MEASURES OF PEDIATRIC HEALTH CARE QUALITY BASED ON HOSPITAL ADMINISTRATIVE DATA

THE PEDIATRIC QUALITY INDICATORS

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Orientation to the Report

This report documents the work undertaken in Phase I of a two-phase process to develop the Pediatric Quality Indicators as part of the Agency for Healthcare Research and Quality (AHRQ) contract, "Support for Quality Indicators II" under subcontract with Battelle Memorial Institute by Stanford University and the University of California at Davis. This work was initiated in response to a charge to develop indicators of children's health care utilizing inpatient administrative data. These indicators examine both the quality of inpatient care, as well as the quality of outpatient care that can be inferred from inpatient data, such as potentially preventable hospitalizations.

The report contains three main sections:

1. The introduction section launches the actual technical report and provides background regarding pediatric indicator development and the current effort to develop an indicator set based on administrative data.

2. The methods section outlines the approach used to gather evidence to identify and evaluate potential patient safety indicators, including the literature review, empirical analyses, and clinician panel review, as well as the operationalization of indicators and evaluation of risk adjustment approaches.

3. The results section is divided into two parts. The first part highlights general themes and summarizes the overall results. The second part provides detailed results for each AHRQ QI examined.

Several appendixes provide additional detail regarding methods and results.

Introduction

Background

The demand for information on quality in healthcare has risen sharply over the past several years. In response to this demand, the Healthcare Cost and Utilization Project (HCUP) Quality Indicators (QIs) were developed at the Agency for Healthcare Research and Quality (AHRQ) in 1994. The 33 initial indicators, based on inpatient hospitalization data, were designed to highlight quality concerns and to target areas for further analysis.

From 1998 to 2002, Stanford University and the University of California (UC), under contract with AHRQ, reviewed the HCUP quality indicators and recommended revised and new indicator sets. The indicators, named the AHRQ Quality Indicators (AHRQ QIs), are divided into three indicator sets: the Inpatient Quality Indicators, the Prevention Quality Indicators and the Patient Safety Indicators.

The Inpatient Quality Indicators (IQI) and Prevention Quality Indicators (PQI) were developed together, and include all mortality indicators and potentially preventable admission indicators. Much of the scientific evidence for these indicators is based on reports in the peer reviewed literature. Structured literature review and empirical analyses were used to establish the validity of these indicator sets. Details regarding the development process are presented in the publication "Refinement of the HCUP Quality Indicators" available at www.qualityindicators.ahrq.gov.

The Patient Safety Indicators (PSIs) provide rates for potentially preventable complications of care. Building from a base of indicators reported in the literature (e.g., the Complications Screening Program developed by Lisa Iezzoni and colleagues), indicators developed internally at AHRQ, and a detailed review of the ICD-9-CM code book, the Stanford-UC project team aimed to identify a set of patient safety related indicators. Given the relative lack of literature outlining or validating such indicators, a structured clinical review process was developed and conducted to refine indicator definitions and establish face validity. Clinical panelists were nominated by professional organizations for the review, and consisted of generalist, specialist, and subspecialist physicians, nurses, and midwives. A few indicators required additional input from surgical subspecialties, and as a result underwent a second review. Details regarding the development of the PSIs are presented in the publication, "Measures of Patient Safety Based on Administrative Data: The Patient Safety Indicators" available at www.qualityindicators.ahrq.gov.

Pediatric Quality Indicator Development

In 2000, children accounted for 18 percent or 6.3 million of the hospitalizations in the U.S. The vast majority of these stays were for newborn infants, with children and adolescents (one to 17 years old) accounting for 1.8 million of the hospital stays (5%).[1]

There are few measure sets exclusively designed to measure quality of care for children, and none for hospital care.[2] Recently, AHRQ has responded to the need for research on potential indicators of pediatric hospital quality by commissioning this project to focus on children's health care quality using routinely collected hospital discharge data as the basis for indicator specification.

Development of quality indicators for the pediatric population involves many of the same challenges associated with the development of quality indicators for the adult population. These challenges include the need to carefully define indicators using administrative data, establish validity and reliability, detect bias and design appropriate risk adjustment, and overcome challenges of implementation and use. However, the special population of children invokes additional, special challenges.

A draft briefing paper, presented at the recent National Quality Forum (NQF) meeting on pediatric quality indicators[3], outlined these challenges as the four 'Ds':

Differential epidemiology of child healthcare relative to adult healthcare **–** In general, children are a relatively healthy population. Except for a subpopulation of children with special healthcare needs, children seldom have multiple concurrent illnesses and have relatively few encounters with the healthcare system. Many encounters children have are for preventive care in an outpatient setting, and most children are rarely hospitalized. Therefore, some may suggest that hospital-based indicators are of limited importance to measuring the overall quality of children's healthcare. Advocates of this view may prefer population-based measures of outpatient care, focusing on the appropriate delivery of preventive care (e.g., immunizations) or outpatient care for chronic diseases (e.g., asthma) or common childhood illnesses (e.g., viral respiratory infections). However, as user requests to the AHRQ QI support service illustrate, hospitals that care for children still need measures for quality improvement purposes, just as others may need such measures for consumer education and informed purchasing.

Dependency **–** A second challenge in children's healthcare is their dependency on parents and other adults for financing, accessing, receiving, and evaluating their care. Many aspects of healthcare from clinical decision-making to patient instructions to actual care delivery depend on involvement by an adult caregiver, as well as the patient (i.e. the child). Evaluating care may further depend on children's caregivers to submit accurate information in a timely manner.

Demographics **–** Children are a diverse group, ranging from premature neonates to adolescents. Children are more likely to live in poverty than adults (resulting in higher dependence on Medicaid), and are more likely than persons in any other age group to belong to a racial or ethnic minority group. Adolescents, along with young adults, are less likely to have health insurance than older adults. Delivering healthcare and evaluating the quality of that care is especially challenging for such a diverse and hard-to-reach population.

Development – Children are in a constant state of physical, emotional and cognitive development. A child's physical and mental health depends on the success of all of these developmental processes. Thus, quality indicators appropriate for one age group may be inappropriate for another. Different measures may be needed for each age group (e.g., neonates, young children, older children, adolescents).

Since these four factors can pervade all aspects of children's healthcare, simply applying adult indicators to younger age ranges is insufficient. For example, many quality indicators dealing with common chronic diseases in adults simply do not apply to children, whereas other indicators derived from the adult setting require careful consideration of their validity due to different causative factors in the pediatric population. Others require modified definitions due to different coding practices for children. Therefore, the development of the Ped QI module requires careful consideration of each of these factors.

Methods

General Approach to Pediatric Indicator Development

The development of the AHRQ Pediatric Quality Indicators utilizes a four pronged approach: identification of candidate indicators, literature review, empirical analyses, and panel review. Candidate indicators were identified through both published literature and a brief survey of national organizations. Literature review provided descriptions and evaluations of some candidate indicators and the underlying relationship to quality of care. Empirical analyses were conducted to explore alternative definitions; to assess nationwide rates and hospital variation; and to develop appropriate methods to account for variation in risk. Clinical panel review helped to refine indicator definitions and risk groupings, and to establish face validity in light of the limited evidence from the literature for most pediatric indicators. Information from these sources was used to specify indicator definitions and make recommendations to AHRQ regarding the best indicators for inclusion in the pediatric indicator set.

Phase I versus Phase II

The development of the Ped QI module is expected to occur in two phases. Phase I, documented in this report, evaluated current AHRQ QIs and their potential adaptation to the pediatric population. Phase II of the pediatric indicator development will examine novel indicators (i.e., not part of the current AHRQ QI set) and any AHRQ QIs that require extensive re-definition and clinical input.

Identification of potential indicators

Current AHRQ Quality Indicators were reviewed for applicability to the pediatric population, including both hospital-level indicators of inpatient care and area-level indicators of access to quality outpatient care (utilizing inpatient admission data). Not all current indicators were considered for inclusion in the pediatric indicator set. Indicators that address chronic or acute diseases that primarily affect the adult population (e.g. COPD, CHF, AMI), or are clinically different in children (e.g., hip fracture), were eliminated. A few other indicators were eliminated due to early concerns about validity in the pediatric population, based on users' chart reviews and validation projects (e.g. Complications of Anesthesia, Failure to Rescue, Death in Low Mortality DRGs).[4] See Table 1 for a list of indicators that were not considered for adaptation to the pediatric population.

Table 1. Current AHRQ QIs not considered for inclusion in pediatric patients

Reason for exclusion	Indicator
Primarily adult diseases	**Inpatient Quality Indicators:** • Acute myocardial infarction (AMI) mortality • Congestive heart failure (CHF) mortality • Stroke mortality

	• Gastrointestinal (GI) hemorrhage mortality • Hip fracture mortality • Hip replacement mortality • Abdominal aortic aneurysm (AAA) repair mortality and volume • Carotid endarterectomy mortality and volume • Esophageal resection mortality and volume • Pancreatic resection mortality and volume • Coronary artery bypass graft (CABG) volume • Percutaneous coronary angioplasty (PTCA) volume • Bilateral catheterization • Incidental appendectomy in the elderly • Laparoscopic cholecystectomy rate • CABG area rate • Hysterectomy area rate • Laminectomy area rate • PTCA area rate **Patient Safety Indicators:** • Post-operative hip fracture **Prevention Quality Indicators** • Long term diabetes complications area rate • Chronic obstructive pulmonary disease (COPD) area rate • Angina area rate • CHF area rate • Lower extremity amputation among diabetics area rate
Rare and often occurs in clinically complex patients or patients in end stage disease	• Pneumonia mortality
Chart review from pediatric institutions raised validity concerns for pediatrics	• Failure to rescue • Death in low mortality Diagnostic Related Groups (DRGs) • Complications of anesthesia • Post-operative pulmonary embolism or deep vein thrombosis
Obstetric indicators – clinical issues are similar for teen and adult mothers	• Obstetric trauma • Cesarean delivery rate • Vaginal birth after cesarean (VBAC) delivery rate • Birth trauma (an indicator of obstetric care) • Low birth weight (an indicator of obstetric care)

Table 2. Organizations contacted for nominations of panelists and potential indicators (for Phase II)

Organizations Contacted for General Input and Potential Indicators
California Perinatal Quality Care Collaborative
Center for Research for Mothers and Children
Centers for Disease Control and Prevention
Centers for Medicare and Medicaid Services
Centers for Medicare and Medicaid Services
Children's Medical Center
Joint Commission on the Accreditation of Healthcare Organizations
Leapfrog Group
National Center for Chronic Disease Prevention and Health Promotion
National Center on Birth Defects and Developmental Disabilities

National Initiative for Children's Healthcare Quality
National Institute of Child Health and Human Development
National Institute of Mental Health
National Institute on Alcohol Abuse and Alcoholism
National Institute on Drug Abuse
National Patient Safety Foundation
National Quality Forum
Parents of Infants and Children with Kernicterus
Substance Abuse and Mental Health Services Administration
Texas Children's Hospital
The Child and Adolescent Health Measurement Initiative
United States Pharmacopeia
Vermont Oxford Network
Zero to Three: National Center for Infants, Toddlers and Families

Organizations contacted for Potential Indicators and Panelist Nominations
Ambulatory Pediatric Association
American Academy of Allergy Asthma and Immunology
American Academy of Child and Adolescent Psychiatry
American Academy of Family Physicians
American Academy of Neurology
American Association for Pediatric Ophthalmology and Strabismus
American Association for the Surgery of Trauma
American Association of Neurological Surgeons
American Association of Pediatrics
AAP, Section on Adolescent Health
AAP, Section on Allergy and Immunology
AAP, Section on Anesthesiology and Pain Medicine
AAP, Section on Cardiology and Cardiac Surgery
AAP, Section on Critical Care
AAP, Section on Emergency Medicine
AAP, Section on Endocrinology
AAP, Section on Gastroenterology and Nutrition
AAP, Section on Hematology/Oncology
AAP, Section on Hospital Care
AAP, Section on Infectious Disease
AAP, Section on Nephrology
AAP, Section on Neurological Surgery
AAP, Section on Neurology
AAP, Section on Ophthalmology
AAP, Section on Orthopaedics
AAP, Section on Otolaryngology/ Head and Neck Surgery
AAP, Section on Pediatric Pulmonology
AAP, Section on Perinatal Pediatrics
AAP, Section on Radiology
AAP, Section on Surgery
AAP, Section on Urology
American College of Cardiology
American College of Chest Physicians
American Hospital Association
American Pediatric Society/Society for Pediatric Research
American Pediatric Surgical Association
American Pediatric Surgical Nurses Association

American Society of Clinical Oncology
American Society of Nephrology
American Society of Pediatric Hematology/Oncology
American Society of Pediatric Nephrology
American Society of Pediatric Neurosurgeons
American Society of Pediatric Otolaryngology
American Thoracic Society
California Association of Neonatologists
Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)
Child Health Corporation of America
Child Neurology Society
Congenital Heart Surgeons' Society
Lawson Wilkins Pediatric Endocrine Society
National Association of Children's Hospitals and Related Institutions and National Association of Children's Hospitals, the policy affiliate
National Association of Neonatal Nurses
National Association of Pediatric Nurse Practitioners
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Pediatric Emergency Medicine Interest Group, Society for Academic Emergency Medicine
Pediatric Infectious Diseases Society
Society for Adolescent Medicine
Society for Maternal-Fetal Medicine
Society for Pediatric Dermatology
Society for Pediatric Radiology
Society for Pediatric Urology
Society of Clinical Child and Adolescent Psychology
Society of Critical Care Medicine, Section on Pediatrics
Society of Pediatric Anesthesia
Society of Pediatric Nurses
Society of Thoracic Surgeons

Literature review

Literature review provided evidence for potential indicators. The results of the literature were presented to panel members to help inform their ratings. Literature review involved searching for pertinent articles on both PubMed and the *Pediatrics* web site. Searches were done using keywords contained in or synonymous with the title of each quality indicator. References to applicable journal articles in bibliographies of retrieved articles were also reviewed. Articles that provided any specific evidence, either confirming or arguing against indicator use, were reviewed. Examples of applicable evidence included articles utilizing the indicator or similar indicators, articles describing the concept of the indicator as a measure of quality of care, and articles evaluating the sensitivity and specificity of the indicators and/or codes utilized by the indicators. For the most part indicators that had evidence not supporting their use were not considered for use in the indicator set. See Appendix A for literature review search terms and limits.

Operationalization of indicators

Applicable current AHRQ QIs were reviewed by two pediatrician health services researchers before panel review, and potential modifications were discussed and implemented (by consensus) in some cases. Empirical analyses of specific codes and alternative indicator definitions further informed draft indicator definitions. All analyses were performed using the 2003 KIDs' Inpatient Sample(NIS) from the Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality. For example, when diagnoses codes for patients with transfusion reaction were analyzed it was determined that this event is often miscoded in the neonatal population. The defining of indicators outside of the current AHRQ QI set (i.e., "novel" indicators) is ongoing, and will be completed as part of Phase II. When possible, definitions begin with an established operationalized definition, and then adaptations are incorporated based on application to a pediatric population, adaptation of the indicator for administrative data or changes in clinical practice.

A structured review of each indicator was undertaken to evaluate face validity (from a clinical perspective). This process mirrored that undertaken during the initial development of the Patient Safety Indicators. Specifically, the panel approach established *consensual validity,* which "extends face validity from one expert to a panel of experts who examine and rate the appropriateness of each item…."[5] The methodology for the structured review was adapted from the RAND/UCLA Appropriateness Method[6] and consisted of an initial independent assessment of each indicator by clinician panelists using an initial questionnaire, a conference call among all panelists, followed by a final independent assessment by clinician panelists using the same questionnaire. The panel process served to refine definitions of some indicators, add new measures, and dismiss indicators with major concerns from further consideration.

A similar standardized panel approach was previously used to evaluate potential indicators of primary care quality[7, 8] as well as ambulatory care sensitive conditions.[9]

Clinician Panel Review Methods

Panel selection

Forty-four distinct professional clinical organizations and hospital associations were invited to submit nominations. These organizations were selected based on the applicability of the specialty or subspecialty to the candidate quality indicators. Nineteen organizations submitted nominations: Ambulatory Pediatric Association, American Academy of Allergy Asthma and Immunology, American Academy of Family Physicians, American Academy of Pediatrics, American College of Chest Physicians, American College of Nurse-Midwives, American Society of Pediatric Hematology/Oncology, American Society of Pediatric Nephrology, California Academy of Family Physicians, Child Health Corporation of America, National Association of Children's Hospitals and Related Institutions, National Association of Pediatric Nurse Practitioners, Pediatric Infectious Diseases Society, Society for Academic Emergency Medicine, Society for Adolescent Medicine, Society for Pediatric Anesthesia, Society of Critical Care Medicine, Society of Pediatric Nurses, and Society of Thoracic Surgeons.

These professional organizations nominated a total of 125 clinicians. All nominees were invited to participate, if eligible, in the evaluation of indicators available in Phase I and Phase II. In order to be eligible to participate, nominees were required to spend at least 30% of their work time on patient care, including hospitalized patients. From the 70 nominees accepting the invitation; five clinicians were ineligible to participate. Nominees were asked to provide information regarding their practice characteristics, including specialty, subspecialty, and setting (i.e., urban vs. rural location, region of country, and service to underserved populations), primary hospital of practice (i.e., funding source), and involvement in education (i.e., clinical training, academic affiliation).

