIDS}$)
- Catharine M. Walsh, MD, PhEd
- Developed via Delphi method
  - >40 pediatric gastroenterologists from across North America
  - Heterogeneous group with broad expertise
  - 5 rounds of surveys (~76% participants all 5!)
- 3 main competency domains of colonoscopy in children
  - Technical (psychomotor skill)
  - Cognitive (knowledge)
  - Integrative (judgment, clinical reasoning)

Walsh, GIE, 2014; Walsh, 2014, JPGN; Walsh, JPGN, *in press (2014)*

Validation of GiECAT$_{KIDS}$

	Demographic Characteristic									
	Training Level % (n)		Hand dominance % (n)		Sex % (n)		Number of Years Performing Colonoscopy % (n)			
	GI Fellow	GI Attending	Right	Left	Male	Female	<1 year	1-5 years	6-10 years	> 10 years
Overall	82.1 (46)	17.9 (10)	91.1 (51)	8.9 (5)	41.1 (23)	58.9 (33)	46.4 (26)	35.7 (20)	7.1 (4)	10.7 (6)
Novice (25)	100.0 (25)	0	96.0 (24)	4.0 (1)	32.0 (8)	68.0 (17)	100.0 (25)	0	0	0
Intermediate (21)	100.0 (21)	0	90.5 (19)	9.5 (2)	42.9 (9)	57.1 (12)	4.8 (1)	5.2 (20)	0	0
Advanced (10)	0	100.0 (10)	80.0 (8)	20.0 (2)	60.0 (6)	40.0 (4)	0	0	40.0 (4)	66.0 (6)

Walsh, JPGN, *in press (2014)*

Components of GiECAT$_{KIDS}$ Score

- 18-item highly structured checklist (CL)
  - Outlines key steps required to complete the procedure
  - Modeled after validated CLs used in General Surgery
  - Scored dichotomously (1 = done correctly or 0 = not done/done incorrectly
  - Potential range of scores 0-18
- 7 domain Global Rating Scale (GRS)
  - Assesses holistic aspects of skill in terms of autonomy
  - Scored on a 5-point Likert scale
  - Higher scores reflective of better performance (more autonomy demonstrated) by the endoscopist
  - Potential range of scores 7-35

Walsh, GIE, 2014; Walsh, 2014, JPGN; Walsh, JPGN, *in press (2014)*

GiECAT$_{KIDS}$ GRS Likert Scale

1	Unable to achieve tasks despite significant verbal and/or hands-on guidance
2	Achieves some of the tasks but requires significant verbal and/or hands-on guidance
3	Achieves most of the tasks independently, with minimal verbal and/or manual guidance
4	Competent for independent performance of all tasks without the need for any guidance
5	Highly skilled advanced performance of all tasks

GiECAT$_{KIDS}$ Global Rating Scale

Global Rating Item	Definition	Competency Domain	Round 5 Mean (SD) (maximum score = 5)	Round 5 Consensus Level (% rating item ≥ 4)
1. Technical Skill	Demonstrates an ability to manipulate the endoscope using angulation control knobs, advancement/withdrawal, and torque steering for smooth navigation.	Technical	4.9 (0.56)	96.8%
2. Strategies for Scope Advancement	Demonstrates an ability to use insufflation, pull-back, suction, loop-reduction, external pressure and patient position change to advance the endoscope independently, expediently and safely.	Technical	4.7 (0.60)	93.6%
3. Visualization of Mucosa	Demonstrates and ability to maintain a clear luminal view required for safe scope navigation and complete mucosal evaluation.	Technical	4.8 (0.37)	100.0%
4. Independent Procedure Completion (Need for Assistance)	Demonstrates an ability to complete the procedure expediently and safely without verbal and/or manual guidance.	Technical	4.4 (0.61)	93.6%
5. Knowledge of Procedure	Demonstrates general procedural knowledge including procedural sequence, endoscopy techniques, equipment maintenance and trouble-shooting, indications and contraindications, and potential complications.	Cognitive	4.7 (0.60)	93.6%
6. Interpretation and Management of Findings	Demonstrates an ability to accurately identify, interpret and appropriately manage pathology and/or complications.	Integrative	4.7 (0.51)	96.8%
7. Patient Safety	Demonstrates an ability to perform the procedure in a manner that minimizes patient risk (atraumatic technique, minimal force, minimal red-out, recognition of personal and procedural limitations, safe sedation practices).	Technical and Integrative	4.9 (0.42)	96.8%

