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Methodological Quality of National Guidelines for Pediatric Inpatient Conditions

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Abstract

Background—Guidelines help inform standardization of care for quality improvement (QI). The Pediatric Research in Inpatient Settings (PRIS) network published a prioritization list of inpatient conditions with high prevalence, cost, and variation in resource utilization across children's hospitals. The methodological quality of guidelines for priority conditions is unknown.

Objective—To rate the methodological quality of national guidelines for 20 priority pediatric inpatient conditions.

Design—We searched sources including PubMed for national guidelines published 2002–2012. Guidelines specific to one organism, test or treatment, or institution were excluded. Guidelines were rated by two raters using a validated tool (AGREE II) with an overall rating on a 7-point scale (7–highest). Inter-rater reliability was measured with a weighted kappa coefficient.

Results—17 guidelines met inclusion criteria for 13 conditions, 7 conditions yielded no relevant national guidelines. The highest methodological quality guidelines were for asthma, tonsillectomy, and bronchiolitis (mean overall rating 7, 6.5 and 6.5 respectively); the lowest were for sickle cell disease (2 guidelines) and dental caries (mean overall rating 4, 3.5, and 3 respectively). The overall weighted kappa was 0.83 (95% confidence interval 0.78–0.87).

Conclusions—We identified a group of moderate to high methodological quality national guidelines for priority pediatric inpatient conditions. Hospitals should consider these guidelines to inform QI initiatives.

Keywords

children; clinical guideline; prioritization; quality improvement

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Background

Researchers from the Pediatric Research in Inpatient Settings (PRIS) network, an open pediatric hospitalist research network,¹ have identified inpatient pediatric medical and surgical conditions considered high priority for quality improvement (QI) initiatives and/or comparative effectiveness research based on prevalence, cost, and inter-hospital variation in resource utilization.² One approach for improving the quality of care within hospitals is to operationalize evidence-based guidelines into practice.³ While guidelines may be used by individual clinicians, systematic adoption by hospitals into clinical workflow has potential to influence providers to adhere to evidence-based care, reduce unwarranted variation, and ultimately improve patient outcomes.^{3–6}

There are critical appraisal tools to measure the methodological quality as defined by the IOM and others, in guidelines.^{7–12} One such validated tool is the AGREE II instrument, created by the AGREE (Appraisal of Guidelines for REsearch and Evaluation) collaboration.^{13,14} It defines methodological quality as “the confidence that the biases linked to the rigor of development, presentation, and applicability of a clinical practice guideline have been minimized and that each step of the development process is clearly reported.”¹³

The objective of our study was to rate the methodological quality of national guidelines for twenty of the PRIS priority pediatric inpatient conditions.² Our intent in pursuing this project was two-fold: first, to inform pediatric inpatient QI initiatives and second, to call out priority pediatric inpatient conditions for which high methodological quality guidelines are currently lacking.

Methods

The study methods involved (1) prioritizing pediatric inpatient conditions (2) identifying national guidelines for the priority conditions and (3) rating the methodological quality of available guidelines. This study was considered non-human subject research¹⁵ and the original prioritization study was deemed exempt from review by the Institutional Review Board of the Children’s Hospital of Philadelphia under 45 CFR 46.102(f).²

Prioritizing pediatric inpatient conditions

Methods for developing the prioritization list are published elsewhere in detail and briefly described here.¹ An *International Classification of Diseases, Ninth Revision, Clinical Modification*, based clinical condition grouper was created for primary discharge diagnosis codes for inpatient, ambulatory surgery, and observation unit encounters accounting for either 80% of all encounters or 80% of all charges for over 3.4 million discharges 2004–2009 for 38 children’s hospitals in the Pediatric Health Information Systems (PHIS) database, which includes administrative and billing data.¹⁶ A standardized cost master index was created to assign the same unit cost for each billable item (calculated as the median of median hospital unit costs) in order to allow for comparisons of resource utilization across hospitals (e.g. the cost of chest x-ray was set to be the same across all hospitals in 2009 dollars). Total hospital costs were then recalculated for every admission by multiplying the

standardized cost master index by the number of units for each item in the hospital bill and then summing the standardized costs of each line item in every bill. Conditions were ranked based on prevalence and total cost across all hospitals in the study period. The variation in standardized costs across hospitals for each condition was determined.