To ensure appropriate clinical expertise on each panel, we identified the specialties that would be required to properly evaluate the indicators assigned to that panel. Panelists were selected so that each panel had diverse membership in terms of practice characteristics and setting. Thus, when a specific geographic area or type of clinician (e.g. academic) was over-represented by the pool of eligible nominees, randomly drawn members from that specific sub-group were contacted first to fill the panels. In addition, conference call scheduling logistics influenced assignments. From the 65 eligible nominees, 45 individuals accepted our invitation to participate on a specific panel.

Panel composition

Four panels were formed to evaluate indicators grouped as follows: Medical and surgical indicators, surgical only indicators, neonatal indicators and prevention indicators. Participants in the panels are listed in Appendix B. All panels had diversity in the geographic location of panelists, and their type of practice (see Table 3).

Table 3. Multi-specialty Panel Composition

Characteristic	% (N)
Gender	
Female	33% (15)
Academic Affiliation	
Yes	91% (41)
No	9% (4)
Not reported	0% (0)
Geographic Region	
East	29% (13)
West	20% (9)
South	27% (12)
Midwest	24% (11)
Community	
Urban	71% (32)
Suburban	36% (16)
Rural	29% (32)
Not reported	13% (6)
Funding of Primary Hospital	
Private	51% (23)
Public	13% (6)
Both	18% (8)
Not Reported	18% (8)
Part of Patient Population Considered Underserved	
Yes	80% (36)
No	7% (3)
Not reported	16% (7)

[1]Clinical and/or research affiliation

Initial evaluation

After agreeing to evaluate each indicator presented in Phase I and Phase II, panelists were sent information (see Appendix C) regarding administrative data, ICD-9-CM coding, assignment of Diagnostic Related Groups (DRGs) and Major Diagnostic Categories (MDCs), and specific definitions for "adverse events or complications," "preventability," and "medical error." Panelists were presented with six to seven indicators (except the neonatal panel, which only reviewed two indicators) in the Phase I review. The standardized text used to describe each ICD-9-CM code was presented along with the specific numeric code. Exclusion and inclusion criteria were also given, as well as the clinical rationale for the indicator and the specification criteria. A summary of literature-based evidence and empirical rates based on the 2000 NIS were provided for reference. Finally, panelists were provided potential questions regarding the indicator definition that the study team planned to explore during the conference call.

Each of the 8 to 13 panelists from a given panel provided input for a given indicator by completing a 10-item questionnaire (see Appendix C for the two versions used: *hospital-based* for complications and mortality indicators, and *prevention* for ambulatory care sensitive area level indicators). The hospital-based indicator questionnaire asked panelists to consider the ability of this indicator to screen out conditions present on admission, to

identify conditions with high potential for preventability, and to identify medical errors. The prevention indicator questionnaire asked panelists to evaluate the ability of this indicator to assess access to high quality outpatient care. In addition, both versions of the questionnaire asked panelists to consider potential sources of bias, reporting or charting problems, potential ways of gaming the indicator, and possible adverse effects of implementing the indicator. Finally, panelists were invited to suggest changes to the indicator.

Conference call

Following the submission of the initial evaluation questionnaires, all panelists participated in a 90-minute conference call for their panel to discuss the indicators. The purpose of each conference call was to allow panelists to discuss their opinions regarding each indicator. Following the instructions in the RAND/UCLA method where the primary goal of interaction among panelists is to allow room for varied opinions about the appropriateness of an indicator, panelists were explicitly told that consensus was not the goal of discussion. In cases when panelists agreed on proposed changes to the indicator definitions, such consensus was noted and the definition was modified accordingly before the final round of rating. Each call was moderated by a team member (KM), who directed the structure of the call, and ensured that all panelists had a chance to share their opinions. Also present was a technical expert, who answered questions regarding administrative data and coding (PR), and silent observers, who maintained comprehensive notes of the call (SD, CH, KC, AK, JG). All team members refrained from offering opinions regarding indicators during the call. Agenda items were set based on the feedback received from the initial evaluation and in general focused on points of disagreement among panelists. Panelists were prompted throughout the process to consider the appropriate population at risk for each indicator (specifically inclusion and exclusion criteria) in addition to the complication or condition of interest. However, if panelists wished to discuss other aspects of the indicator, this discussion was allowed within the time allotted for that indicator. The calls were recorded and transcribed for purposes of summarizing themes and determining definitional changes.

Final evaluation

Following each conference call, changes to each indicator were made where suggested by panelists. In each case, every panelist present on the call must have either endorsed the proposed change or indicated neutrality for the change to be implemented. The indicators were then redistributed to panelists along with questionnaires used in the initial evaluation. Each indicator description included explication of any definitional changes that were adopted and the reason. Panelists were asked to re-rate each indicator based on their current opinion. They were asked to keep in mind the discussion during the conference call. Four indicators were not re-distributed due to ongoing extensive revisions. These indicators underwent a second round of review by the same panel, following revisions.

Tabulation of results

To examine the results of the panels, we applied a modified version of the "appropriateness" criteria outlined in the RAND/UCLA Appropriateness Method. Results from the final evaluation questionnaire were used to calculate median scores from the 9 point scale for each question and to categorize the degree of agreement among panelists (see Table 4). Median scores determined the level of acceptability of the indicator, and dispersion of ratings across the panel for each applicable question determined the agreement status. Therefore the median and agreement status were independent measurements for each question. The following six criteria covered in the questionnaire were used to summarize the panel's opinions (i.e., median, agreement status category) on the following aspects of each indicator:

1. Overall usefulness of the indicator, both for internal quality improvement purposes and comparisons between hospitals,
2. Likelihood that indicator measures a complication and not a comorbidity (specifically, present on admission),
3. Preventability of complication,
4. Extent to which complication is due to medical error,
5. Likelihood that complication is charted given that it occurs, and
6. Extent that indicator is subject to bias (systematic differences, such as case mix that could affect the indicator, in a way not related to quality of care).

For area based indicators panelists provided feedback on the following aspects:

1. Overall usefulness of the indicator, both internally within an area and for comparisons between areas
2. Extent to which event reflects poor access to quality outpatient care
3. Consistency in terminology for charting principal diagnosis
4. Extent that indicator is subject to bias

These evaluations are included in the summary of results for each indicator.

Table 4. Criteria for Agreement Status

Category	Panel size	Criteria
Agreement	8-13 panelists	Two or fewer members rated indicator outside specific three-point range (1-3.9, 4-6.9, 7-9) in which the median falls.
	5-7 panelists	One or fewer panelists rated indicator outside specific three-point range (1-3.9, 4-6.9, 7-9) in which the median falls.
Disagreement	8-13 panelists	Three or more panelists rated indicator in each of the extreme three-point ranges (1-3.9, 7-9), demonstrating a split in opinion.
	5-7 panelists	Two or more panelists rated indicator in each of the extreme three point ranges (1-3.9, 7-9), demonstrating a split in opinion.
Indeterminate Agreement	All panel sizes	Any panel rating not qualifying as either "agreement" or "disagreement" by above criteria.

We used the ratings regarding the overall appropriateness of the indicator for internal quality improvement (i.e., criterion number 1 above based on question #8a on questionnaire in Appendix C) to assess the overall usefulness as a screen for potential quality problems at the hospital or area level (see Table 5). This score mirrored the criterion used for selection of the PSIs during the initial development process. The median score and agreement category for this usefulness question were combined into modified RAND groupings. Akin to the RAND "Appropriate" levels, we created two categories, "Acceptable" and "Acceptable (-)." "Acceptable (-)" refers to indicators that were considered acceptable because the median rating was 7 or higher (on a 1-7 scale), but there was at least one participant (or two, in the case of larger panels) whose rating fell below this range. The RAND "Uncertain" level was likewise divided into two sub-levles, "Unclear," and the slightly worse category, "Unclear (-)." The RAND "Inappropriate" level was defined identically but named "Unacceptable." These designations, along with some initial administrative data testing and subsequent coding clarifications, were used to form recommendations regarding inclusion in the pediatric indicator set.

Table 5. Definitions for Overall Appropriateness of Indicator for Internal QI

Acceptable	Median falls between 7 and 9 (inclusive of both), agreement
Acceptable (-):	Median falls between 7 and 9 (inclusive of both), indeterminate agreement
Unclear:	Median falls between 7 and 9 (inclusive of both), disagreement, OR
	Median falls between 5 and 7 (inclusive of neither), agreement or indeterminate agreement
Unclear (-):	Median between 4 and 5 (inclusive of both), agreement, indeterminate agreement or disagreement, OR
	Median falls between 1 and 3.9 with disagreement
Unacceptable:	Median falls between 1 and 3.9, agreement or indeterminate agreement

Peer Review Methods

We received 40 nominations from federal agencies, advocacy groups and health care quality associations for peer reviewers. In addition, a few physicians who were nominated for the clinician review panels agreed to participate in the peer review process instead. Twenty-six of the peer reviewers we invited have expressed an interest in participating and were sent materials. Among the peer reviewers are clinicians, policy advisors, professors, researchers, and managers in quality improvement. Participants in the review process are listed in Appendix D.

Empirical Methods

Purpose of Analyses

Empirical analyses were conducted to provide the clinical panels and peer review participants with additional information about the indicators. These analyses were also used by the development team to test the alternative specifications and the relative contribution of indicator components in the numerator and denominator. The results are included in the "detailed results by indicator" section. These analyses were not intended to inform issues of precision, bias and construct validity, which will be addressed separately.

Analysis Approach

Data Source

The data source used in the empirical analyses was the 2003 Kids' Inpatient Sample (KID). The KID contains all-payer data on hospital inpatient stays from States participating in the Healthcare Cost and Utilization Project (HCUP). The 2003 KID provides information on 3 million inpatient stays from about 3,400 hospitals. The KID sampling frame included all pediatric discharges from community, non-rehabilitation hospitals in the HCUP State Inpatient Databases (SID) that could be matched to the corresponding American Hospital Association (AHA) survey data (subject to state-specific restrictions). The KID includes a sample of pediatric discharges from all hospitals in the sampling frame. For the sample, the pediatric discharges were stratified by uncomplicated in-hospital birth, complicated in-hospital birth, and pediatric non-birth and a random sampling taken of 10 percent of uncomplicated in-hospital births and 80 percent of other pediatric cases from each frame hospital. To obtain national estimates, discharge weights using the AHA universe as the standard based on six characteristics contained in the AHA hospital files: geographic region, control, location, teaching status, bed size and hospital type. In this report, we used the discharge level weights and PROC SURVEYMEANS in SAS (cite) to compute the weighted national rates and variances and indicator denominators (i.e., the sum of the discharge weights). For more information, see *Design of the Hcup Kids' Inpatient Database (Kid), 2003* (http://hcup-us.ahrq.gov/db/nation/kid/reports/KID_2003_Design_Edited_013006.pdf).

Definition of Neonate and Newborns

Several of the indicators require a definition of "neonate" and "newborn" in the specification as inclusion or exclusion criteria or to stratify the rate. For this report, we used the following definitions to define these populations.

A "neonate" is any discharge record with an admission date during the neonatal period (birth to 28 days). To determine the neonatal period, we use the age in days (AGEDAY) data element. That is, a neonate is any discharge record with AGEDAY<=28. If that data element is missing, and age in years (AGE) equals zero, then a neonate is any discharge record with ANY one of five conditions: 1) MDC 15 (Newborns & Other Neonates with Condition Originating in the Perinatal Period); or 2) DRG 385-391; or 3) Admission Type of "newborn" (ATYPE=4); or 4) a diagnosis code of V29.xx (Observation and evaluation of newborns for suspected condition not found); or 5) a diagnosis code indicating a live birth (see below).. The latter definition is slightly too broad, as it includes some discharges occurring outside the neonatal period.

A "newborn" is a neonate discharge record originating from a live birth. To identify a live birth, we use discharge records with EITHER 1) any diagnosis code of V3x.0x (i.e. V3x codes – Liveborn Infants accoring to Type of Birth - with a "0" in the fourth digit) OR 2) an admission type of "newborn" (ATYPE=4) and age in years equal to zero, excluding discharges with any diagnosis code of V3x.1x or V3x.2x (i.e. V3x codes with a "1" or "2" in the fourth digit). These latter codes indicate live births that occurred outside the hospital or prior to admission.

A "normal newborn" is a newborn without significant complications. To identify normal newborns we use the newborn definition above along with DRG 391 (Normal Newborn).

Population Denominators

The area level indicators use a population denominator. Although hospital zip code may be used, it is recommended that patient zip code be used to calculate area level indicators. This reduces effects of tertiary referral centers. Our intercensal population estimates come from the U.S. Census Bureau. The default age categories reported by Census for the pediatric population are 0 to 4, 5 to 9, 10 to 14 and 15 to 19. Several of the indicators require a more refined age definition in the specification as inclusion or exclusion criteria or to stratify the rate. In addition, we report age categories used by AHRQ in their child health publications (see, for example *Care of Children and Adolescents in U.S. Hospitals HCUP Fact Book No. 4* at http://www.ahrq.gov/data/hcup/factbk4/factbk4.htm). To estimate these more refined age categories, we allocated the population estimates uniformly within the census five-year age categories. In other words, we assumed no growth in population or cohort size within these five year age categories. The specific calculation is described below.

PedQI Age Category	U.S. Census Age Category	Allocation
0 to 28 days	0 to 4 years	(28/365) * (1/5)
29 to 60 days	0 to 4 years	(32/365) * (1/5)
61 to 90 days	0 to 4 years	(30/365) * (1/5)
91 to 365 days	0 to 4 years	(275/365) * (1/5)
1 to 2 years	0 to 4 years	(2/5)
3 to 5 years	0 to 4 years	(2/5)
	5 to 9 years	(1/5)
6 to 12 years	5 to 9 years	(4/5)

	10 to 14 years	(3/5)
13 to years	10 to 14 years	(2/5)
	15 to 19 years	(3/5)

Birth Weight Categories

For exclusions based on birth weight, or to stratify rates based on birth weight, we use the following ICD-9-CM diagnosis codes:

Birth weight category	ICD-9-CM Diagnosis Codes
<500g	76401, 76411, 76421, 76491, 76501, 76511, V2131
500-999g	76402, 76403, 76412, 76413, 76422, 76423, 76492, 76493, 76502, 76503, 76512, 76513, V2132
1000-1499g	76404, 76405, 76414, 76415, 76424, 76425, 76494, 76495, 76504, 76505, 76514, 76515, V2133
1500-1999g	76406, 76407, 76416, 76417, 76426, 76427, 76496, 76497, 76506, 76507, 76516, 76517, V2134
2000-2500g	76408, 76418, 76428, 76498,76508, 76518, V2135

Hospital Type Categories

The analyses report rates separately by hospital type (children's vs. non-children's). The KID data contains the American Hospital Association (AHA) identifier for a subset of hospitals (about 79% of hospitals and 73% of discharges). For those hospitals that we could link to the AHA Annual Survey, we identified children's hospitals as those hospitals with either 1) a service type of children's hospital (see below) or 2) that answered "yes" to the question: do you restrict admissions primarily to children?.

AHA Service Type	
50	children's general
51	children's hospital unit of an institution
52	children's psychiatric
53	children's tuberculosis and other respiratory disease
55	children's eye, ear, nose and throat
56	children's rehabilitation
57	children's orthopedic
58	children's chronic disease
59	children's other specialty

Results

Summary of Results

All current AHRQ QIs were considered for adaptation to a pediatric population. Four indicators were already designed specifically for use in a pediatric population: Pediatric Heart Surgery Mortality/Volume (IQI), Pediatric Asthma Admission Rate (PQI) and Pediatric Gastroenteritis Admission Rate (PQI). In a preliminary review, most Inpatient Quality Indicators were eliminated from further consideration because the conditions in question are primarily adult conditions: These include mortality (and volume for those starred) for AMI, CHF, Stroke, GI hemorrhage, Hip fracture, Hip replacement, Esophageal resection*, Pancreatic resection*, AAA repair*, Carotid endarterectomy*, PTCA* and CABG*. Pneumonia mortality was eliminated since death from pneumonia is rare among children and typically occurs only in the setting of multiple or severe chronic diseases. Rates of Incidental Appendectomy, Bilateral Cathterization (validated for an elderly population), Laparoscopic cholecystectomy, CABG, PTCA, Laminectomy and Hysterectomy were also excluded for lack of relevance to children. Prevention Quality Indicators excluded for similar reasons included Long term diabetes complications, COPD, Angina, CHF, and Lower extremity amputation among diabetics. Among the PSIs, two indicators were eliminated due to either the absence of the event in children (Post-operative hip fracture), or because the event was felt to be clinically different in children (Post-operative PE or DVT). Three other indicators—Failure to rescue, Death in low mortality DRGs and Complications of anesthesia—were eliminated due to serious validity concerns when applied as defined in the pediatric population. This evidence included chart reviews and information obtained through user reports. Use of these indicators would require extensive redefinition beyond the scope of this project. For Low Mortality DRG, the validity of this indicator would need to be investigated further, since mortality is so rare in children and DRGs are generally not specific for children. Failure to rescue will require identification of complications in high risk populations and testing to establish a link with outcomes in patients with those complications and quality of care. Finally, Obstetric trauma, Cesarean delivery rate, and VBAC delivery rate were excluded because little evidence demonstrates a meaningful clinical difference between adolescent and adult obstetric patients. Adolescents could remain in the existing obstetric indicators without compromising the value or integrity of those indicators. Panels reviewed a total of 23 current AHRQ QIs.