Walsh, 2014, JPGN

GiECAT$_{KIDS}$ Checklist Items (1=Y, 0=not done/N)

- Pre-procedure
  - Technical (1)
    - i.e. Item 5: Checks that equipment is functioning
  - Cognitive (n=3)
    - i.e. Item 1: Reviews and obtains patient history
  - Integrative (2)
    - i.e. Item 2:Takes action in response (i.e. SBE prophylaxis)
- Procedure
  - Technical (6); Cognitive (3); Integrative (3)
- Post-procedure
  - Intergrative (2)
    - I.e. Item 18: Education patient/caregivers about findings and makes follow-up plan

Reliability of GiECAT$_{KIDS}$ (Each Component and Total Score)

- Inter-item

Component of GiECAT$_{KIDS}$ Scale	$ICC_{1,1}$ single measure			$ICC_{1,1}$ average measure		
	ICC	95% CI	*p* Value	ICC	95% CI	*p* Value
Total GiECAT score	0.88	0.74-0.95	< 0.001	0.94	0.85-097	< 0.001
Global Rating Scale score	0.79	0.56-0.91	< 0.001	0.88	0.72-0.95	< 0.001
Checklist score	0.89	075-0.95	< 0.001	0.94	0.86-0.98	< 0.001

- Test-retest

Component of GiECAT$_{KIDS}$ Scale	$ICC_{2,1}$ single measure			$ICC_{2,1}$ average measure		
	ICC	95% CI	*p* Value	ICC	95% CI	*p* Value
Total GiECAT score	0.94	0.90-0.97	< 0.001	0.97	0.95-0.98	< 0.001
Global Rating Scale score	0.94	0.91-0.97	< 0.001	0.97	0.95-0.98	< 0.001
Checklist score	0.84	0.74-0.91	< 0.001	0.92	0.85-0.92	< 0.001

Walsh, JPGN, *in press (2014)*

Validity of GiECAT$_{KIDS}$ (Each component and Total Score)

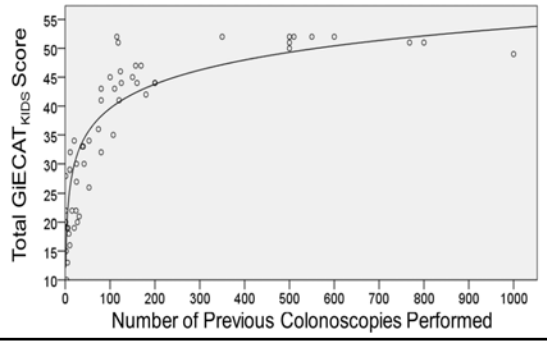
- Distinguishes novices vs. intermed vs. advanced

Component of GiECAT$_{KIDS}$ Scale	Score				Maximum possible score
	Novice	Intermediate	Advanced	*p Value**	
Total GiECAT score**	22.00 [10.50]	44.00 [7.00]	51.00 [2.25]	< 0.001	53
Global Rating Scale score**	14.00 [7.00]	27.00 [5.50]	34.00 [1.00]	< 0.001	35
Checklist score**	9.00 [4.00]	16.00 [2.50]	17.00 [2.00]	< 0.001	18

- Concurrent validity (p<.001 for each)

Component of GiECAT$_{KIDS}$ Scale	Correlation Coefficient			
	Number of previous colonoscopies	Cecal intubation rate	Terminal ileal intubation rate	Physician global assessment of skill
Total GiECAT score	0.91	0.82	0.82	0.95
Global Rating Scale score	0.92	0.85	0.82	0.94
Checklist score	0.84	0.77	0.80	0.89

GiECAT$_{KIDS}$ Scores vs. Procedural Experience



GiECAT$_{KIDS}$Summary To Date

- Rigorously developed metric of colonoscopy in the context of pediatric care
  - By and for MDs trained to be pediatric endoscopists
  - In children who require colonoscopy
- Rigorously validated (reliability, validity)
- Ready for "prime-time"
  - Training programs…!
  - Credentialing…?