For the current study, conditions were considered if they had a top 20 prevalence rank, a top 20 cost rank, high variation (intra-class correlation coefficient (ICC) > 0.1) in standardized costs across hospitals, a minimum number of PHIS hospitals with annualized over-expenditures (using the standardized cost master) of at least \$50,000 when compared to the mean, or a minimum median of 200 cases per hospital over the 6 year study period to assure sufficient hospital volume for future interventions. This resulted in 29 conditions; the selected 20 conditions matched the top 20 prevalence rank (see supplemental table online).²

Identifying National Guidelines

We developed a search protocol (available in online supplementary materials) using condition-specific keywords and the following criteria; guideline, pediatric, 2002–2012. A medical librarian (EE) used the protocol to search PubMed, National Guidelines Clearing House, and the American Academy of Pediatrics website for guidelines for the 20 selected conditions.

We limited our study to US national guidelines published or updated 2002–2012 to be most relevant to the 38 US children's hospitals in the original study. Guidelines had to address either 'medical' or 'surgical' or both types of inpatient management for the condition depending on how the condition was categorized on the PRIS prioritization list. For example, to target inpatient issues otitis media was treated as a 'surgical' condition when the prioritization list was created, thus guidelines included in our study needed to address surgical management (i.e. myringotomy or tympanostomy tubes).² Guidelines specific to one organism, test or treatment were *a priori* excluded, as they would not map well to the prioritization list, and would be difficult to interpret. Guidelines focusing exclusively on condition prevention were also excluded. Guidelines with a broad subject matter (e.g. 'abdominal infection') or unclear age inclusion were included if they contained a significant focus on the condition of interest (e.g. appendicitis without peritonitis) such that the course of pediatric inpatient care was described for that condition. Retracted or outdated (superseded by a more current version) guidelines were excluded.

An investigator (GH) reviewed potentially relevant results from the librarian's search. For example, the search for "tonsillectomy" guidelines retrieved a guideline on the use of polysomnography prior to tonsillectomy in children but did not cover the inpatient management or tonsillectomy procedure.¹⁷ This guideline was excluded from our study as it focused on one specific test and did not discuss surgical management of the condition.

Rating Methodological Quality of Guidelines

Methodological quality of guidelines was rated with the AGREE II tool by two investigators (GH and KN).^{13,18} This tool has two overall guideline assessments and 23 subcomponents within 6 domains reflecting many of the IOMs recommendations for methodological quality

in guidelines: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence.^{8,18}

The AGREE II tool rates each of the 23 subcomponent questions using a 7-point scale (1–strongly disagree to 7–strongly agree). We followed the AGREE II User’s Manual suggestion in rating subcomponents “1” indicating an absence of information for that question if the question was not addressed within the guideline.¹³ The AGREE II User’s Manual describes the option of creating standardized domain scores, however as the objective of our study was to assess the overall methodological quality of the guideline and not to highlight particular areas of strengths/weaknesses in the domains, we elected to present raw scores only.¹³

For the overall guideline rating item 1 (“Rate the overall quality of this guideline.”) the AGREE II tool instructs that a score of 1 indicates “lowest possible quality” and 7 indicates “highest possible quality”.¹³ As these score anchors are far apart with no guide for interpretation of intermediate results we modified the descriptive terms on the tool to define scores < 3 as “low quality,” scores 3–5 as “moderate quality,” and scores > 5 as “high quality” in order to allow for easier interpretation of our results. We also modified the final overall recommendation score (on a 3-point scale) from “I would recommend this guideline for use” to “I would recommend this guideline for use in the pediatric inpatient setting.”^{13,18} A score of 1 indicated to not recommend, 2 indicated to recommend with modifications and 3 indicated to recommend without modification.

Significant discrepancies (> 2 point difference on overall rating) between the two raters were to be settled by consensus scoring by three senior investigators blinded to previous reviews, using a modified Delphi technique.¹⁹

Inter-rater reliability was measured using a weighted kappa coefficient, and reported using a bootstrapped method with 95% confidence intervals. Interpretation of kappa is such that 0 is the amount of agreement that would be expected by chance, and 1 is perfect agreement, with previous researchers stating scores >0.81 indicate “almost perfect” agreement.²⁰

Results

The librarian’s search retrieved 2,869 potential results, see figure 1. Seventeen guidelines met inclusion criteria for 13 of the 20 priority conditions. Seven conditions did not have national guidelines meeting inclusion criteria. Table 1 displays the 20 medical and surgical conditions on the modified PRIS prioritization list, including overall guideline scoring, recommendation scores, and kappa results for each guideline. The highest methodological quality guidelines were for asthma,²¹ tonsillectomy,²² and bronchiolitis²³ (mean overall rating 7, 6.5 and 6.5 respectively). The lowest methodological quality guidelines were for two sickle cell disease guidelines^{24,25} and one dental caries guideline²⁶ (mean overall rating 4, 3.5, 3 respectively). Seven guidelines were rated as high overall quality, 10 guidelines were rated as moderate overall quality. Eight of the 17 guidelines^{21–23,27–31} were recommended for use in the pediatric inpatient setting without modification by both

reviewers. Two guidelines (for dental caries²⁶ and sickle cell²⁴) were not recommended for use by one reviewer.