Tables 6 – 7 summarize the recommendations for each indicator based on our review of the evidence, including literature review, empirical analyses and clinician panel review. Based on final definitions tailored to the pediatric population, 19 indicators are recommended for inclusion in the Ped QI module at this time. Fourteen of those indicators are intended for use at the hospital level, while the other five are area level indicators, intended to measure access to high quality outpatient care. Finally, 3 indicators are not considered suitable for inclusion in the Ped QI module. One indicator will be considered in Phase II.

Table 6. Indicators recommended for inclusion in the Pediatric Quality Indicator Set

Indicator name	Panel recommendation		Special notes
	Internal QI purpose	Comparative reporting purpose	
Inpatient Indicators			
Accidental puncture and laceration	Acceptable (-)	Not recommended	
Decubitus ulcer	Acceptable (-)	Acceptable (-)	
Foreign body left in after procedure	Acceptable (+)	Acceptable (+)	
Iatrogenic pneumothorax in neonates at risk	Acceptable (+)	Acceptable (-)	Denominator for community hospitals will be very low.
Iatrogenic pneumothorax in non-neonates	Acceptable (+)	Acceptable (-)	Barotrauma and procedure related pneumothoraxes captured together.
Pediatric heart surgery mortality	Acceptable (+)	Acceptable (+)	Ratings based on preliminary ratings, dependent on adequate risk adjustment.
Pediatric heart surgery volume	Acceptable (+)	Acceptable (+)	Ratings based on preliminary ratings, dependent on adequate risk adjustment.
Postoperative hemorrhage and hematoma	Acceptable (+)	Acceptable (+)	Some acquired coagulapathies will only be diagnosed in patients who have bleeding complications, leading to uncorrectable bias.
Postoperative respiratory failure	Acceptable (+)	Acceptable (-)	
Postoperative sepsis	Acceptable (-)	Not recommended	
Postoperative wound dehiscence	Acceptable (+)	Acceptable (+)	
Selected infection due to medical care	Acceptable (-)	Not recommended	
Transfusion reaction	Acceptable (+)	Acceptable (-)	
Area Level Indicators			
Asthma admission rate	Acceptable (+)	Acceptable (-)	Socioeconomic Status (SES) risk adjustment recommended. Data does not capture admission to short stay or extended emergency department (ED) stays.
Diabetes short term complication admission rate	Acceptable (+)	Not recommended	SES risk adjustment recommended. Initial diagnosis admissions included for patients age 6 and older.
Gastroenteritis admission rate	Acceptable (-)	Not recommended	SES risk adjustment recommended. Data does not capture admission to short stay or extended ED stays.
Perforated appendix admission rate	Acceptable (-)	Acceptable (-)	SES risk adjustment recommended.
Urinary tract infection admission rate	Acceptable (-)	Not recommended	SES risk adjustment recommended. Data does not capture admission to short stay or extended ED stays. Hospitals

			differ on evaluation for chronic urinary tract disorders (exclusion criteria), leading to bias.

Table 7. Indicators no longer being considered for inclusion

Indicator name	Reason
Postoperative physiologic and metabolic derangement	Not recommended by panel and no strong evidence base for useful application to pediatric population.
Dehydration admission rate	Admissions due to dehydration combined with gastroenteritis admission rate indicator. Other causes not recommended by panel.
Bacterial pneumonia	Not recommended by panel and no strong evidence base for useful application to pediatric population.
Craniotomy mortality	Requires further specialized development to define risk groups as suggested by clinical panel. Will be considered as a new indicator in Phase II.

Overall Results from Clinician Panel Review

Four clinician panels were convened to evaluate the face validity of the AHRQ QIs adapted and applied solely to a pediatric population. This section covers general themes highlighted by panelists during the course of review, which are in many cases applicable to several or all indicators. Results of the pediatric clinician panels specific to each indicator are outlined in the section, “Detailed Results By Indicator”.

Most panelists were enthusiastic about pediatric quality indicators and articulated important considerations particularly pertinent to pediatric application. Panelists expressed that such indicators, if used appropriately, could improve the quality of patient care by providing an initial screen for quality concerns. In addition, panelists suggested or reinforced some overarching themes important to developing and using pediatric quality indicators.

Importance of assessing health care quality in high risk groups

For several indicators (e.g. Postoperative sepsis, Decubitus ulcer) panelists noted that the indicators are of minimal value when excluding the high risk populations, as done in the AHRQ QIs. In pediatrics, unlike adult settings, uncomplicated patients are much less likely to develop the types of outcomes measured by the QIs. Interventions are best aimed at populations that are more likely to develop a complication, and these interventions may in turn lower the overall rate of the indicator. Further, focusing only on low risk populations reduces the complication rate to a level where meaningful comparisons over time and institutions may be difficult. Such low numbers may remain a problem for community hospitals that do not treat high risk patients.

Concerns about bias and preferences for addressing differing risk groups

Expanding an indicator to include high risk populations may have the consequence of increasing potential bias. Higher risk children tend to be concentrated in children's hospitals, potentially biasing any comparisons between children's hospitals and community hospitals. Because of differing distributions of complicated cases, indicators that include lower and higher risk patients require adjustment for comorbidities, reasons for admission, age and other measures of severity of illness. Panelists noted that risk adjustment using administrative data will be limited in effectiveness, so comparisons should generally focus on similar types of hospitals. For instance, tertiary care children's hospitals should be compared only to other children's hospitals.

Stratification of indicators was also preferred by panelists. Stratification allows an institution to examine the rate in populations of differing risk, to better target interventions, in addition to providing a means for less biased inter-institutional comparisons. Stratification however does reduce the denominator for each comparison; in some cases, this reduction may make meaningful comparisons impractical.

One area of concern, particularly for panelists examining potentially avoidable hospitalization indicators, was adjustment for social factors. Examples of social factors that may influence outcomes, but remain beyond provider control, include cultural traditions that inhibit early presentation to a health care provider, or fear of repercussions of presenting, such as deportation for illegal residents. Other factors raised as potentially associated with different socio-economic settings include higher rates of poor health behaviors leading to poorer overall health and poorer outcome, and poor adherence to medical care. Risk adjustment for these types of factors is not straightforward. For instance, in one area cultural factors associated with a certain ethnic group may adversely affect outcomes, while that same ethnic group in another area of the country may not exhibit the same cultural factors. In addition, broad ethnic categorizations, such as Asian, Black or Hispanic, are unlikely to be refined enough to capture specific groups with differential ability to derive benefits consistently from high quality care. Other factors, such as illegal immigrant status, are not available in any state database at this time. Some panelists grappled with the issue that risk adjustment may not be desirable for indicators that examine area level health care, since interventions to target high risk groups may still be effective in reducing poor outcomes, by reducing poor health behaviors or providing culturally sensitive care to improve compliance. Further supporting the argument against risk adjustment is that social factors tend to be correlated with poor access to quality care, and it may be important to focus policy-makers' attention on these high-risk communities. Risk adjustment may in fact adjust away some of the poor access to care the indicator is intended to measure. Despite these concerns, panelists felt that the potential impact of the health care community on these overarching social factors is small, and that risk adjustment is essential for fair comparisons between areas. Since detailed risk adjustment by cultural group is not possible, socioeconomic status adjustment was recommended as a minimal risk adjustment approach for social factors. It should be noted that such adjustment may result in less ability to detect disparities between socioeconomic groups. Both raw and risk adjusted rates are important when investigating area level rates.

Additional data elements to improve indicator definitions

Panelists frequently requested modifications to indicators that would require additional data elements to address suggestions more fully than is feasible with the current national data set. Currently, present on admission data elements are available in two states only. These data allow the differentiation between complications and comorbidities. Specific codes for some important comorbidities, such as coagulopathies, include conditions that could be acquired during the hospitalization and reflect poor quality of care (or simply be recorded only due to poor outcomes). In addition, present on admission data would allow the expansion of surveillance for potential complications that cannot be otherwise distinguished from comorbidities. For example, acute renal failure and diabetic complications measured by the QI "Postoperative Metabolic and Physiologic Derangements" are rare in children; however, panelists expressed interest in expanding the complication set to include less severe, but clinically important electrolyte imbalances. Currently these complications are impossible to distinguish from imbalances which may be present on admission. Present on admission data is also important for adult indicators, and in recent years have attracted more attention from the quality improvement field and researchers. Other data elements of interest included expansion of the base dataset to outpatient surgeries to track complications of outpatient surgery; readmission data to track readmissions for complications or for chronic diseases; clinical and pharmacy data to improve risk adjustment and specificity of the indicators; and linkages to vital or maternal records to improve risk adjustment and specificity for neonatal indicators.

Purpose of indicators

The intended use of the indicators affected the opinion of the panelists regarding their overall usefulness. As with the AHRQ QIs, panelists were more interested in establishing broader definitions when the indicators would only be used for internal quality improvement instead of comparative reporting. As discussed above, the importance of including high risk populations in children heightened the concern about appropriate use of the indicators. We asked panelists for two overall usefulness ratings, one for quality improvement and one for comparative reporting. In general, panelists were more conservative in the recommendations for comparative reporting, with panelists not recommending six indicators for comparative reporting that were recommended for internal quality improvement.

Overall Results from Peer Review

We received fifteen responses from peer reviewers. Peer reviewers offered favorable comments with constructive suggestions for content and presentation enhancements. Peer reviewers offered both general recommendations and feedback targeted to specific indicators. This section describes three major themes of the peer review responses.

Expanded data

Like our panelists, our peer reviewers also advocated for indicators based on expanded data sets. Citing the limitations of the discharge data based on administrative data, peer reviewers called for the option to use more clinically rich data. Some reviewers argued that many hospital systems do have access to additional data fields, and would benefit from tools that would help them use such additional data for quality improvement purposes. Some of the additional data for which peer reviewers suggested included: 1) outpatient surgical data which would better track complications following common operations in children, such as tonsillectomy and adenoidectomy; 2) condition present on admission data, which could improve specificity of the indicators and allow the expansion of complications monitored by the indicators, such as the addition of physiologic derangements; 3) readmission data, which would allow for tracking complications occurring after discharge; and 4) laboratory data and pharmacy data which could improve sensitivity and specificity of the indicators, and expand the possible indicator set to include process based measures and expand risk adjustment options.

Data standards

Peer reviewers noted that data quality and detail vary from institution to institution and state to state. For instance, some states require more diagnosis fields than others. With the truncation of diagnosis codes, some secondary diagnosis codes may not be included, systematically biasing the data. One peer reviewer noted that E codes are not consistently used in pediatric patients, creating bias for indicators based on E codes. Like E-codes, another peer reviewer noted that procedure dates are also not standard in data sets. Finally, some reviewers noted that systems that are in place for adult coding, through the Medicare audit program, do not affect coding for children. As a result, coding for children may be more problematic. They advocated for standardized quality control approaches for pediatric hospital data.

The desire to ensure data standards can sometimes be at odds with the desire to use additional data available to some but not all hospitals. The balance between improving the indicator set through use of better and additional data, and the potential bias created when using data only consistently available at some institutions should be considered carefully.

Validity testing

Peer reviewers noted that while the current development work was rigorous and thoughtful, establishing the validity of these indicators will require further testing. Testing should include the examination of the sensitivity and specificity of the individual codes used in each indicator, as well as the sensitivity and specificity of the indicators to identify potential quality concerns. Peer reviewers suggested using chart review methods.

Reinforcement of panel commentary

Peer reviewers in general agreed with panelist thoughts about modifications and overall usefulness of the indicators. For instance, several peer reviewers expressed support for the removal of Bacterial Pneumonia and Postoperative Metabolic and Physiologic Derangement from the candidate indicator set. Peer reviewers also agreed with panelists regarding the expansion of some indicators to include high risk children. Similarly, they reiterated the desirability of stratification in some instances, while noting the potential issue of rates being too low for some strata or subgroups (e.g., stratification by procedure class of Accidental Puncture and Laceration indicator). The need for risk adjustment was also identified as crucial by both peer reviewers. Rarely, peer reviewers suggested views that contradicted panelist input. These cases were carefully considered and appropriate adjustments to indicator definitions were made. In general, when panelists specifically discussed or recommended a change, which later a peer reviewer disagreed with, the change was investigated empirically and clinically evaluated. If no further evidence substantiated a change, the panel's recommendation remained. If further evidence highlighted potential problems with indicator definitions recommended by the panelists, appropriate adjustments were made.

Additional suggestions for existing and future indicators

In addition to commenting on the panelists' responses to the indicators, the peer reviewers offered new recommendations. Some suggested additional indicators for consideration, such as central line thromboses, craniotomy volume, or admission rates for pneumonia that may be preventable through vaccination (i.e. Prevnar). They also suggested indicator-specific modifications, such as expanding the definition of "immunocompromised patients," or adding additional exclusion criteria. Some suggestions require additional data for implementation, but others, that are feasible with current data constraints, were evaluated and implemented (e.g. expansion of conditions considered "immunocompromised". Finally, based on their own experiences as quality experts and clinicians, peer reviewers offered advice regarding the implementation of these indicators in the real world setting. For instance, they noted that since transfusion reactions are rare, that indicator is more useful as a case finding tool, and highlighted the need for clear communication regarding the distinction between area level and hospital level indicators.

Detailed Results by Indicator

This section provides detailed results for each indicator reviewed by clinical panels in Phase I. Each indicator section is organized as follows:

1.) Table summarizing the indicator definition followed by a table summarizing associated national rates calculated from the 2003 KID data set, including, for recommended indicators, a comparison of children's versus community hospitals, whenever applicable (i.e., for hospital level indicators, not for area level indicators). Except for population based denominators, all numerators are strict subsets of the denominators;
2.) Paragraph describing the final recommendation for indicator implementation;
3.) Series of three tables summarizing the revisions from the original AHRQ QIs as indicators underwent research team review, panel input and final research team deliberation;
4.) Succinct clinical rationale providing a description akin to what might be used in the National Quality Measures Clearinghouse;
5.) Text presenting a summary of findings from the original panels reviewing the AHRQ QIs (for Patient Safety Indicators only), as presented to the pediatric panels for their review;
6.) Text presenting a summary of the pediatric panel review discussion, followed by final ratings where applicable;
7.) Short summary of empirical analyses conducted to refine indicator definitions, whenever applicable;
8.) Paragraph providing general additional evidence (i.e., not specific to pediatric population) from non-literature sources, if available;
9.) Results of the literature review providing pertinent pediatric evidence (i.e., for or against the indicator or its underlying concept) found in the published literature.

ACCIDENTAL PUNCTURE OR LACERATION (PSI)

Indicator definition:

Cases of technical difficulty (e.g., accidental cut or laceration during procedure) per 1,000 eligible discharges (population at risk). See Pediatric Quality Indicator Technical Specifications.