Walsh, 2014, JPGN; Walsh, JPGN, *in press (2014)*

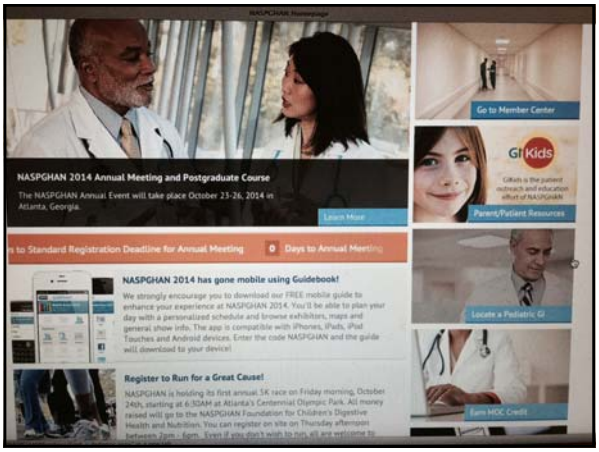
Other Quality Metrics for Pediatric Endoscopy

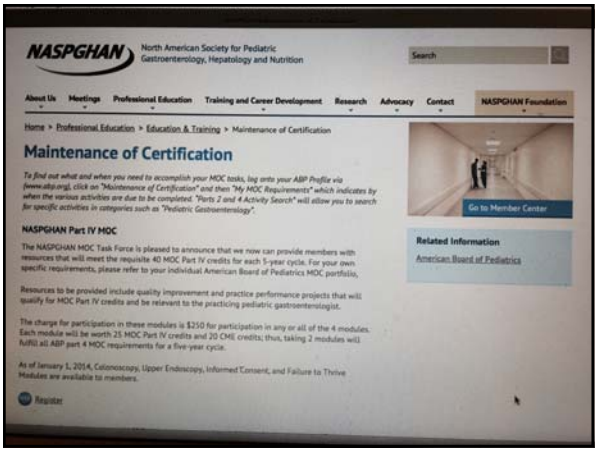
- NASPGHAN MOC Part IV "IQ=E" modules
  - Endoscopy Quality (25 points)
  - Colonoscopy Quality (25 points)
  - Informed Consent (25 points)
- Referenced
- Less well validated
- Practical
- Process oriented
- Involve universally important outcomes
- Can be tracked by reviewing documentation

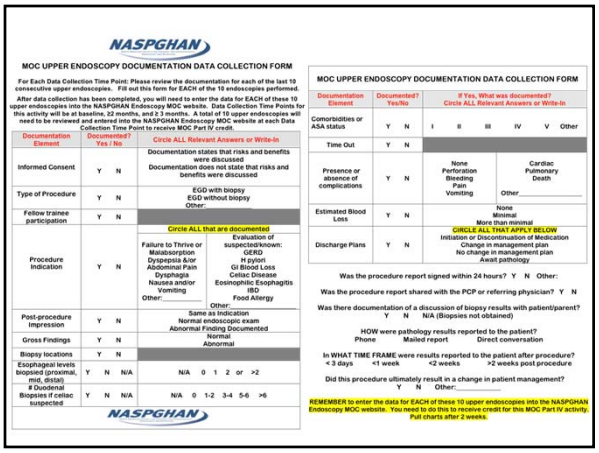
Quality of Endoscopy Documentation

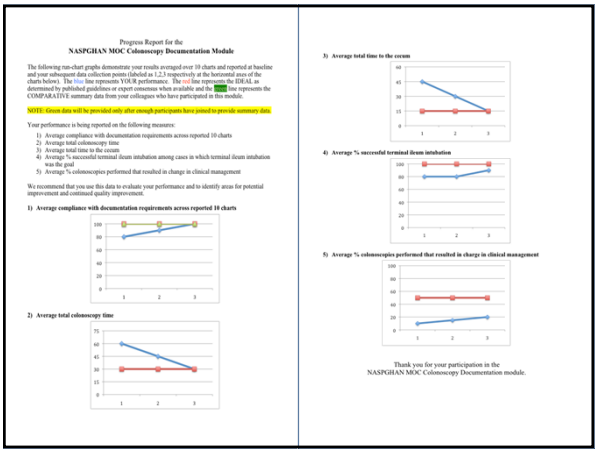
- Data shows tremendous variation in reporting among endoscopists
  - 438,000 procedures (2004-2006) from the Clinical Outcomes Research Initiative (CORI) *
- Data from pediatrics shows same pattern!
  - 21,800 pediatric procedures from PEDS-CORI network:**
  - Similar variation in documentation

*Lieberman, 2009; **Thakkar, 2013









IOM's 6 Domains of Quality

- **Effective**
- **Patient-centered**
- **Safe**
- **Efficient/high value**
- **Timely**
- **Equitable**

IOM's 6 Domains of Quality

- Effective
- **Patient-centered**
  - Did procedure change patient management?
- Safe
- Efficient/high value
- **Timely**
  - How long to communicate path results?
- Equitable