As an example of scoring, a national guideline for asthma had high overall scores (7 from each reviewer) and high scores across most AGREE II subcomponents. The guideline was found by both reviewers to be systematic in describing guideline development with clearly stated recommendations linked to the available evidence (including strengths and limitations) and implementation considerations.²¹ Conversely, a national guideline for sickle cell disease had moderate overall scores (3, 4) and low-moderate scores across the majority of the subcomponent items.²⁴ The reviewers believe that this guideline would have been strengthened by increased transparency in guideline development, discussion of the evidence surrounding recommendations and discussion of implementation factors. A table with detailed scoring of each guideline is available in online supplementary materials.

Agreement between the two raters was ‘almost perfect’²⁰ with an overall boot-strapped weighted kappa of 0.83 (95% confidence interval 0.78–0.87) across 850 scores. There were no discrepancies between reviewers in overall scoring requiring consensus scoring.

Discussion

Using a modified version of a published prioritization list for inpatient pediatric conditions, we found national guidelines for 13 of 20 conditions with high prevalence, cost and inter-hospital variation in resource utilization. Seven conditions had no national guidelines published within the past 10 years applicable for use in the pediatric inpatient setting. Of 17 guidelines for 13 conditions, 10 had moderate and 7 high methodological quality.

Our findings add to literature describing methodological quality of guidelines. Many publications focus on the methodological quality of guidelines as a group and use a standardized instrument (e.g. AGREE II tool) to rate within domains (e.g. Domain 1-Scope and Purpose) across guidelines in efforts to encourage improvement in developing and reporting in guidelines.^{32,33} Our study differs in that we chose to focus on the overall quality rating of individual guidelines for specific prioritized conditions in order to allow hospitals to guide QI initiatives. One study that had a similar aim to ours surveyed Dutch pediatricians to select priority conditions and used the AGREE II tool to rate 17 guidelines, recommending 14 for use in the Netherlands.³⁴

Identifying high methodological quality guidelines is only one in a series of steps prior to successful guideline implementation in hospitals. Other aspects of guidelines including the strength of the evidence (e.g. from randomized controlled trials) and subsequent force and clarity (e.g. use of ‘must’ instead of ‘consider’) of recommendations may affect clinician or patient adherence, work processes, and ultimately patient outcomes. Strong evidence should translate into forceful and clear recommendations. Authors with the Yale Guideline Recommendation Corpus describe significant variation in reporting of guideline recommendations and further studies have shown that the force and clarity of a recommendation is associated with adherence rates.^{35–38} Unfortunately, current guideline

appraisal tools lack the means to score the strength of evidence and force and clarity of recommendations.¹⁰

Implementation science demonstrates that there are many important factors in translating best practice into improvements in clinical care. In addition to implementation considerations such as adherence, patient preferences and work processes; variability in methodological quality, strength of evidence, and force and clarity of recommendations may be additional reasons why evidence for the impact of guidelines on patient outcomes remains mixed in the literature.³⁹ One recent study found that adherence to antibiotics recommended within a national pediatric community-acquired pneumonia guideline, which had a high methodological quality score in our study, did not change hospital length of stay or readmissions.^{30,40} There are several possible interpretations for this. Recommendations may not have been based upon strong evidence, research methodology assessing how adherence to recommendations impacts patient outcomes may have been limited, or the outcomes measured in current studies (such as readmission) are not the outcomes that may be improved by adherence to these recommendations (such as decreasing antimicrobial resistance). These are important considerations when hospitals are incorporating recommendations from guidelines into practice. Hospitals should assess the multiple aspects of guidelines, including methodological quality (which our study helps to identify), strength of evidence and force and clarity of recommendations, as well as adherence, patient preferences, work processes and key outcome measures when implementing guidelines into clinical practice. A study utilizing a robust QI methodology demonstrated that clinician adherence to several elements in an asthma guideline, which also had a high methodological quality score in our study, led to a significant decrease in 6-month hospital and emergency department readmission for asthma.^{6,21}

Our study also highlights that several pediatric conditions with high prevalence, cost, and inter-hospital resource utilization variation lack recent national pediatric guidelines applicable to the inpatient setting. If strong evidence exists for these priority conditions, professional societies should create high methodological quality guidelines with strong and clear recommendations. If evidence is lacking for these priority conditions then investigators should focus on generating research in these areas.