Definition of technical difficulty (e.g. accidental cut or laceration):	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: Accidental cut, puncture, perforation or hemorrhage during medical care: • Surgical operation [E870.0] • Infusion or transfusion [E870.1] • Kidney dialysis or other perfusion [E870.2] • Injection or vaccination [E870.3] • Endoscopic examination [E870.4] • Aspiration of fluid or tissue, puncture, and catheterization [E870.5] • Heart catheterization [E870.6] • Administration of enema [E870.7] • Other specified medical care [E870.8] • Unspecified medical care [E870.9] Accidental puncture or laceration during a procedure [998.2]	***a. All medical and surgical discharges (defined by DRGs), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with specified principal diagnosis of accidental cut, puncture or laceration.*** ***c. Stratify rates by low birth weight neonate (under 2000g) and other patients.*** ***d. Risk adjust rates by procedure type recorded in patient record:*** ***i. no therapeutic*** ***ii. minor therapeutic*** ***iii. one major therapeutic without diagnostic*** ***iv. one major therapeutic with minor diagnostic*** ***v. one major therapeutic with major diagnostic*** ***vi. two major therapeutic*** ***vii. three or more major therapeutic*** ***e. Stratify rates by clinical category:*** ***i. Eye, ear, nose, mouth, throat, skin, breast, and other low-risk procedures*** ***ii. Thoracic, cardiovascular, and specified neoplastic procedures*** ***iii. Kidney, and male/female reproductive procedures*** ***iv. Infectious, immunological, hematological, and ungroupable procedures*** ***v. Trauma, orthopedic, and neurologic procedures*** ***vi. Gastrointestinal, hepatobiliary, and endocrine procedures*** ***f. Exclude normal newborns [DRG 391].*** ***g. Exclude newborns with a birth weight less than 500g.*** ***h. Exclude obstetric patients (MDC 14).***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):	
OVERALL	0.801
Age stratified rates:	
Neonate, < 2000g	0.819
Neonate, ≥ 2000g	0.495
29 days – 364 days	1.008
1 – 2 years	0.642
3 – 5 years	0.908
6 – 12 years	0.990
13 – 17 years	1.113

Clinical stratification	
Strata 1. Eye, ear, nose, mouth, throat, skin, breast, and other low-risk procedures	0.259
Strata 2. Thoracic, cardiovascular, and specified neoplastic procedures	0.734
Strata 3. Kidney, and male/female reproductive procedures	2.261
Strata 4. Infectious, immunological, hematological, and ungroupable procedures	0.418
Strata 5. Trauma, orthopedic, and neurologic procedures	1.143
Strata 6. Gastrointestinal, hepatobiliary, and endocrine procedures	1.768

Hospital type			
Children's		**Non-Children's**	
OVERALL	1.578	**OVERALL**	0.440
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	1.717	**Neonate, < 2000g**	0.502
Neonate, ≥ 2000g	1.257	**Neonate, ≥ 2000g**	0.339
29 days – 364 days	2.058	**29 days – 364 days**	0.301
1 – 2 years	1.328	**1 – 2 years**	0.224
3 – 5 years	1.628	**3 – 5 years**	0.386
6 – 12 years	1.470	**6 – 12 years**	0.646
13 – 17 years	1.717	**13 – 17 years**	0.824
Clinical strata:		**Clinical strata:**	
Strata 1	0.480	**Strata 1**	0.145
Strata 2	1.724	**Strata 2**	0.128
Strata 3	3.138	**Strata 3**	1.746
Strata 4	0.599	**Strata 4**	0.235
Strata 5	1.666	**Strata 5**	0.594
Strata 6	2.917	**Strata 6**	1.163

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator will be included in the pediatric quality indicator set. Panelists rated this indicator favorably, with indeterimimate agreement for internal quality improvement, but did not recommend the indicator for comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Includes all patients.	Exclude normal newborns [DRG 391].	Normal newborns do not usually undergo procedures that put them at risk for these complications
Includes all patients	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
No stratification.	Stratify rates by low birth weight neonate (under 2000g) and other patients.	Small infants may be at higher risk for this procedure than larger patients due to smaller anatomy and fragile structures.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
All procedures analyzed together.	Stratification by procedure type, based on clinical MDC groups.	Risks vary by procedure type. Stratification by clinically coherent categories improves the usefulness of the indicator.
No indicator specific risk adjustment.	Risk adjustment specific to this indicator based on procedure type (i.e. diagnostic, therapeutic) and number of procedures.	Risks vary by number of surgical encounters, the intensity of the procedure and the purpose of the procedure.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None		

Clinical rationale

This indicator is intended to track injuries occurring during a procedure, specifically accidental cut, puncture, perforation, or laceration. These procedures may be prevented through proper technique during procedures.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the panel consisted of eight physicians: an internist and gastroenterologist, a general surgeon, a cardiologist and critical care physician, two interventional radiologists, two specialized nurses, and an anesthesiologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The original indicator reviewed by this panel was entitled “Technical difficulty with care.” During the course of review, the panel suggested removing complications such as failure of sterile precautions, cataract fragments in the eye following cataract surgery, emphysema arising from a procedure and air embolism, due to questionable clinical significance and variability in reporting.

- Panelists noted that for the remaining codes (those in the indicator presented here) reporting may be variable, although they thought only severe cases would be reported in most cases.
- One panelist suggested that limiting the indicator to re-operations may be one way to improve the indicator. Further investigation is required to determine whether or not this is feasible or desirable, given the small number that would remain in the numerator.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of ten pediatric clinicians, including one neonatologist, one infectious disease specialist, one ambulatory care pediatrician, one pediatric hospitalist, one pediatric cardiovascular surgeon, one pediatric oncologist, two pediatric surgeons, one pediatric interventional radiologist, and one pediatric critical care physician. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists noted that the risk of accidental puncture or laceration varies greatly by the type of procedure. Panelists suggested that this indicator be stratified by procedure class, namely 1) endoscopy, 2) catheter-based procedures, 3) venous access, and 4) major surgeries. Some patients will have more than one procedure type. Panelists suggested that these patients may be placed in yet another category for multiple procedures, or that a hierarchy of procedures could be developed. Extensive redefinition work is required to implement this change. For this reason this indicator was re-rated by this panel only after significant modification to the definition and a second round of rating (see below).

The same panel participated in a second round of rating, which included preliminary rating, followed by a conference call, and a final rating. The panel was identical except for the attrition of three panelists (pediatric cardiovascular surgeon, pediatric oncologist, pediatric hospitalist). The panel re-reviewed three other indicators. In the course of review the panel further suggested the following, in addition to the comments from the previous review:

- The panelists were presented with a stratification scheme based on the number and type (i.e. diagnostic or therapeutic) of procedures a patient underwent during a hospitalization. This is the same scheme that is now used as risk adjustment in this indicator. As a stratification scheme the panelists felt that it was too complex. They expressed concern about potential low sample size in some of the strata at individual hospitals. In addition, they felt that the usefulness of the scheme was questionable, since it would be difficult to understand how and in which service to intervene if rates were high. They suggested an alternative stratification scheme that would group together procedures in a more clinically coherent manner, such as all endoscopy procedures, or cardiac catheterizations. As with the original

stratification scheme, the panel expressed concern over low sample sizes in each strata and suggested empirically investigating more clinically coherent strata.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	7	Indeterminate agreement
Overall rating – comparative purposes	6.5	Indeterminate agreement
Not present on admission	7.5	Agreement
Preventability	7	Indeterminate agreement
Due to medical error	6	Agreement
Charting by physicians	6	Indeterminate agreement
Lack of bias	5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Not recommended

Empirical analyses to inform indicator definition

The following empirical analyses were completed after the initial panel review using the 2003 KIDs' Inpatient Database (KID).

We investigated several approaches to stratification through a series of empirical analyses. These approaches included applying the HCUP Procedure Classes developed by AHRQ. We found that both the number of major therapeutic procedures, and the presence of a diagnostic procedure increased the risk of this complication. Based on these analyses we developed a seven strata system, which we tested empirically. Each strata represented a stepwise increase in risk. See table below to see the rate for each strata based on the definition at the time of the analysis. This stratification system was presented to panelists, who suggested that the system was clinically less useful than one based on more clinical concepts (e.g. organ system, procedure operator). We investigated several options, by identifying which DRGs appeared in the numerator and denominator in each of our original strata, as well as by MDC. See table below for rates by MDC based on the definition at the time of analysis. We found no clear patterns that enabled maping of our original seven strata, which empirically performed well, to more clinical concepts. Based on these analyses and panel feedback we adopted the empirically derived classification system as risk adjustment and the MDC based system as stratification.

Rates for strata based on definition at time of analysis

Stratum based on empirical results	Rate/1000
No therapeutic	0.047
Minor therapeutic	0.362
1 major therapeutic, with no diagnostic	1.155
1 major therapeutic, with minor diagnoistic	2.317
1 major therapeutic, with major diagnoistic	4.784
2 major therapeutic	7.031
3 or more major therapeutic	14.25

Rates for MDCs, based on definition at time of analysis

MDC	Rate per 1000
Ungroupable or Pre-MDC	6.52
MDC 1. Diseases and Disorders of the Nervous Systems	2.79
MDC 2. Diseases and Disorders of the Eye	0.99
MDC 3. Diseases and Disorders of the Ear, Nose, Mouth and Throat	1.12
MDC 4. Diseases and Disorders of the Respiratory System	5.04
MDC 5. Diseases and Disorders of the Circulatory System	8.66
MDC 6. Diseases and Disorders of the Digestive System	5.33
MDC 7. Diseases and Disorders of the Hepatobiliary System and Pancreas	7.48
MDC 8. Diseases and Disorders of the Musculoskeletal System and Connective Tissue	2.79
MDC 9. Diseases and Disroders of the Skin, Subcutaneous Tissue and Breast	0.55
MDC 10. Endocrine, Nutritional and Metabolic Diseases and Disorders	12.55
MDC 11. Diseases and Disorders of the Kidney and Urinary Tract	6.55
MDC 12. Diseases and Disorders of the Male Reproductive System	3.97
MDC 13. Diseases and Disorders of the Female Reproductive System	6.55
MDC 16. Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders	6.35
MDC 17. Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms	9.18
MDC 18. Infectious and Parasitic Disease (Systemic or unspecified sites)	4.96
MDC 19. Mental Diseases and Disorders	0.00
MDC 21. Injuries, Poisonings and Toxic Effects of Drugs	2.96
MDC 22. Burns	0.67
MDC 23. Factors Influencing Health Status and Other Contacts with Health Services	0.00
MDC 24. Multiple Significant Trauma	1.98
MDC 25. Human Immunodeficiency Virus Infections	0.00

Literature based evidence specific to pediatric population

Surgeries in pediatric patients, because of their smaller anatomy, can be technically more complex and can carry a high risk of accidental puncture or laceration (e.g., 2.22 per 1,000 discharges at 0-17 years, 1.84 at 18-44 years, 2.82 at 45-64 years, and 3.47 at 65 or more years).[10] This indicator was investigated by two groups, although the definition differed slightly from the definition proposed above. Miller and colleagues analyzed HCUP data in 2000, using a publicly released version of this indicator applied to a pediatric population, and found a significant incidence of accidental puncture or laceration in pediatric patients (1.0 per 1,000 in 2000 among 0-18 year old children).[11] Additionally, Miller & Zhan found that this error resulted in increased mean length of stay (by 7.7 days) and charges per stay ($41,204 on average) in affected patients, with 2.7 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11] Sedman et al found observed rates varying from 1.7 per 1,000 in 1999 to 1.9 per 1,000 in 2002 in the NACHRI database (i.e., a slight upward trend over time), when applying the publicly released AHRQ QI definition to a pediatric population.[12]

DECUBITUS ULCER (PSI)

Indicator definition:

Number of patients with decubitus ulcer (see definition and exclusions below) per 1,000 eligible admissions (population at risk). See Pediatric Quality Indicator Technical Specifications.

Definition of decubitus ulcer:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: Decubitus ulcer: • Unspecified site [707.00] • Elbow [707.01] • Upper back [707.02] • Lower back [707.03] • Hip [707.04] • Buttock [707.05] • Ankle [707.06] • Heel [707.07] • Other site [707.09]	***a. All medical and surgical patients (defined by DRG), age 0-17 years, except exclusions (see below).*** ***b. Include only patients with a length of stay of 5 or more days.*** ***c. Exclude patients in MDC 9 (Diseases and disorders of the skin, subcutaneous tissue and breast).*** ***d. Exclude all neonates (age < 28 days).*** ***e. Stratify by high risk (hemi-, para-, and quadriplegia, spinia bifida and anoxic brain damage (dx codes 348.1, 768.5), mechanical ventilation >96 hrs.*** ***f. Exclude newborns with a birth weight less than 500g.*** ***g. Exclude patients transferring in from long term care facility or an acute care facility.*** ***h. Exclude obstetric patients (MDC 14)*** ***i. Exclude patients with a principal diagnosis of decubitus ulcer.*** ***j. Patients with an ICD-9-CM procedure code for debridement or pedicle graft before or on the same day as the major operating room procedure (surgical cases only).***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):			
OVERALL	3.16		
Age stratified rates:			
Neonate, < 2000g			
Neonate, ≥ 2000g			
29 days – 364 days	0.86		
1 – 2 years	1.93		
3 – 5 years	1.86		
6 – 12 years	3.58		
13 – 17 years	4.89		
Clinical stratification			
High risk: Quadri, hemi-, paraplegia, spina bifida, anoxic brain damage	23.08		
Low risk: All other patients	1.43		
Hospital type			
Children's		**Non-Children's**	
OVERALL	4.33	**OVERALL**	1.79
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g		**Neonate, < 2000g**	
Neonate, ≥ 2000g		**Neonate, ≥ 2000g**	
29 days – 364 days	1.38	**29 days – 364 days**	0.26
1 – 2 years	2.14	**1 – 2 years**	1.40
3 – 5 years	2.29	**3 – 5 years**	1.05
6 – 12 years	4.92	**6 – 12 years**	1.80
13 – 17 years	7.99	**13 – 17 years**	2.66
Clinical strata:		**Clinical strata:**	
High risk	21.76	**High risk**	24.53
Low risk	2.06	**Low risk**	0.76

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator will be included in the pediatric quality indicator set. Panelists rated this indicator favorably and with indeterminate agreement for internal quality improvement and comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
Age 0 – 85	Age 0 – 17	Pediatric age range
Premature neonates included.	Exclude normal neonates.	Normal neonates not at risk for developing condition.
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
No stratification	Stratify by low birth weight neonates (2000 g and under) and other patients.	Premature neonates are at risk for decubiti by different mechanism, due to fragile skin.
Exclude patients in MDC-9 or patients with any diagnosis of	Patients with paralysis are included.	Children rarely develop decubiti without underlying high risk

hemiplegia, paraplegia, or quadriplegia.		conditions.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
All patients, including high risk patients, examined together.	Although not yet implemented, panelists requested that high risk patients (paralysis, spina bifida, anoxic brain damage, mechanical ventilation) be examined separately.	These patients are at high risk for developing decubiti and are cared for disproportionately by tertiary care facilities.
Neonates included.	Exclude neonates.	"Skin breakdown," common terminology used for neonates, is coded to a separate and non-specific code. This complication cannot be captured in this population.
Include patients transferred from another acute care facility.	Exclude patients transferred from another acute care facility.	Like patients transferred from a long term care facility, these patients are at high risk for having decubiti present on admission.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
Exclude patients admitted from long term care facility	Include patients admitted from long term care facility	Although more rare for children to be admitted from a long term care facility, these patients are at higher risk for having decubiti present on admission

Clinical rationale

This indicator is intended to flag cases of in-hospital decubitus ulcers (pressure sores). Common practice asserts that decubiti can be prevented by frequent movement, close monitoring of at risk patients, and specialized beds or bedding.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the panel consisted of seven physicians: two general surgeons, a geriatrician, two adult hospitalists, an internist, and a nurse specialist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The panel modified several exclusion criteria that were based on the original Complications Screening Program indicator. Instead of excluding all very elderly patients because they may have pre-existing decubiti, panelists argued for the more limited exclusion of patients admitted from a long term care facility. Panelists also reduced the original length of stay requirement of 10 days to 4 days.

- Panelists noted that a few decubiti may not be preventable, and that charting will vary with the less severe decubiti.
- Panelists noted that very ill patients are at higher risk for decubiti.
- Panelists were interested in tracking decubiti in high risk patients, such as paralysis patients, and argued that these patients should be tracked separately.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of ten pediatric clinicians, including one neonatologist, one infectious disease specialist, one ambulatory care pediatrician, one pediatric hospitalist, one pediatric cardiovascular surgeon, one pediatric oncologist, two pediatric surgeons, one pediatric interventional radiologist, and one pediatric critical care physician. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The panel felt that the indicator was most useful when tracking high risk populations, including patients with hemiplegia, paraplegia, quadriplegia (e.g., due to cerebral palsy), spina bifida, muscular dystrophy or glycogen storage diseases and neurodevastation due to trauma. These patients are at high risk for developing ulcers due to neurologic impairments, and as a result may have ulcers present on admission. Despite the inability to easily distinguish ulcers present on admission, panelists felt they desired to have separates rates available for high risk and lower risk patients.
- Panelists noted that “skin breakdown” or “decubiti” in newborns rarely stem from gravity related causes, but rather from friction from equipment and other processes. These sores are rarely identified as decubiti, but rather as skin breakdown and panelists felt these are likely to be coded differently. Coding consultation will help inform the inclusion of newborns in this indicator.
- Given the need to accurately identify premature infants and light for gestational age infants as requested, additional definitional work is required and this indicator was not re-rated by panelists. It will be re-examined in the second round of pediatric indicator development.

The same panel participated in a second round of rating, which included preliminary rating, followed by a conference call, and a final rating. The panel was identical except for the attrition of three panelists (pediatric cardiovascular surgeon, pediatric oncologist, pediatric hospitalist). The panel re-reviewed three other indicators. In the course of review the panel further suggested the following, in addition to the comments from the previous review:

- The panel agreed that the inclusion and stratification of high risk patients is useful. They suggested that if possible ICU patients be included in the high risk patient groups, since these patients may be at high risk of developing the complication in hospital. The original stratification was proposed to stratify those that are at high risk of having a decubitus present on admission. Patients in the

ICU, unless chronically ill, however, are unlikely to have been admitted with decubiti.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	7	Indeterminate agreement
Overall rating – comparative purposes	7	Indeterminate agreement
Not present on admission	8	Indeterminate agreement
Preventability	7	Indeterminate agreement
Due to medical error	6	Indeterminate agreement
Charting by physicians	7	Indeterminate agreement
Lack of bias	4	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Acceptable (-)

Empirical analyses to inform indicator definition

Prior to panel review we examined the percentage of complications in this indicator related to high risk conditions, including paralysis, spina bifida, muscular dystrophy and glycogen storage diseases. Patients with high risk conditions constituted 30% of the numerator. No patients with glycogen storage disease were in the numerator.

The following empirical analyses were completed after the initial panel review using the 2003 KIDs' Inpatient Database (KID).