IQ=E and Measuring Quality

- 225 participants
  - Most of whom have completed at least the first of three required data entry steps
- Upper Endoscopy Module
  - N=81
- Colonoscopy Module
  - N=58

NASPGHAN
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

MOC Upper Endoscopy – Data Entry Period 1

1. Average compliance with procedural documentation requirements across reported 10 charts	84.2%
2. Average % of procedure reports shared with PCP or referring physician	63.8%
3. Average % documentation of discussion of biopsy results with patient/parent	90.4%
4. Average time frame for results to be reported to the patient/parent after the procedure	8.0 days
5.Average % upper endoscopies performed that resulted in change in clinical management	59.6%

Colonoscopy – Data Entry 1

1. Average compliance with documentation requirements across reported 10 charts	91.3%
2. Average total colonoscopy time	35.7 minutes
3. Average total time to the cecum	20.9 minutes
4. Average % successful terminal ileum intubation among cases in which terminal ileum intubation was the goal	91.8%
5. Average % colonoscopies performed that resulted in change in clinical management	68.0%

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Safety of Endoscopy in Children

- Pediatric endoscopy is inherently risky…
- Adverse events are rare
- Tracking AEs at the provider or institutional levels may not provide a *meaningful* measure of quality

- Peds-CORI data from >10,000 procedures*
  - Overall rate of complications 2.3%
  - Risks of hypoxia from sedation related events most common 1.5%
  - Risk of bleeding 0.3%

*Thakkar, 2007

Safety of Endoscopy in Children

- Characteristics of patients most at risk for complications during pediatric EGD*
  - Younger age
  - Higher ASA class
- Presence of a trainee may be more associated with complications*
- Performance of therapeutic manuevers

*Thakkar, 2007

Tracking Complications

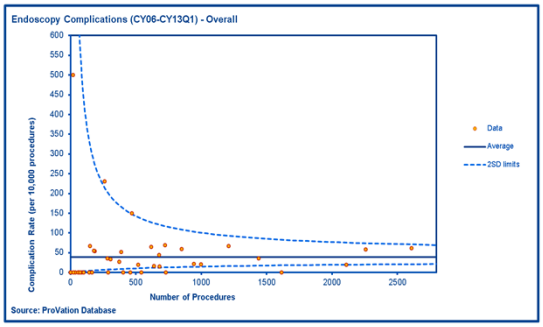
- Requires standardized definitions*
  - "Complications"
  - "Adverse events"
  - i.e. How much bleeding is an AE?
- Feasible
- Institutionally required
- Methodologies
  - Not standardized
  - Vary by institution

*Jacobson, GIE, 2011

Tracking Complications

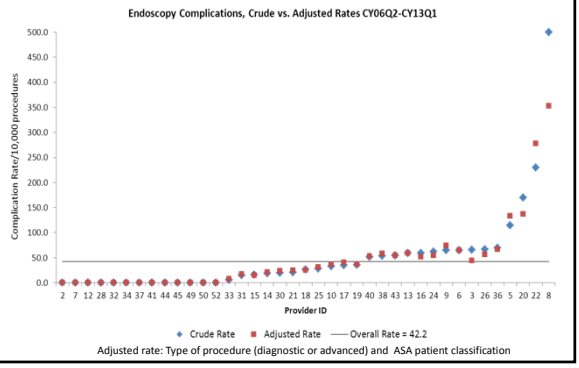
- BCH (ProVation Database)
  - Total # procedures – 24,004 (4/2006 – 2/2013)
  - Overall complication rate of 0.437%
- Possible to statistically estimate a crude and adjusted rate per 10,000 procedures/provider
  - Patient ASA status (complexity)
  - Procedure type (diagnostic vs. advanced)
- Funnel plot methodology
  - Upper control limit
  - Assumes common cause variation
  - Can be used to identify "special cause variation"

Tracking Complications



Unpublished data; N= 23,714 Complication Rate= 38.8/10,000 procedures

Complication Rates (Crude vs Adjusted)



Adjusted rate: Type of procedure (diagnostic or advanced) and ASA patient classification

Tracking Complications – Next Steps

- Refining and standardizing definitions
  - Complications, Adverse events
- Reducing provider variability
  - Definitions
  - Thresholds to report
- Standardizing methodologies
- Refining measures – crude vs. adjusted
  - What factors are most important to consider?
  - i.e. ASA, patient age, weight, fellow presence?