There are several limitations to this study. The AGREE II tool does not have a mechanism to measure the strength of evidence used in a guideline. Methodological quality of a guideline alone may not translate into improved outcomes. Conditions may have national guidelines published before 2002, institution-specific or international guidelines, or adult guidelines that might be amenable to use in the pediatric inpatient setting but were not included in this study. Several conditions on the prioritization list are broad in nature (e.g. “dehydration”) and may not be amenable to the creation of guidelines. Other conditions on the prioritization list (e.g. chemotherapy or cellulitis) may have useful guidelines within the context of specific conditions (e.g. acute lymphoblastic leukemia) or for specific organisms (e.g. methicillin resistant staph aureus). We elected to exclude these narrower guidelines in order to focus on broad and comprehensive guidelines applicable to a wider range of clinical situations. Additionally, while use of a validated tool attempts to objectively guide ratings, the rating of ‘quality’ is to some degree subjective. Finally, our study used a previously

published prioritization list using data from children's hospitals and the list likely underrepresents conditions commonly managed in community hospitals (e.g. hyperbilirubinemia).² Exclusion of these conditions was not reflective of importance or quality of available national guidelines.

Conclusions

Our study adds to recent publications on the need to prioritize conditions for QI in children's hospitals. We identified a group of moderate to high methodological quality national guidelines for pediatric inpatient conditions with high prevalence, cost and variation in inter-hospital resource utilization. Not all prioritized conditions have high methodological quality national guidelines available. Hospitals should prioritize conditions with high methodological quality guidelines to allocate resources for QI initiatives. Professional societies should focus efforts on producing methodologically sound guidelines for prioritized conditions currently lacking high quality guidelines if sufficient evidence exists.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

AGREE	Appraisal of Guidelines for REsearch and Evaluation
ICC	intra-class correlation coefficient
IOM	Institute of Medicine
PHIS	Pediatric Health Information System
PRIS	Pediatric Research in Inpatient Settings
QI	Quality Improvement
US	United States

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Figure 1.
Condition-specific guideline search results

*Conditions may have been excluded for more than one reason

Table 1

Overall methodological quality ratings of guidelines for the Pediatric Research in Inpatient Settings (PRIS) Network 20 Priority conditions with high prevalence, cost and variability in resource utilization.

Condition by PRIS priority rank {m=medical, s=surgical}	Guidelines Meeting Inclusion Criteria/	Guidelines Citation	Mean overall reviewer methodological quality rating ² (rater 1, rater 2)	Recommended for use in the pediatric inpatient setting ³ Mean (rater 1, rater 2)	Weighted kappa (95% confidence interval)
Otitis Media, Unspecified {s}	1	'American Academy of Family Physicians Clinical Practice Guideline: Otitis Media with Effusion', (May 03, 2004).	6 (6, 6)	3 (3, 3)	0.76 (0.49–0.93)
Hypertrophy Of Tonsils And Adenoids {s}	1	R. F. Baugh et al.: 'Clinical Practice Guideline: Tonsillectomy in Children', <i>Otolaryngol Head Neck Surg.</i> 144 (2011), S1–30.	6.5 (7, 6)	3 (3, 3)	0.49 (0.05 – 0.81)
Asthma {m}	1	'Expert Panel Report 3 (Epr-3): Guidelines for the Diagnosis and Management of Asthma-Summary Report 2007', <i>J Allergy Clin Immunol</i> , 120 (2007), S94–138. [NHLBI GUIDELINE]	7 (7, 7)	3 (3, 3)	0.62 (0.21 – 0.87)
Bronchiolitis {m}	1	Diagnosis American Academy of Pediatrics Subcommittee on, and Bronchiolitis Management of, 'Diagnosis and Management of Bronchiolitis', <i>Pediatrics</i> , 118 (2006), 1774–93.	6.5 (6, 7)	3 (3, 3)	0.95 (0.87 – 1.00)
Pneumonia {m}	1	J. S. Bradley et al. The Management of Community-Acquired Pneumonia in Infants and Children Older Than 3 Months of Age: Clinical Practice Guidelines by the Pediatric Infectious Diseases Society and the Infectious Diseases Society of America', <i>Clin Infect Dis</i> , 53 (2011), e25–76.	6 (6, 6)	3 (3, 3)	0.82 (0.64 – 0.96)
Dental Caries {s}	1	'Guideline on Pulp Therapy for Primary and Young Permanent Teeth', <i>Pediatr Dent</i> , 30 (2008), 170–4.	3 (3, 3)	1.5 (1,2)	0.51 (0.14 – 0.83)
Chemotherapy {m}	0				
Cellulitis {m}	1	D. L. Stevens et al. 'Practice Guidelines for the Diagnosis and Management of Skin and Soft-Tissue Infections', <i>Clin Infect Dis</i> , 41 (2005), 1373–406.	4.5 (4, 5)	2.5 (2,3)	0.52 (0.15 – 0.79)
Inguinal Hernia {s}	0				
Gastroesophageal Reflux And Esophagitis {m,s}	2	Y. Vandenplas, et al. 'Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of NASPGHAN and ESPGHAN', <i>J Pediatr Gastroenterol Nutr</i> , 49 (2009), 498–547. G. T. Furuta et al. 'Eosinophilic Esophagitis in Children and Adults: A Systematic Review and Consensus Recommendations for Diagnosis and Treatment', <i>Gastroenterology</i> , 133 (2007), 1342–63.	5 (5, 5) 5 (5, 5)	3 (3, 3) 2.5 (2, 3)	0.69 (0.45 – 0.87) 0.93 (0.85 – 0.98)
Dehydration {m}	0				
Redundant Prepuce And Phimosis {s}	1	Circumcision Task Force On, 'Male Circumcision', <i>Pediatrics</i> , 130 (2012), e756–85.	6 (6, 6)	3 (3, 3)	0.66 (0.25 – 0.89)