First, we examined the effect of adding an exclusion for patients transferred from an acute care facility, as suggested by the panelists. The change decreased the overall rate by 12%.

Second, we examined the risk of this complication based on several groups theorized to be higher risk. Based on the working definition at the time we found that three disorders were associated with higher risk: paralysis (RR = 12.3), spina bifida (RR = 22.8), and anoxic brain damage (RR =6.3). Patients with muscular dystrophy were not at elevated risk.

Finally we examined patients with a procedure code for mechanical ventilation. Current codes designate patients based on the duration of ventilation. Patients with continuous mechanical ventilation for less than 96 hours (96.71) were not at significantly higher risk for decubitus ulcer = (RR 1.34). Few patients had a code denoting "unspecified duration (code 96.70) (n=171) and none of those patients also had a code for decubitus ulcer. In contrast, patients with continuous ventilation for 96 hours or more had a significantly elevated risk (RR = 6.68).

Literature based evidence specific to pediatric population

While children, on the whole, are more active and less chronically ill than their adult counterparts, decubitus ulcers are of great concern to those caring for critically ill infants and children. These skin injuries represent a significant iatrogenic problem in pediatric health care. It is known that interventions such as frequent turning, repositioning, softer bedding surfaces (e.g. egg crate foam), and elevating heels off bed surfaces can be used to lessen pressure-related injuries.[13, 14] Also, studies have attempted to modify existing adult risk assessment tools to the pediatric population to help medical personnel assess the risk for decubitus ulcers in their patients.[14-16]

Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. This indicator was applied to pediatric hospital populations (e.g., 7.67 per 1,000 discharges at 0-17 years, 4.95 at 18-44 years, 9.84 at 45-64 years, and 25.17 at 65 or more years).[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. Miller and colleagues analyzed HCUP data from 2000 and found a significant incidence of decubitus ulcers in pediatric patients 0-18 years of age (2.4 per 1,000).[11] Sedman et al found observed rates varying from 4.1 per 1,000 in 1999 to 4.3 per 1,000 in 2001 in the NACHRI database (i.e., a slight upward trend over time).[12] Additionally, Miller & Zhan found that this complication resulted in increased mean length of stay (by 18 days) and $85,344 in increased charges in affected patients, with 3.5 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11]

FOREIGN BODY LEFT IN DURING PROCEDURE (PSI)

Indicator definition:

Number of patients with a foreign body unintentionally left in during a procedure (see definition and exclusions below) per 1,000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of foreign body left in during procedure:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Foreign body accidentally left during a procedure [998.4] • Acute reactions to foreign substance accidentally left during a procedure [998.7] Foreign body left in during: • Surgical operation [E871.0] • Infusion or transfusion [E871.1] • Kidney dialysis or other perfusion [E871.2] • Injection or vaccination [E871.3] • Endoscopic examination [E871.4] • Aspiration of fluid or tissue, puncture, and catheterization [E871.5] • Heart catheterization [E871.6] • Removal of catheter or packing [E871.7] • Other specified procedures [E871.8] • Unspecified procedure [E871.9]	***a. All medical and surgical patients (defined by DRG), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis code for foreign body left in during procedure.*** ***c. Exclude normal newborns [DRG 391].*** ***d. Exclude newborns with a birth weight less than 500g.*** ***e. Exclude obstetric patients (MDC 14).***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):

OVERALL	0.031		
Age stratified rates:			
Neonate, < 2000g	0.036		
Neonate, ≥ 2000g	0.003		
29 days – 364 days	0.035		
1 – 2 years	0.029		
3 – 5 years	0.036		
6 – 12 years	0.051		
13 – 17 years	0.063		
Hospital type			
Children's		**Non-Children's**	
OVERALL	0.067	**OVERALL**	0.013
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	0.097	**Neonate, < 2000g**	0.017
Neonate, ≥ 2000g	0.011	**Neonate, ≥ 2000g**	0.002
29 days – 364 days	0.081	**29 days – 364 days**	0.000
1 – 2 years	0.070	**1 – 2 years**	0.006
3 – 5 years	0.091	**3 – 5 years**	0.000
6 – 12 years	0.072	**6 – 12 years**	0.017
13 – 17 years	0.084	**13 – 17 years**	0.058

Status summary. Based on the current evidence base, from the pediatric literature review pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably for use both for internal quality improvement and comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Newborns included.	Exclude normal newborns [DRG 391].	Normal newborns rarely undergo procedures that place them at risk for this complication.
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional changes.		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to flag cases of a foreign body accidentally left in a patient's body during a procedure. It is based on an indicator originally developed as part of the Complications Screening Program by Lisa Iezzoni and colleagues. Interventions such as surgical instrument counting and post-operative imaging have been implemented to reduce the number of foreign bodies unintentionally left in during a procedure.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed twice during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator, the first panel (multispecialty) consisted of 6 clinicians: a general surgeon, an internist, two adult hospitalists, and two specialized nurses. The second (surgery specialist) panel consisted of 9 clinicians: a urologist, a transplant surgeon, two orthopedic surgeons, a pediatric neurosurgeon, a neurosurgeon, and two colon and rectal surgeons. Both panels reviewed several other indicators. In the course of review the panels suggested or noted the following:

- Suture granulomas requiring treatment are also detected by this indicator (because the retained suture is a foreign body). Panelists noted that these are substantially different than other foreign bodies, but did not feel this invalidated the indicator.

- Panelists expressed concern that some foreign bodies are left in intentionally and may be coded due to lack of clear documentation by physicians. Also some foreign bodies do not cause substantial morbidity.
- The patients included in the denominator may not actually undergo a procedure. Panelists felt that limiting the denominator to surgical patients would too severely reduce the sensitivity of this indicator, because foreign bodies may be left in during bedside procedures such as central line placement.

Results of pediatric clinician panel review

This indicator was also reviewed, during the current development process by a panel of eleven pediatric clinicians, including one general pediatrician, one pediatric hospitalist, one pediatric critical care physician, one neonatologist, one pediatric infectious disease specialist, one pediatric hematologist/oncologist, one pediatric cardiothoracic surgeon, one pediatric emergency medicine specialist, on pediatric interventional radiologist, and two pediatric surgeons. In the course of review the panels suggested or noted the following:

- Panelists agreed that many foreign bodies will not be discovered until after discharge or may result from outpatient surgery. In order to track these complications, an area level indicator will be developed for this indicator, which includes principal diagnoses for foreign body, and which utilizes a population denominator. The area level indicator is intended to capture transfers and readmissions for foreign body. It will be available in addition to this hospital-based indicator.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating – comparative purposes	8	Agreement
Not present on admission	8	Agreement
Preventability	8	Agreement
Due to medical error	7	Indeterminate agreement
Charting by physicians	7	Agreement
Lack of bias	7.5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (+)

Literature based evidence specific to pediatric population

Children, as adults, are at risk for having foreign bodies left in the surgical field after a procedure. The incidence of this indicator, using the publicly available definition was investigated in pediatric populations (e.g., 0.07 per 1,000 discharges at 0-17 years, 0.07 at 18-44 years, 1.10 at 45-64 years, and 0.09 at 65 or more years).[10] Miller and colleagues analyzed HCUP data from 1997, using a predecessor of the AHRQ Patient Safety Indicators, and found a rate of 0.02 per 1,000 discharges in 1997.[17] Other groups

have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. Miller et al analyzed HCUP data from 2000, and found a rate of 0.05 per 1,000 discharges in 2000, for foreign body left in during procedure among 0-18 year old children.[11] Sedman et al found observed rates varying from 0.14 per 1,000 in 2000 to 0.10 per 1,000 in 1999 in the NACHRI database (without any consistent trend over time).[12] Additionally, Miller & Zhan found that this error resulted in an increased mean length of stay (by 5.7 days) and an average of $31,366 in increased charges in affected patients, with no significant effect on in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11]

IATROGENIC PNEUMOTHORAX (IN NEONATES AT RISK) (PSI)

Indicator definition:

Number of patients with an iatrogenic pneumothorax (see definition and exclusions below) per 1,000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of iatrogenic pneumothorax:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Iatrogenic pneumothorax [512.1]	***a. All neonates (defined by DRG), with a birthweight 2500 g or less, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis of iatrogenic pneumothorax.*** ***c. Exclude patients with any diagnosis of chest trauma.*** ***d. Exclude patients with any code indicating thoracic surgery or lung or pleural biopsy or assigned to cardiac surgery DRGs.*** ***e. Exclude normal newborns.*** ***f. Stratify rates by birthweight (500 g increments).*** ***g. Exclude newborns with a birth weight less than 500g.*** ***h. Exclude patients with any procedure code for diaphragmatic surgery.*** ***i. Exclude patients with any diagnosis of pleural effusion.***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):

OVERALL	0.372
Weight stratified rates:	
500 – 999 g	2.084
1000 – 1499 g	0.447
1500 – 1999 g	0.234
2000 – 2499 g	0.081

Hospital type			
Children's		**Non-Children's**	
OVERALL	0.675	**OVERALL**	0.296
Age stratified rates:		**Age stratified rates:**	
500 – 999 g	3.321	**500 – 999 g**	1.457
1000 – 1499 g	0.505	**1000 – 1499 g**	0.464
1500 – 1999 g	0.230	**1500 – 1999 g**	0.254
2000 – 2499 g	0.080	**2000 – 2499 g**	0.087

Status summary. Based on the current evidence base, from the pediatric literature review pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably and with agreement for use in internal quality improvement and favorably with indeterminate agreement for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review
NOTE: The pre-panel definition combined neonatal and non-neonatal patients

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
No stratification.	Stratify rates by low birth weight neonate (500g increments) and other patients.	Risk for pneumothorax increases dramatically with lower birth weight.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
One indicator included both barotrauma and procedural caused pneumothoraces.	Two indicators were created – one for high risk neonates (birthweight less than 2500 g) and one for other patients.	It is not possible to separate barotrauma from procedural caused pneumothoraces. Since premature infants are at higher risk for barotrauma, panelists suggested they be examined in a separate indicator.
All trauma patients excluded.	Chest trauma patients excluded.	Only chest trauma patients are at elevated risk for traumatic pneumothoraces.
Include patients with any procedure code of diaphragm surgery	Exclude discharges with any procedure code of diaphragm surgery	Pneumothorax is an expected complication for these patients.
Include patients with pleural effusion.	Exclude patients with pleural effusion.	These patients almost always receive chest tubes to drain the effusion and pneumothorax is expected following removal. Although such an expected complication is not technically a codable complication, it is “cleaner” to remove these patients.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to flag cases of pneumothorax caused by medical care in high risk neonates. Premature neonates are at higher risk of developing barotrauma due to

ventilation. Close monitoring of ventilation and pressures decreases the risk of pneumothorax. These patients may also sustain pneumothoraces secondary to procedures. Good technique may reduce the rate of these pneumothoraces.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the panel consisted of 8 physicians: an internist and gastroenterologist, a general surgeon, a cardiologist and critical care physician, two interventional radiologists, two specialized nurses, and an anesthesiologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The exclusion (currently implemented) of patients undergoing a procedure that involves entering the lung parenchyma or opening the pleural space (because incidental pneumothoraces are anticipated after these procedures).
- Restriction to patients receiving a central line, Swan-Ganz catheter or thoracentesis (because these are the patients for whom iatrogenic pneumothoraces are most likely to be preventable). However, empirical analyses revealed that these procedures were not reliably identified using administrative data, and this recommendation could not be implemented.
- Identification of central line placement approach, since pneumothoraces may be reduced by using specific approaches (e.g., internal jugular instead of subclavian), while increasing other potentially serious complications. Because the placement approach is not designated in ICD-9-CM, this recommendation could not be implemented.
- The exclusion or stratification of pneumothoraces with barotrauma. Because it is not possible to identify the cause of pneumothoraces using administrative data, this recommendation could not be implemented.

Results of pediatric clinician panel review

This indicator was also reviewed, during the current development process by a panel of eleven pediatric clinicians, including one general pediatrician, one pediatric hospitalist, one pediatric critical care physician, one neonatologist, one pediatric infectious disease specialist, one pediatric hematologist/oncologist, one pediatric cardiothoracic surgeon, one pediatric emergency medicine specialist, one pediatric interventional radiologist, and two pediatric surgeons. In the course of review the panels suggested or noted the following:

- At the onset of the review, this indicator included both neonates and other pediatric patients. Panelists, like the previous panel, argued for the stratification by cause of pneumothoraces (i.e. barotrauma vs. procedure related). Again, cause is not discernible using the data. In order to better analyze the data, the panel split the indicator into two separate indicators: 1.) iatrogenic pneumothorax (neonates), and 2.) iatrogenic pneumothorax (non-neonates). The first indicator, presented

here, examines iatrogenic pneumothorax in neonates under 2500g, as a group that is at particularly elevated risk for pneumothorax due to barotrauma, in addition to line-related pneumothorax. This indicator is limited to neonates with a recorded birthweight of less than 2500 g. This indicator is stratified by birthweight groups in 500 gram increments.

- Panelists argued for the narrowing of the previous exclusion of all trauma patients to include only chest trauma, as panelists expressed that only chest trauma patients are truly at higher risk for pneumothorax. This exclusion is unlikely to affect the neonatal version of this indicator.
- An exclusion for patients undergoing diaphragmatic surgery was added, as these patients may incur a pneumothorax as an expected complication.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating – comparative purposes	7	Indeterminate agreement
Not present on admission	8	Agreement
Preventability	5	Agreement
Due to medical error	3	Indeterminate agreement
Charting by physicians	8	Agreement
Lack of bias	4	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (-)

Literature based evidence specific to pediatric population

In children procedures like central line placement, thoracentesis, or Swan-Ganz catheter placement can be technically more complex than in older patients, due to their smaller anatomy (though they are more likely to be performed in a monitored setting). Also, in comparison to adults, iatrogenic pneumothoraces in neonates are primarily due to barotrauma, with the very smallest infants being at greatest risk (as shown by our preliminary empirical analyses). In an older pediatric population, while barotrauma can occur, the risks for iatrogenic pneumothoraces are more clinically similar to an adult population (e.g. at risk while receiving a central line, catheter, or undergoing thoracentesis procedures).

Important interventions are available which have been shown to decrease the incidence of barotrauma and pneumothoraces in the low birth weight neonate population. For example, timely administration of antenatal steroids, use of prophylactic surfactant, and appropriate resuscitation and ventilation of the smallest infants (<30 weeks gestational age) have all been shown to reduce the risk of iatrogenic pneumothoraces in these patients.[18-21] While low birth weight infants are also at risk for pneumothoraces when undergoing medical procedures, the prevention of pneumothoraces in this population is more focused on preventing injury to an immature lung during ventilation.

Using 1997 HCUP data, the National Healthcare Quality Report, cited rates of iatrogenic pneumothoraces in the pediatric population (< 19 years). These analyses showed that this patient safety event occurred frequently and at rates comparable to those in adults (e.g., 0.48 per 1,000 discharges at 0-17 years, 0.42 at 18-44 years, 0.43 at 45-64 years, and 0.74 at 65 or more years).[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. In 2000, Miller et al found iatrogenic pneumothoraces occurred at a rate of 0.3 per 1,000 discharges among 0-18 year old children.[11] Also, iatrogenic pneumothorax was found to result in, on average, 11.6 days increased length of stay, $61,991 increased charges, and 7.5 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11] An analysis of NACHRI data from 1999 to 2002 showed a range of rates (risk adjusted) from 0.74 per 1,000 discharges in 2002 to 0.82 per 1,000 discharges in 1999 (i.e., a slight downward trend over time).[12]

IATROGENIC PNEUMOTHORAX IN NON-NEONATES (PSI)

Indicator definition:

Number of patients with an iatrogenic pneumothorax (see definition and exclusions below) per 1,000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of iatrogenic pneumothorax:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Iatrogenic pneumothorax [512.1]	***a. All medical and surgical patients (defined by DRG), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis of iatrogenic pneumothorax.*** ***c. Exclude patients with any diagnosis of chest trauma.*** ***d. Exclude patients with any code indicating thoracic surgery or lung or pleural biopsy or assigned to cardiac surgery DRGs.*** ***e. Exclude normal newborns and newborns with a birthweight of 2500 g or less.*** ***h. Exclude all obstetric discharges (MDC 14).*** ***i. Exclude patients with any procedure code for diaphragmatic surgery.*** ***j. Exclude patients with any diagnosis of pleural effusion.***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):			
OVERALL	0.213		
Age stratified rates:			
Neonate	0.105		
29 days – 364 days	0.246		
1 – 2 years	0.186		
3 – 5 years	0.222		
6 – 12 years	0.202		
13 – 17 years	0.417		
Hospital type			
Children's		**Non-Children's**	
OVERALL	0.439	**OVERALL**	0.108
Age stratified rates:		**Age stratified rates:**	
Neonate	0.234	**Neonate**	0.080
29 days – 364 days	0.452	**29 days – 364 days**	0.117
1 – 2 years	0.355	**1 – 2 years**	0.090
3 – 5 years	0.354	**3 – 5 years**	0.137
6 – 12 years	0.363	**6 – 12 years**	0.092
13 – 17 years	0.860	**13 – 17 years**	0.182

Status summary. Based on the current evidence base, from the pediatric literature review pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably with agreement for use in internal quality improvement and favorably with indeterminate agreement for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review
NOTE: The pre-panel definition combined neonatal and non-neonatal patients

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
No stratification.	Stratify rates by low birth weight neonate (500g increments) and other patients.	Risk for pneumothorax increases dramatically with lower birth weight.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
One indicator included both barotrauma and procedural caused pneumothoraces.	Two indicators were created – one for high risk neonates (birthweight less than 2500 g) and one for other patients.	It is not possible to separate barotrauma from procedural caused pneumothoraces. Since premature infants are at higher risk for barotrauma, panelists suggested they be examined in a separate indicator.
All trauma patients excluded.	Chest trauma patients excluded.	Only chest trauma patients are at

		elevated risk for traumatic pneumothoraces.
Include patients with any procedure code of diaphragm surgery	Exclude discharges with any procedure code of diaphragm surgery	Pneumothorax is an expected complication for these patients.
Include patients with pleural effusion.	Exclude patients with pleural effusion.	These patients almost always receive chest tubes to drain the effusion and pneumothorax is expected following removal. Although such an expected complication is not technically a codable complication, it is "cleaner" to remove these patients.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to flag cases of pneumothorax caused by medical care, which is sustained following a procedure or due to barotrauma. Good technique when performing vascular access or thorocentesis may reduce the risk of this complication. For patients on ventilators, monitoring of pressures may also reduce the risk of this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the panel consisted of 8 physicians: an internist and gastroenterologist, a general surgeon, a cardiologist and critical care physician, two interventional radiologists, two specialized nurses, and an anesthesiologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The exclusion (currently implemented) of patients undergoing a procedure that involves entering the lung parenchyma or opening the pleural space (because incidental pneumothoraces are anticipated after these procedures).
- Restriction to patients receiving a central line, Swan-Ganz catheter or thoracentesis (because these are the patients for whom iatrogenic pneumothoraces are most likely to be preventable). However, empirical analyses revealed that these procedures were not reliably identified using administrative data, and this recommendation could not be implemented.
- Identification of central line placement approach, since pneumothoraces may be reduced by using specific approaches (e.g., internal jugular instead of subclavian), while increasing other potentially serious complications. Because the placement approach is not designated in ICD-9-CM, this recommendation could not be implemented.