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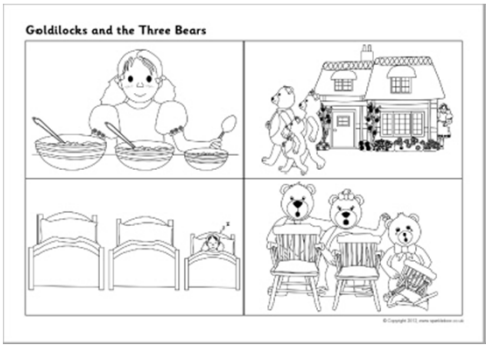
Measuring Efficiency and Value

- Increasing pressures to reduce costs of pediatric endoscopy
  - Proceduralist (me, you) is actually just a small part of costs
  - Anesthesia (OR time)
  - Pathology
- Reducing unnecessary and/or prolonged procedures may be very important
  - Exposure to anesthetics in children linked to neurotoxicity
  - PANDA U01 (Pediatric Anesthesia NeuroDevelopmental Assessment)*
  - "PACD" (Post-anesthesia cognitive dysfunction)

*Monteleone, 2014



Measuring Efficiency and Value

- Appropriateness of procedure performance
  - Indications (Underuse vs. Overuse)
  - Duration (Too long vs. too short)
  - Technical Skill
  - Completeness
  - Tissue Sampling (Underuse vs. Overuse)

Pediatric Endoscopy and Tissue Sampling

- Standard of care is to obtain biopsies in the absence of specific findings*
  - Different from adult endoscopy
- Risks of performing repeat endoscopy in pediatric populations
  - Considered to outweigh risks of obtaining biopsies
- Important to obtain biopsies *appropriately* when it is of value vs. Not to obtain them if unnecessary
  - May add cost

*Kori, 2002; Khakoo, 1999; Lightdale, 2013

Celiac Disease

- AGA recommends 4 to 6 proximal small bowel biopsies*
- May be additional value to bulb biopsies
  - Weir (2009)
  - Gastrointestinal Endoscopy (2010)
  - Gebrail (Abstract #174, NASPGHAN 2014)

*Rostrom, 2006; Weir 2009; Gebrail, 2014(AB)

Eosinophilic Esophagitis

- May be a patchy disease
- Requires biopsies for diagnosis
  - Pathologically defined by >15 Eos/HPF
- Increased sensitivity for diagnosis
  - 5 or more biopsies
  - Distal, mid, and proximal esophagus

*Liacouras, 2011

Normal Appearing Colonic Mucosa

- Likely to be normal on pathological examination
  - Especially in the absence of diarrhea or elevated sedimentation rate
- Reducing the number of biopsies obtained from normal-appearing colons
  - May not significantly affect diagnostic yield
  - May lower healthcare costs
  - May improve efficiency
- Future studies are needed to determine best protocols for routine sampling during pediatric colonoscopy

*Manfredi, 2014; Troendle, 2014AB

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Are we there yet?

- Depends upon the question
- Ar… …easuring?
- …
- …ure?
- Do …
- YES

Hell yeah!!!!

Some metrics more validated than others

Measuring Quality in Pediatric Endoscopy

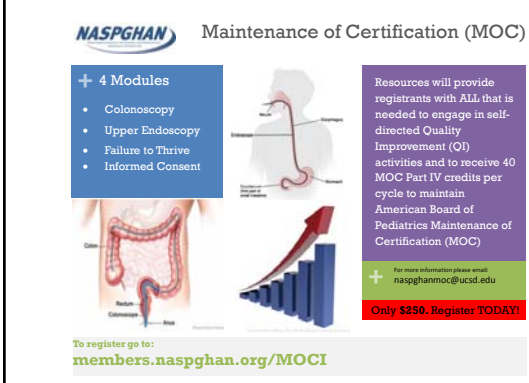
- Learned a lot from GiECAT$_{KIDS}$
  - Developing metrics
  - Validating them
- Should be employed by training programs
  - Provides standardized metrics

Are we there yet?

- GiECAT$_{KIDS}$ also confirms pediatric colonoscopy differs from colonoscopy in adults
  - Patient preparation
  - Sedation
  - Frequency with which TI intubation is desirable
  - Spectrum of therapeutic manipulations
- Performance of colonoscopy in children requires
  - Pediatric-specific medical knowledge
  - Pediatric-specific technical competency
  - **Pediatric-specific quality metrics

NASPGHAN MOC IQ=E

- Individual level
  - Offers ABP MOC credit
- Across NASPGHAN and greater field of pediatric endoscopy
  - May help to better establish and refine metrics
  - Comparators
  - Benchmarks



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