Condition by PRIS priority rank {m=medical, s=surgical}	Guidelines Meeting Inclusion Criteria ¹	Guidelines Citation	Mean overall reviewer methodological quality rating ² (rater 1, rater 2)	Recommended for use in the pediatric inpatient setting? ³ Mean (rater 1, rater 2)	Weighted kappa (95% confidence interval)
Abdominal Pain {m}	0				
Other Convulsions {m}	0				
Urinary Tract Infection {m}	1	K. B. Roberts et al. 'Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial Uti in Febrile Infants and Children 2 to 24 Months', <i>Pediatrics</i> , 128 (2011), 595–610.	5.5 (5, 6)	2.5 (2, 3)	0.62 (0.23 – 0.84)
Acute Appendicitis Without Peritonitis {s}	1	J. S. Solomkin et al. 'Diagnosis and Management of Complicated Intra-Abdominal Infection in Adults and Children: Guidelines by the Surgical Infection Society and the Infectious Diseases Society of America', <i>Clin Infect Dis</i> , 50 (2010), 133–64.	4.5 (5, 4)	2.5 (3, 2)	0.37 (–0.11 – 0.81)
Eso- Exo- Hetero- And Hyper-Tropia {s}	0				
Fever {m}	0				
Seizures W And W/O Intractable Epilepsy {m}	3	G. M. Brophy et al. and Committee Neurocritical Care Society Status Epilepticus Guideline Writing, 'Guidelines for the Evaluation and Management of Status Epilepticus', <i>Neurocrit Care</i> , 17 (2012), 3–23. D. Hirtz et al. 'Practice Parameter: Treatment of the Child with a First Unprovoked Seizure: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society', <i>Neurology</i> , 60 (2003), 166–75. J. J. Rivello Jr et al. 'Practice Parameter: Diagnostic Assessment of the Child with Status Epilepticus (an Evidence-Based Review): Report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society', <i>Neurology</i> , 67 (2006), 1542–50.	5 (5, 5) 5 (5, 5) 5 (4, 6)	3 (3, 3) 2.5 (2, 3) 2.5 (2, 3)	0.95 (0.87 – 0.99) 0.73 (0.41 – 0.94) 0.80 (0.63 – 0.94)
Sickle Cell Disease With Crisis {m}	2	'Health Supervision for Children with Sickle Cell Disease', <i>Pediatrics</i> , 109 (2002), 526–35. Lung National Heart, and Blood Institute, 'Management and Therapy of Sickle Cell Disease. National Institutes of Health', <i>In press</i> (2002).	3.5 (3, 4) 4 (4, 4)	1.5 (1, 2) 2.5 (2, 3)	0.92 (0.80 – 0.98) 0.91 (0.80 – 0.97)

¹ Inclusion criteria include: national guideline published 2002–2012, describing pediatric inpatient medical or surgical management for given condition. Guidelines specific to one organism, test or treatment or condition prevention alone were excluded.

² Overall methodological quality rating on the AGREE II instrument, using a 7-point scale; 1=lowest, 7=highest.

³ Recommended for use scoring on a 3-point scale: 1= not recommended, 2= recommended with modifications, 3= recommended