- The exclusion or stratification of pneumothoraces with barotrauma. Because it is not possible to identify the cause of pneumothoraces using administrative data, this recommendation could not be implemented.

Results of pediatric clinician panel review

This indicator was also reviewed, during the current development process by a panel of eleven pediatric clinicians, including one general pediatrician, one pediatric hospitalist, one pediatric critical care physician, one neonatologist, one pediatric infectious disease specialist, one pediatric hematologist/oncologist, one pediatric cardiothoracic surgeon, one pediatric emergency medicine specialist, one pediatric interventional radiologist, and two pediatric surgeons. In the course of review the panels suggested or noted the following:

- At the onset of the review, this indicator included both neonates and other pediatric patients. Panelists, like the previous panel, argued for the stratification by cause of pneumothoraces (i.e. barotrauma vs. procedure related). Again, cause is not discernible using the data. In order to better analyze the data, the panel split the indicator into two separate indicators: 1.) iatrogenic pneumothorax (neonates), and 2.) iatrogenic pneumothorax (non-neonates). The second indicator, which is presented here, examines all other pediatric patients, using an exclusion of both normal newborns and neonates with a recorded birthweight of less than 2500 grams.
- Panelists argued for the narrowing of the previous exclusion of all trauma patients to include only chest trauma, as panelists expressed that only chest trauma patients are truly at higher risk for pneumothorax.
- An exclusion for patients undergoing diaphragmatic surgery was added, as these patients may incur a pneumothorax as an expected complication.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating – comparative purposes	7	Indeterminate agreement
Not present on admission	7.5	Agreement
Preventability	7	Indeterminate agreement
Due to medical error	6	Indeterminate agreement
Charting by physicians	7.5	Agreement
Lack of bias	4	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (-)

Empirical analyses to inform indicator definition

The following empirical analyses were completed after the initial panel review using the 2003 KIDs' Inpatient Database (KID).

We examined codes for pleural effusion, since patients with pleural effusion receive chest tubes and pneumothorax often follows the removal of chest tubes. While these, when not requiring further treatment, are not codable complications, we wished to see whether these patients appeared in this indicator. We found that the rate of iatrogenic pneumothorax in these patients to be very high (13.46 – 45.52 per 1000 patients with pleural effusion compared to 0.21 per 1000 patients overall). We found that a little over 20% of numerator patients had a diagnosis code of pleural effusion.

Literature based evidence specific to pediatric population [Same as previous iatrogenic pneumathorax indicator]

In children procedures like central line placement, thoracentesis, or Swan-Ganz catheter placement can be technically more complex than in older patients, due to their smaller anatomy (though they are more likely to be performed in a monitored setting). Also, in comparison to adults, iatrogenic pneumothoraces in neonates are primarily due to barotrauma, with the very smallest infants being at greatest risk (as shown by our preliminary empirical analyses). In an older pediatric population, while barotrauma can occur, the risks for iatrogenic pneumothoraces are more clinically similar to an adult population (e.g. at risk while receiving a central line, catheter, or undergoing thoracentesis procedures).

Important interventions are available which have been shown to decrease the incidence of barotrauma and pneumothoraces in the low birth weight neonate population. For example, timely administration of antenatal steroids, use of prophylactic surfactant, and appropriate resuscitation and ventilation of the smallest infants (<30 weeks gestational age) have all been shown to reduce the risk of iatrogenic pneumothoraces in these patients.[18-21] While low birth weight infants are also at risk for pneumothoraces when undergoing medical procedures, the prevention of pneumothoraces in this population is more focused on preventing injury to an immature lung during ventilation.

Using 1997 HCUP data, the National Healthcare Quality Report, cited rates of iatrogenic pneumothoraces in the pediatric population (< 19 years). These analyses showed that this patient safety event occurred frequently and at rates comparable to those in adults (e.g., 0.48 per 1,000 discharges at 0-17 years, 0.42 at 18-44 years, 0.43 at 45-64 years, and 0.74 at 65 or more years).[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. In 2000, Miller et al found iatrogenic pneumothoraces occurred at a rate of 0.3 per 1,000 discharges among 0-18 year old children.[11] Also, iatrogenic pneumothorax was found to result in, on average, 11.6 days increased length of stay, $61,991 increased charges, and 7.5 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11] An analysis of NACHRI data from 1999 to 2002 showed a range of rates (risk adjusted) from 0.74 per 1,000 discharges in 2002 to 0.82 per 1,000 discharges in 1999 (i.e., a slight downward trend over time).[12]

POSTOPERATIVE PHYSIOLOGIC AND METABOLIC DERANGEMENT (PSI)

Indicator definition:

Number of patients with physiologic and metabolic derangements (see definition and exclusions below) per 1000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of physiologic and metabolic derangements:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Diabetes with ketoacidosis (type I and type II) [250.10 – 250.13] • Diabetes with hyperosmolarity (type I and type II) [250.20 – 250.23] • Diabetes with other coma (type I and type II) [250.30 – 250.33] • Acute renal failure [584.5 – 584.9] Codes for acute renal failure must be accompanied with a procedure code for dialysis.	***a. All elective surgical patients (defined by DRG and admission type), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis code for physiologic and metabolic derangements and patients where a procedure for dialysis occurs before or on the same day as the first operating room procedure.*** ***c. Exclude patients with both a diagnosis code of ketoacidosis, hyperosmolarity, or other coma (subgroups of physiologic and metabolic derangements coding) AND a principal diagnosis of diabetes.*** ***d. Exclude patients with both a secondary diagnosis code for acute renal failure (subgroup of physiologic and metabolic derangements coding) AND a principal diagnosis of AMI, cardiac arrhythmia, cardiac arrest, shock, hemorrhage or gastrointestinal hemorrhage.*** ***e. Exclude obstetric patients (MDC 14)*** ***f. Exclude newborns with a birth weight less than 500g.*** ***g. Exclude patients with any diagnosis for cancer.***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):			
OVERALL			
Age stratified rates:			
Neonate, < 2000g			
Neonate, ≥ 2000g			
29 days – 364 days			
1 – 2 years			
3 – 5 years			
6 – 12 years			
13 – 17 years			
Hospital type			
Children's		**Non-Children's**	
OVERALL		**OVERALL**	
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g		**Neonate, < 2000g**	
Neonate, ≥ 2000g		**Neonate, ≥ 2000g**	
29 days – 364 days		**29 days – 364 days**	
1 – 2 years		**1 – 2 years**	
3 – 5 years		**3 – 5 years**	
6 – 12 years		**6 – 12 years**	
13 – 17 years		**13 – 17 years**	

Status summary. Based on the current evidence base from the pediatric literature review, and pediatric panel review, this indicator is not recommended for inclusion in the pediatric quality indicator set. See summary of evidence below for justification.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
Cancer patients included.	Cancer patients excluded.	Cancer patients are at higher risk for these complications, as a result of tumor lysis syndrome or chemotherapy. However, their preventability is in question,.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
Per panel recommendation, only acute renal failure and diabetic complications included.	Other derangements, including hypokalemia, hyper or hyponatremia, or hyper or hypocalcemia considered.	Distinguishing between clinically significant complications and minor derangements is difficult. Distinguishing between derangements present on

		admission and complications is also difficult.
Adults have higher rates of diabetes and these complications than children.	Because of very low rate, consider limiting denominator to cardiac patients only.	More clinician feedback and investigation regarding validity of suggestion needed before implementation.

Clinical rationale

This indicator is intended to flag cases of selected postoperative metabolic or physiologic complications, specifically acute renal failure and diabetes related complications. The population at risk is limited to elective surgical patients, as patients undergoing non-elective surgery may develop less preventable derangements or may have these derangements present at admission. High quality care may reduce the rate of this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed twice during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the first panel (multispecialty) consisted of 5 clinicians: a critical care physician, an adult hospitalist, two specialized nurses, and an anesthesiologist. The second (surgery specialist) panel consisted of 6 clinicians: a spine surgeon, a pediatric neurosurgeon, a transplant surgeon, a female urologist, a colon and rectal surgeon, and an orthopedic surgeon. Both panels reviewed several other indicators. In the course of review the panels advocated for the following:

- The multispecialty panel suggested that in addition to the diabetic complications, hyponatremia should also be included.
- Both panels considered and rejected a code for post-operative shock, due to the non-specific nature of this condition.
- Both panels argued for the restriction of this indicator to elective surgery patients.
- Both panels noted that some conditions may be variably coded and of varied clinical significance, leading the second panel to reject hyponatremia, oliguria and anuria, and restricting acute renal failure to cases requiring dialysis.
- The two panels created two different definitions for this indicator. The most conservative definition was selected.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of twelve pediatric clinicians, one pediatric critical care specialist, one pediatric hospitalist, one pediatric anesthesiologist, one pediatric hematologist/oncologist, one pediatric cardiologist, two pediatric surgeons, one pediatric neurosurgeon, one pediatric urologist, two pediatric cardiovascular surgeons, and one neonatologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists noted that this complication is rare in children. Unlike other rare indicators, they suggested that it would be of limited use, with the possible exception of renal failure in cardiac surgery patients. Preventability of cases may be unclear and quality review in hospitals is almost always undertaken. Limiting the indicator to cardiac surgery patients was not implemented since further feedback would be necessary to implement.
- Panelists discussed other types of derangements such as hyponatremia and hypo/hyperkalemia, but these were rejected since the presence of the condition on admission and the severity of the complication cannot be discerned using administrative data.
- Panelists requested an exclusion for oncology patients, as these patients may develop derangements as a result of tumor lysis syndrome or from chemotherapy.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	6.5	Indeterminate agreement
Overall rating - comparative	6.5	Indeterminate agreement
Not present on admission	8	Agreement
Preventability	7	Indeterminate agreement
Due to medical error	6	Agreement
Charting by physicians	7	Indeterminate agreement
Lack of bias	6.5	Indeterminate agreement
Final recommendation	Not recommended for internal QI or comparative purposes	

Additional evidence not specific to pediatric population

Recent unpublished work using linked administrative and clinical data from the VA Healthcare System showed that the current definition of this indicator has a sensitivity of 39% (i.e., capturing only 39% of the patients who truly experienced postoperative renal failure) with a positive predictive value of 54%. The latter finding is not surprising because the VA clinical definition is limited to acute renal failure, and does not include diabetic complications. [22]

Literature based evidence specific to pediatric population

While the pediatric population has lower rates of diabetes and renal failure than adult patients, children are also at risk for metabolic and physiologic complications after surgeries. The incidence of these complications was investigated in pediatric populations (e.g., 0.91 per 1,000 discharges at 0-17 years, 0.54 at 18-44 years, 0.86 at 45-64 years, and 1.33 at 65 or more years).[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. Miller and Zhan analyzed HCUP data from 2000 and found 6 pediatric patients (0-18 years of age) per 10,000 discharges with the diagnosis of postoperative physiologic / metabolic derangement. Additionally, they

found that this complication resulted in an increased mean length of stay (by 16.3 days) and $112,532 in increased charges in affected patients, with 45.8 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11, 17]

POSTOPERATIVE HEMORRHAGE AND HEMATOMA (PSI)

Indicator definition:

Number of patients with postoperative hemorrhage or hematoma requiring a procedure (see definition and exclusions below) per 1000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of hemorrhage and hematoma requiring a procedure:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Hematoma complicating a procedure [998.12] ***With any procedure code for drainage of hematoma.*** ***OR*** ***Secondary diagnosis code for:*** • Hemorrhage complicating a procedure [998.11] ***With any procedure code for control of hemorrhage.***	***a. All elective surgical patients (defined by DRG), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with a principal diagnosis of hemorrhage or hematoma, patients where the only operating room procedure is control of hemorrhage or drainage of hematoma, or patients where a procedure for control of hemorrhage or drainage of hematoma occurs before the first operating room procedure.*** ***c. Exclude newborns with a birth weight less than 500g.*** ***d. Exclude obstetric patients (MDC 14)*** ***e. Stratified rates will be available for patients with any diagnosis code indicating for specified coagulopathies (Congenital clotting factor deficiencies, Von Willebrand's disease, primary, secondary and unspecified thrombocytopenia, intrinsic circulating anticoagulants, defibrination syndrome and acquired coagulation factor deficiency) or any procedure code for Extracorporeal Membrane Oxygenation (ECMO).***

See rates on following page.

Rates based on year 2003 KIDs' Inpatient Database (per 1000):			
OVERALL	1.76		
Age stratified rates:			
Neonate, < 2000g	0.00		
Neonate, ≥ 2000g	1.04		
29 days – 364 days	4.12		
1 – 2 years	1.27		
3 – 5 years	1.32		
6 – 12 years	1.41		
13 – 17 years	1.27		
Clinical stratification			
High risk: Specified coagulopathies and ECMO	18.47		
Low risk: All other patients	1.50		
Hospital type			
Children's		**Non-Children's**	
OVERALL	2.06	**OVERALL**	1.28
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	0.00	**Neonate, < 2000g**	0.00
Neonate, ≥ 2000g	1.88	**Neonate, ≥ 2000g**	0.00
29 days – 364 days	4.92	**29 days – 364 days**	1.57
1 – 2 years	1.63	**1 – 2 years**	0.36
3 – 5 years	1.07	**3 – 5 years**	2.18
6 – 12 years	1.47	**6 – 12 years**	1.43
13 – 17 years	1.25	**13 – 17 years**	1.17
Clinical strata:		**Clinical strata:**	
High risk	18.50	**High risk**	24.54
Low risk	1.74	**Low risk**	1.08

Status summary. Based on the current evidence base, from the pediatric literature review pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric indicator set. Panelists rated this indicator favorably and with agreement for both internal quality improvement and comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
Patients with coagulopathies identifiable through administrative data included (tend to be a small percentage in adults).	Exclude patients with any diagnosis code indicating specified coagulopathies	Congenital coagulopathies constitute a higher percentage of total coagulopathies than in adults and pediatric patients are at higher risk.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
All surgery types included.	Limit to elective surgery patients.	Limiting to elective surgery

		patients allows for the inclusion of high risk patients, as these patients should be adequately controlled if surgery is elective.
Exclude patients with specified congenital coagulopathies.	Stratify patients with any coagulopathy (acquired or congenital) ascertainable with administrative data. Include patients on ECMO in high risk stratum.	With proper prophylaxis, most serious bleeding in patients with coagulopathies is preventable in elective surgeries. Only a mimimal number of cases where the coagulopathy was not previously known will be included. Nonetheless, all patients with coagulopathy are at higher risk for bleeding, and are generally cared for by tertiary care centers.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to flag cases of hemorrhage or hematoma following a surgical procedure. It is based on an indicator developed as part of the Complications Screening Program. This indicator limits hemorrhage and hematoma codes to secondary procedure and diagnosis codes in order to isolate those hemorrhages that can truly be linked to a surgical procedure. High quality surgical technique and proper prophylaxis in high risk patients may reduce the risk of this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed twice during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator, the first panel (multispecialty) consisted of 7 clinicians: a cardiologist, a trauma surgeon, a critical care physician, a hospitalist, an internist, and two nurse specialists. The second (surgery specialist) panel consisted of 6 clinicians: a trauma surgeon, a pediatric neurosurgeon, three orthopedic surgeons and a female urologist. Both panels reviewed several other indicators. In the course of review the panels advocated for the following:

- Panelists argued for risk adjustment by procedure type and comorbidity as possible.
- Surgeons removed seromas from the definition of this indicator, citing the insignificant nature of many seromas.
- Surgeons noted that post-procedural (non OR) hemorrhages are not included in this indicator, although such procedure-related hemorrhages may be clinically significant.

- Surgeons argued for the exclusion of patients on anticoagulant therapies or coagulopathies, although in adult populations few of the common conditions can be identified using administrative data.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of twelve pediatric clinicians, one pediatric critical care specialist, one pediatric hospitalist, one pediatric anesthesiologist, one pediatric hematologist/oncologist, one pediatric cardiologist, two pediatric surgeons, one pediatric neurosurgeon, one pediatric urologist, two pediatric cardiovascular surgeons, and one neonatologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- First, panelists argued that this indicator should be limited to elective surgery patients, but should include children with congenital and acquired coagulopathies. This would then allow the indicator to evaluate peri-operative management of hemostasis in high risk groups in a, theoretically, controlled situation.
- Despite the desire to track high risk children, panelists requested that rates in patients with coagulopathy be available separately, since children are not routinely screened for coagulopathy and may be more likely to have hemorrhage due to coagulopathy than adults. Panelists requested both acquired and congenital coagulopathies be included, since both types are related to higher risk of bleeding.

NOTES: Although not expressly discussed by the panel, we would like to note that many coagulation disorders are diagnosed only after bleeding occurs. Because of this, the strata of patients with coagulopathies likely does not include all high risk patients, as some patients with coagulopathies may not be diagnosed if they do not have a bleed. In addition, some patients may have acquired coagulopathies due to suboptimal care during the hospitalization. Consequently, an adverse effect of providing a high risk stratum is the possibility for hospitals to code more patients with coagulopathies in uncertain circumstances in order to reduce the low risk strata rates. We suggest reviewing the overall rate as well as the stratified rates.

During a discussion of a separate indicator, panelists noted that the definition of elective may be “fuzzy” in some instances. Panelists struggled to define exactly what elective surgery would entail, given the use of the ATYPE variable. Although not expressly noted by the panel, we should note that the validity of the ATYPE variable for defining elective surgery in children is not known, although analyses in adults have demonstrated that ATYPE often captures types of surgeries which are commonly elective.[23] Children may be at higher risk for having “urgent” rather than “emergent” surgeries, due to the higher use of tertiary care centers. It is unknown whether these “urgent” surgeries are mis-classified as emergent in subsequent numbers to affect the indicator.

Post-conference call panel ratings

Question	Median	Agreement status

Overall rating – internal QI	7	Agreement
Overall rating - comparative	7	Agreement
Not present on admission	8	Agreement
Preventability	7	Agreement
Due to medical error	4.5	Indeterminate agreement
Charting by physicians	8	Agreement
Lack of bias	6	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (+)

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

Before panel review, we reviewed the risk of developing this complication for patients with congenital coagulopathies (ICD-9-CM codes 286.0-286.4 and 286.5, although this former code may include some acquired coagulopathies). The results of the analyses demonstrated an almost 10-fold increased risk of coagulopathy, although the frequency of these codes was rare (5 cases in the numerator and 696 in the denominator). The inclusion of 286.5 was questioned at this stage, because this code includes "hyperheparinemia". In other words, if a patient receives an overdose of heparin, with subsequent hemorrhage, the diagnosis would be 286.5 plus an E-code from the drug toxicity chapter of the ICD-9-CM coding system. None of the cases in the numerator had code 286.5.

The panelists then suggested that all coagulopathies are of interest and asked that all be stratified (i.e., congenital and acquired). A second analysis, using the most current definition, was undertaken to determine the relative risk for post-operative hemorrhage and hematoma complication among patients with coagulopathies. When undergoing elective surgery none of the 539 children with congenital/chronic coagulopathies (ICD-9-CM codes 286.0-286.4, 287.1, 287.3, 287.8, 287.9) had this complication. The majority of the numerator events that involved coagulopathies occurred among patients with the vaguest codes, specifically "other and unspecified coagulation defects (286.9)" and "thrombocytopenia unspecified (287.5)." We recommend that this issue be examined further using so-called “present on admission” data from the CA and NY SID data. If through these follow-up analyses, it is confirmed that these conditions are not known to be present on admission, then the complication itself could trigger a diagnosis of the coagulopathy and lead to substantial bias.

The following empirical analysis was completed after the initial panel review using the 2003 KIDs’ Inpatient Sample(NIS).

We examined the rate for patients undergoing ECMO. We found that the number of patients in the denominator was very small (53 using the NIS), but we also found that

these patients were at much higher risk of this complication (rate is 92.5 per 1000 patients with ECMO code vs. 2.12 per 1000 patients overall).

Literature based evidence specific to pediatric population

Post-operative hemorrhage or hematoma is an issue of significant concern in the pediatric population. For example, one of the most common surgical procedures performed in this patient group is tonsillectomy (with or without adenoidectomy) and peri-operative or post-operative bleeding is one of the most concerning complications.[24, 25]

The incidence of post-operative hemorrhage or hematoma, using the original AHRQ PSI definition was investigated in pediatric populations (e.g., 1.02 per 1,000 discharges at 0-17 years, 1.50 at 18-44 years, 1.99 at 45-64 years, and 2.54 at 65 or more years).[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. Miller and Zhan analyzed HCUP data from 2000 and found 13 pediatric patients (0-18 years of age) per 10,000 discharges with the complication of postoperative hemorrhage or hematoma. Additionally, they found that this complication resulted in an increased mean length of stay (by 7.9 days) and $75,932 in increased charges in affected patients, with 3.5 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11] Sedman et al analyzed NACHRI data from 1999-2002 and found observed rates varying from 2.6 per 1,000 patients in 2001 to 2.7 per 1,000 patients in 2002 (with no consistent trend over time).[12]

POSTOPERATIVE RESPIRATORY FAILURE (PSI)

Indicator definition:

Number of patients with respiratory failure (see definition and exclusions below) per 1000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of respiratory failure:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Acute respiratory failure [518.81, 518.84, 518.5] ***OR*** ***Secondary procedure code for:*** • Insertion of endotracheal tube [96.04], when it occurs one or more days after the index surgery • Continuous mechanical ventilation of unspecified duration [96.70], when it occurs two or more days after the index surgery • Continuous mechanical ventilation < 96 consecutive hrs [96.71], when it occurs two or more days after the index surgery • Continuous mechanical ventilation for 96 consecutive hrs or more [96.72], when it occurs on the same day or after the index surgery	***a. All elective surgical patients (defined by DRG and admission type), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis code for acute respiratory failure, patient where a procedure for tracheostomy is the only operating room procedure or tracheostomy occurs before the first operating room procedure.*** ***c. Exclude patients in MDC 4 and 5 (respiratory and circulatory diseases).*** ***d. Exclude newborns with a birth weight less than 500g.*** ***e. Exclude obstetric patients (MDC 14)*** ***f. Exclude patients with neuromuscular disorders (e.g. Muscular dystrophy and other myopathies, myosthenia gravis, Guillain Barre)***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):

OVERALL	14.25
Age stratified rates:	
Neonate, < 2000g	411.26
Neonate, ≥ 2000g	98.08
29 days – 364 days	21.40
1 – 2 years	21.49
3 – 5 years	13.43
6 – 12 years	10.40
13 – 17 years	9.11

Hospital type			
Children's		**Non-Children's**	
OVERALL	17.03	**OVERALL**	6.76
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	430.41	**Neonate, < 2000g**	508.43
Neonate, ≥ 2000g	91.20	**Neonate, ≥ 2000g**	17.97
29 days – 364 days	20.27	**29 days – 364 days**	17.34
1 – 2 years	23.94	**1 – 2 years**	12.83
3 – 5 years	15.13	**3 – 5 years**	5.87
6 – 12 years	12.07	**6 – 12 years**	5.71
13 – 17 years	14.12	**13 – 17 years**	4.01

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated this indicator favorably with agreement internal quality improvement use and favorably with indeterminate agreement for comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Definition based on diagnosis code only.*	Definition based on both diagnosis and procedure codes for mechanical ventilation.	Change prompted by chart review study (see below) from an adult population that demonstrated inclusion of procedure codes increased the sensitivity of this indicator.
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).

*Note: The change incorporated in the pediatric indicator has also been implemented for the current AHRQ QI, as part of the February 2006 PSI update.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
Patients with neuromuscular disorders included.	Exclude patients with neuromuscular disorders (e.g. Muscular dystrophy and other myopayhies, myosthenia gravis, Guillain Barre)	Patients with neuromuscular disorders are more likely to remain ventilated for a longer period of time, regardless of quality of care.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to flag cases of postoperative respiratory failure. This indicator limits the code for respiratory failure to secondary diagnosis and procedure codes in order to eliminate respiratory failure that was clearly present on admission. High quality care may reduce the risk of this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed twice during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator, the first panel (multispecialty) consisted of 6 clinicians: a general surgeon, an internist, two adult hospitalists, and two specialized nurses. The second (surgery specialist) panel consisted

of nine clinicians: a urologist, a transplant surgeon, two orthopedic surgeons, a pediatric neurosurgeon, a neurosurgeon, and two colon and rectal surgeons. Both panels reviewed several other indicators. In the course of review the panels advocated for the following:

- The panels reviewed an indicator called "Postoperative Pulmonary Compromise" which included additional complications such as acute edema of the lung. The surgical panel advocated for the retention only of acute respiratory failure, as this complication is clinically significant and somewhat preventable. In addition, acute respiratory failure, which requires mechanical ventilation, is less likely to be coded variably.
- Both panels advocated for the population at risk to be limited to elective surgery patients.
- Panelists noted that preventability varies greatly by case mix and type of surgery, and risk adjustment is necessary.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of twelve pediatric clinicians, one pediatric critical care specialist, one pediatric hospitalist, one pediatric anesthesiologist, one pediatric hematologist/oncologist, one pediatric cardiologist, two pediatric surgeons, one pediatric neurosurgeon, one pediatric urologist, two pediatric cardiovascular surgeons, and one neonatologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists suggested that patients with neuromuscular disorders be excluded, since these patients may remain on the ventilator longer than other patients, even with high quality care.
- Panelists also noted several other high risk groups, including infants undergoing cardiac surgery and tracheal reconstruction; these patients are excluded via MDC 4 and 5.
- Finally, panelists noted that children with posterior fossa tumors may also remain on the ventilator longer than other patients, even with high quality care. However, we cannot identify these patients reliably using ICD-9-CM coding.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating - comparative	7	Indeterminate agreement
Not present on admission	8	Agreement
Preventability	7	Indeterminate agreement
Due to medical error	4.5	Indeterminate agreement
Charting by physicians	8	Agreement
Lack of bias	5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (-)

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

Following the panel suggestion that patients with neuromuscular disorders be excluded, we identified potential ICD-9-CM codes and conducted analyses to better understand the risk of postoperative respiratory failure associated with these codes. Patients with hereditary and idiopathic peripheral neuropathy (ICD-9-CM codes 356.X) were not at increased risk for respiratory failure. Patients with inflammatory and toxic neuropathy (ICD-9-CM codes 357.X) were also not at increased risk, although these codes were rare, presumably because, in addition to the disorders being rare, these patients do not generally undergo elective surgery. Several other categories of codes were not associated with increased risk, but were very rare or non-existent in the denominator. Clinically these disorders may be associated with higher risk, but we were not able to determine the risk empirically using the NIS. These codes include myoneural disorders (358.X), myotonic disorders (359.2), familial periodic paralysis (359.3), toxic myopathy (359.4), myopathy in endocrine diseases classified elsewhere (359.5), symptomatic inflammatory myopathy in diseases classified elsewhere (359.6), other myopathies (critical illness myopathy, myopathies nec) (359.81, 359.89), and myopathy, unspecified (359.9). Patients with muscular dystrophy (ICD-9-CM codes 359.0, 359.1) were clearly at an increased risk for this complication (relative risks ranged 11.1 - 18.0).

Additional evidence not specific to pediatric population

The original definition of this indicator was limited to diagnosis codes. Subsequent work using linked administrative and clinical data from the VA Healthcare System showed that the original definition had a sensitivity of just 18% (i.e., capturing only 18% of the patients who truly experienced postoperative respiratory failure) with a positive predictive value of 74%. By modifying the definition to include diagnosis or related procedure codes, the sensitivity increased dramatically to 63% while the positive predictive review fell only slightly to 66%.[22]

Literature based evidence specific to pediatric population

Post-operative respiratory failure is a potential complication after pediatric surgery, as after adult surgery. The incidence of post-operative respiratory failure, using the original AHRQ PSI definition, was investigated in pediatric populations (e.g., 2.27 per 1,000 discharges at 0-17 years, 1.41 at 18-44 years, 2.32 at 45-64 years, and 3.85 at 65 or more years). Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. Using HCUP data from 2000, Miller and Zhan found 33 pediatric patients (0-18 years of age) per 10,000 discharges with the complication of postoperative respiratory failure. Additionally, they found that this complication resulted in an increased mean length of stay (by 24.4 days) and $140,507 in increased charges in affected patients, with 76.6 times increased odds of in-hospital mortality (after adjusting

for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11]

POSTOPERATIVE SEPSIS (PSI)

Indicator definition:

Number of patients with sepsis (see definition and exclusions below) per 1,000 eligible admissions (population at risk).

Definition of sepsis:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Streptococcal septicemia [038.0] • Staphylococcal septicemia [038.1] • Staphylococcal septicemia, unspecified [038.10] • Staphylococcal aureus septicemia [038.11] • Other staphylococcal septicemia [038.19] • Pneumococcal septicemia [038.2] • Septicemia due to anaerobes [038.3] • Septicemia due to gram negative organism, unspecified [038.40] • Septicemia due to hemophilus influenzae [038.41] • Septicemia due to escherichia coli [038.42] • Septicemia due to pseudomonas [038.43] • Septicemia due to serratia [038.44] • Septicemia due to other gram-negative organisms [038.49] • Other specified septicemias [038.8] • Unspecified septicemia [038.9] • Septic shock [785.52] • Other shock without mention of trauma [785.59] • Systemic inflammatory response syndrome due to infectious process without organ dysfunction [995.91] • Systemic inflammatory response syndrome due to infectious process with organ dysfunction [995.92] • Postoperative shock, NEC [998.0]	***a. All surgical patients (defined by DRG and admission type), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis code for sepsis, infection, or any patient in DRG 164, 165 or 415.*** ***c. Stratify by risk group:*** ***i. High risk: Immunodeficient patients (HIV, AIDs, immune system disorders, transplant, short bowel syndrome, specified leukemias and lymphomas, renal failure and severe malnutrition).*** ***ii. Intermediate risk: Lupus, renal disease and other rare autoimmune, hepatic failure, cachexia, spleen disorders.*** ***iii. Low risk: All other patients*** ***c. Include only patients with a length of stay of 4 days or more.*** ***d. Exclude all newborns and neonates (age<28 days) transferred from an acute care facility.*** ***e. Exclude obstetric patients (MDC 14)***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):			
OVERALL	27.39		
Age stratified rates:			
Neonate, < 2000g	230.85		
Neonate, ≥ 2000g	82.70		
29 days – 364 days	55.79		
1 – 2 years	29.73		
3 – 5 years	18.53		
6 – 12 years	15.44		
13 – 17 years	15.04		
Clinical stratification			
Strata 1. Clean Procedures Elective	9.10		
Strata 2. Clean Procedures Non-Elective	18.10		
Strata 3. Potentially Contaminated Elective	24.82		
Strata 4. Potentially Contaminated Non-Elective	48.93		
Strata 5. Dirty or Infected			
Hospital type			
Children's		**Non-Children's**	
OVERALL	31.33	**OVERALL**	16.72
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	246.53	**Neonate, < 2000g**	132.30
Neonate, ≥ 2000g	84.06	**Neonate, ≥ 2000g**	56.31
29 days – 364 days	57.68	**29 days – 364 days**	44.91
1 – 2 years	30.99	**1 – 2 years**	20.39
3 – 5 years	19.78	**3 – 5 years**	16.79
6 – 12 years	17.35	**6 – 12 years**	9.85
13 – 17 years	18.08	**13 – 17 years**	11.11
Clinical strata:		**Clinical strata:**	
Strata 1	9.68	**Strata 1**	5.70
Strata 2	17.22	**Strata 2**	16.23
Strata 3	31.43	**Strata 3**	8.78
Strata 4	57.87	**Strata 4**	28.69
Strata 5		**Strata 5**	

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator will be included in the pediatric quality indicator set. Panelists rated this indicator favorably with indeterminate agreement for internal quality improvement, but did not recommend the indicator for comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Premature neonates included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
Newborns included.	Exclude all newborns.	Newborns may acquire infection in utero or during delivery

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
Only elective surgery patients included.	Include high risk patients, (i.e. immunocompromised patients) and all surgery types.	As defined this complication is rare. Panelists felt the indicator would be more useful with the inclusion of patients at risk for this complication.
Exclude infection based on DRG and specific ICD-9-CM codes.	Exclude infection based entirely on ICD-9-CM codes.	Previous definition was not adequate for excluding infections in the pediatric population and all surgery types.
No stratification.	Stratify by procedure field class (i.e. clean, clean-contaminated, contaminated, dirty/infected). Categorization imputed from DRG and admission type (e.g. elective).	Risk varies substantially by procedure.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
No outer time limit for developing sepsis.	Define outer time limit after surgery for developing sepsis.	Not possible with data.
Definition only includes inpatients.	Expand to track sepsis after outpatient surgery.	Not possible with data.

Clinical rationale

This indicator is intended to flag cases of nosocomial postoperative sepsis. It is closely related to a complications indicator developed as part of the Complications Screening Program. In order to better screen out cases of sepsis that are likely to be present on admission, this indicator limits its definition of sepsis to secondary diagnoses (meaning sepsis was not labeled as the principal diagnosis). High quality of care may reduce the risk for this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the panel consisted of seven physicians: two general surgeons, a geriatrician, two adult hospitalists, an internist, and a nurse specialist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists reviewed an indicator called “Septicemia” which limited the population at risk to certain MDCs and DRGs for which it was judged that sepsis would be a potentially preventable complication. Panelists rejected this definition as too broad, and argued for the restriction of the population at risk to elective surgery patients. This complication was felt to be largely preventable in this population. This suggestion was implemented.

- Panelists noted that varying definitions of "sepsis" may affect the rate of this indicator.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of ten pediatric clinicians, including one neonatologist, one infectious disease specialist, one ambulatory care pediatrician, one pediatric hospitalist, one pediatric cardiovascular surgeon, one pediatric oncologist, two pediatric surgeons, one pediatric interventional radiologist, and one pediatric critical care physician. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The panel felt that sepsis in pediatric patients following elective surgery was exceedingly rare. They felt that tracking sepsis after all surgeries was more useful in this population, and that tracking immunocompromised and other high risk patients would be desirable. They requested that rates be available for high risk patients separately from low risk patients. Further work is necessary to define the high and low risk groups.
- Panelists discussed that neonates readmitted for elective surgery would be useful to track, especially if sepsis due to organisms known to be contracted from birth could be excluded (e.g. Group B strep). Some sepsis cases where the organism is unspecified will be attributable to these infections acquired in utero or during birth.
- Some panelists desired changes that were not feasible using unlinked inpatient administrative data, these included tracking outpatient procedures, and setting an outer time limit post-surgery for the development of sepsis.

The same panel participated in a second round of rating, which included preliminary rating, followed by a conference call, and a final rating. The panel was identical except for the attrition of three panelists (pediatric cardiovascular surgeon, pediatric oncologist, pediatric hospitalist). The panel re-reviewed three other indicators. In the course of review the panel further suggested the following, in addition to the comments from the previous review:

- Panelists argued that postoperative sepsis only accounts for a small percentage of postoperative infection. They advocated for the addition of indicators that examine other postoperative infections, including abscesses and wound infections. They agreed though that this narrower indicator was an important first step.
- Panelists noted that many cases (approximately 1/3) would not have an organism identified, and without an isolated organism the term "sepsis" may actually be used to describe a variety of clinical scenarios, depending on the physician.
- The panelists were presented with a stratification scheme based on comorbidities that would entail immunocompromised states. This stratification is now incorporated in risk adjustment. Panelists noted that such a scheme could never completely incorporate all the cases that would be at slightly elevated risk.

- Panelists noted that the most important distinction meriting stratification is procedure type, specifically whether the surgical field is considered clean or contaminated. Surgical fields are standardly classified into four categories: clean, clean-contaminated, contaminated, and dirty/infected, which is assigned at the time of surgery. Although this information is not contained in the administrative record, panelists suggested that these categories be imputed based on the procedures performed.
- Panelists discussed the inclusion of neonates in this indicator. It is difficult to distinguish perinatally acquired infection from postoperative sepsis, especially if an organism is not specified. Panelists noted that the rate of perinatally acquired infection is low, but that it would be cleaner to exclude if the indicator is used to inter-hospital comparisons. They did note that the complication is important, particularly in babies that are hospitalized for extended periods, and argued that sepsis in neonates be examined in a separate indicator.
- Finally, panelists noted that infection control personnel are the best source of information on postoperative infection, since they look closely at each case and contributing factors.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	7	Indeterminate agreement
Overall rating – comparative purposes	6	Indeterminate agreement
Not present on admission	7	Indeterminate agreement
Preventability	6	Indeterminate agreement
Due to medical error	5	Indeterminate agreement
Charting by physicians	7.5	Agreement
Lack of bias	7	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Not recommended

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

Prior to panel review we investigated the procedure codes for neonates with this complication in an attempt to better understand if this complication was clearly associated with infection acquired in utero. The associated procedure codes did not reveal a clear association, nor a consistent pattern in types of procedures. As a result the question of whether or not to exclude neonates (patients age 0-30 days) was posed to the clinician panel.

The following empirical analyses were completed after the initial panel review using the 2003 KIDs' Inpatient Database (KID).

Panelists proposed expanding this indicator to include all patients. We found, as expected, that patients undergoing elective surgery had a lower rate of this complication than other surgical patients (12.3 per 1000 vs. 31.7 per 1000). We also found that patients with infections appeared in the non-elective surgery group, motivating a new definition for the infection exclusion.

In examining this indicator, we recognized the need for a more comprehensive definition of infection. We selected infection codes from the ICD-9-CM coding manual that represented either: explicitly stated bacterial infections (e.g. streptococcal pneumonia) or inflammatory conditions that may reflect bacterial conditions (e.g. peritonitis). To ensure that the non-specific codes we had selected were truly associated with sepsis we calculated the relative risk of these codes as compared to all cases in the indicator and found a significantly elevated rate (RR = 4.19).

During panel review, one panelist noted that unspecified septicemia may be clinically more subjective than those cases with an isolated organism. Since organisms are often not isolated, we analyzed the distribution of the codes in the numerator for the panelists' information. We found that unspecified septicemia accounted for 1/3 of all cases.

Also, in response to panel and peer reviewer suggestions, we investigated expanding the definition of immunocompromised patients. We examined each of the following strata, which are associated with impaired immunity separately: HIV, primary immunodeficiencies, transplant, high risk cancer (leukemia, lymphoma), other cancers, lupus, other rare autoimmune diseases, juvenile rheumatoid arthritis, other rheumatoid arthritis, short bowel syndrome, renal conditions treated with immune suppressants, renal failure, hepatic failure, severe malnutrition, cachexia and spleen disorders.

We found that patients with rheumatoid arthritis, lupus, other autoimmune disorders, cachexia, and renal diseases were not at elevated risk for this complication (relative risk less than 1.4), although the sample size was low for these strata. Patients with spleen disorders and cancers other than specific leukemia and lymphomas had a slightly elevated risk (relative risk between 1.4 and 3). Hepatic failure, renal failure, primary immunodeficiency or having undergone a transplant procedure had a moderately elevated risk (relative risk between 3 and 9). Patients with HIV, specific leukemia or lymphomas, short bowel syndrome, or severe malnutrition had a greatly elevated risk (relative risk above 9).

Finally, panelists suggested that the type of surgery may be more predictive of this complication than the comorbidities of a patient. Specifically, they were interested in stratification by surgical field class, a standard classification widely associated with postoperative wound infection. The categories of clean, clean-contaminated, contaminated, and dirty/infected, take into account various aspects of the procedure field which are assessed at the time of surgery. However, this classification is not contained in the administrative data. We attempted to devise a scheme based on the likely classification of a surgery. For instance, most heart procedures are typically clean, whereas intestinal procedures would be clean-contaminated or contaminated. By

combining DRG and the admission type (i.e. elective, non-elective), we devised a stratification scheme which predicts the surgical type of the patient. For patients with more than one procedure, the highest risk class is assigned.

In order to investigate this scheme we first analyzed the risk of postoperative sepsis based on admission type. We confirmed that admissions designated "elective" in the administrative record, were at lower risk for this infection than patients designated "urgent" or other (i.e. "emergent" "newborn" "invalid/missing" or "other") (RR = 0.34, 1.95. and 1.36 respectively).

We then assigned each DRG to one of five risk classes. Risk class one included DRGs for surgeries that were typically clean procedures if done electively. Risk class 2 included DRGs for surgeries that were typically clean contaminated if done electively. Risk class 3 included trauma and cellulitis. Risk class 4 included DRGs for infections. Risk class 5 included DRGs where the procedure was not defined (e.g. major OR procedures in patients with HIV). We excluded DRGs for burns and transplants from this analysis since these patients are at higher risk due to comorbid conditions rather than surgical field class and examined these cases seperately. We examined the risk of postoperative sepsis, applying all exclusions for the indicator, for each risk class and the admission type and the interaction of the two. We found for each risk class, elective admission type had lower relative risk than any other admission type. Using these analyses we constructed a stratification scheme which grouped together risk class/admission type combinations with similar risk of postoperative sepsis. Five strata were identified.

Additional evidence not specific to pediatric population

Recent work using linked administrative and clinical data from the VA Healthcare System showed that the current definition of this indicator has a sensitivity of 25% (i.e., capturing only 25% of the patients who truly experienced postoperative sepsis) with a positive predictive value of 44%.[22]

Literature based evidence specific to pediatric population

As in adult surgery, post-operative sepsis is a potential complication in pediatric surgery. The incidence of post-operative sepsis, using the original AHRQ PSI definition, was investigated in pediatric populations (e.g., 3.87 per 1,000 discharges at 0-17 years, 3.71 at 18-44 years, 9.08 at 45-64 years, and 11.16 at 65 or more years).[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. Using HCUP data from 2000, a rate of 10.3 per 1,000 discharges was seen for the complication of postoperative sepsis in pediatric patients 0-18 years of age.[11] Additionally, it was found that this complication resulted in an increased mean length of stay (by 26 days) and $117,815 in increased charges in affected patients, with 11 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching

status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11]

POSTOPERATIVE WOUND DEHISCENCE (PSI)

Indicator definition:

Number of abdominopelvic surgery patients with disruption of abdominal wall (see definition and exclusions below) per 1000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of disruption of abdominal wall:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary procedure code for: • Reclosure of disruption of abdominal wall [54.61]	***a. All abdominopelvic surgical patients (defined by procedure codes), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with procedure for reclosure of postoperative disruption of abdominal wall occurs before or on the same day as the first abdominopelvic surgery procedure.*** ***c. Exclude patients with any procedure code for gastroschisis repair OR umbilical hernia repair in newborns (omphalacele repair) performed before the reclosure procedure.*** ***d. Exclude newborns with a birth weight less than 500g.*** ***e. Exclude obstetric patients (MDC 14)*** ***f. Exclude patients with any diagnosis code for immunocompromised state (ie. Organ transplant, bone marrow or stem cell transplant, HIV or AIDs, humoral immunodeficiencies, deficiencies of cell-mediated immunity, other specified and unspecified immunodeficiency, renal failure, severe malnutrition) .*** ***g. Exclude patients with a length of stay of less than 2 days.***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):			
OVERALL	0.76		
Age stratified rates:			
Neonate, < 2000g	2.46		
Neonate, ≥ 2000g	0.77		
29 days – 364 days	1.70		
1 – 2 years	0.68		
3 – 5 years	0.22		
6 – 12 years	0.32		
13 – 17 years	0.49		
Hospital type			
Children's		**Non-Children's**	
OVERALL	0.82	**OVERALL**	0.69
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	0.70	**Neonate, < 2000g**	5.21
Neonate, ≥ 2000g	0.33	**Neonate, ≥ 2000g**	1.25
29 days – 364 days	1.54	**29 days – 364 days**	1.86
1 – 2 years	0.52	**1 – 2 years**	1.33
3 – 5 years	0.40	**3 – 5 years**	0.00
6 – 12 years	0.43	**6 – 12 years**	0.28
13 – 17 years	1.09	**13 – 17 years**	0.30

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric indicator set, with the revised definition summarized above. Panelists rated this indicator favorably, with agreement for both internal quality improvement and comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages.	Age 0 – 17	Pediatric age range
All birth weights included.	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
All procedures included.	Exclude patients with any procedure code for gastrochesis repair, repair of umbilical hernia with prosthesis, or umbilical herniorrhaphy performed before the reclosure procedure.	These staged procedures are planned re-openings relatively common in pediatrics that should not be included in the indicator.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
Immunocompromised patients included	Exclude immunocompromised patients.	Patients at high risk for complication with questionable preventability.
Include all length of stay zero or one.	Exclude patients with length of stay of zero or one.	Admission patterns vary and these patients are unlikely to

		develop this complication during a short stay.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
Cancer patients examined with all other patients.	Decomposed rates for cancer patients available.	One panelist felt that cancer patients may be at higher risk, but complication may still be preventable. However, empirical analyses demonstrated that cancer patients are not at higher risk.

Clinical rationale

This indicator is intended to flag wound dehiscence in patients who have undergone abdominal and pelvic surgery. A specific code is available to detect wound dehiscence in this patient population. The indicator is restricted to secondary diagnoses, and is intended to capture cases occurring within the same hospitalization. High quality surgical technique may reduce the risk for this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed twice during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the first panel (multispecialty) consisted of 6 clinicians: a general surgeon, an internist, two adult hospitalists, and two specialized nurses. The second (surgery specialist) panel consisted of nine clinicians: a urologist, a transplant surgeon, two orthopedic surgeons, a pediatric neurosurgeon, a neurosurgeon, and two colon and rectal surgeons. Both panels reviewed several other indicators. In the course of review, the panels advocated for the following:

- Panelists rejected a diagnosis code for postoperative wound disruption, since the code did not distinguish between minor and severe dehiscence. Instead the panelists argued for an indicator based only on procedure codes.
- Surgical panelists argued that trauma, cancer and immunocompromised patients be excluded.
- Risk adjustment for comorbidity and procedure type was advocated.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of twelve pediatric clinicians, one pediatric critical care specialist, one pediatric hospitalist, one pediatric anesthesiologist, one pediatric hematologist/oncologist, one pediatric cardiologist, two pediatric surgeons, one pediatric neurosurgeon, one pediatric urologist, two pediatric cardiovascular surgeons, and one neonatologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelests suggested that immunocompromised patients be excluded since these patients are more at risk for non-preventable wound dehiscence.
- Panelist requested that rates for cancer patients be available separately, since they also may be at a higher risk for these complications, but these complications in cancer patients are still important to monitor.
- Panelists noted that some dehiscences may occur after discharge. In order to track these complications, an area level indicator will be developed for this indicator, which includes principal procedures to close operative wounds identified by this indicator, and which utilizes a population denominator. The area level indicator is intended to capture transfers and readmissions for wound dehiscence. It will be available in addition to this hospital-based indicator.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating - comparative	7.5	Agreement
Not present on admission	9	Agreement
Preventability	7	Agreement
Due to medical error	5.5	Indeterminate agreement
Charting by physicians	8	Agreement
Lack of bias	4	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (+)

Additional evidence not specific to pediatric population

Recent unpublished work using linked administrative and clinical data from the VA Healthcare System showed that the current definition of this indicator has a sensitivity of 23% (i.e., capturing only 23% of the patients who truly experienced postoperative wound dehiscence) with a positive predictive value of 72%. The former finding is not surprising because the VA clinical definition does not require surgical reclosure, which the PSI definition does. [22]

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

Prior to panel review, we conducted analyses to determine whether the most frequent procedures captured by this indicator in the pediatric population were planned staged procedures (as reported by chart review from NACHRI and The Johns Hopkins Hospital).[4, 26] We examined the most frequent procedures found with the AHRQ QI version of this indicator applied to a pediatric population. Results indicated that the most frequent staged procedure captured was repair of gastroschisis (ICD-9-CM code, 54.71). Many other procedures unlikely to be planned staged procedures also were captured. Finally an analysis of the change of the rate of complication after applying exclusions for known staged procedures showed an expected reduction in rate.

One panelist suggested stratification of the indicator for patients with cancer. However, empirical analyses demonstrated that the rate in this population was not elevated, so this indicator was removed after the panel review.

Following the initial panel review, in conjunction with analyses completed for other indicators or in response to peer review, we examined two additional aspects of this indicator. These empirical analyses were completed using the 2003 KIDs' Inpatient Database (KID).

We examined the length of stay for patients with wound dehiscence given peer review comments on patents with short stays (length of stay of zero or one days). We found that almost 19% of the denominator patients had a length of stay of less than 2 days, but none of these patients appeared in the numerator.

We examined each of the following strata, which are associated with impaired immunity separately: HIV, primary immunodeficiencies, transplant, high risk cancer (leukemia, lymphoma), other cancers, lupus, other rare autoimmune diseases, juvenile rheumatoid arthritis, other rheumatoid arthritis, short bowel syndrome, renal conditions treated with immune suppressants, renal failure, hepatic failure, severe malnutrition, cachexia and spleen disorders.

Since this complication is relatively rare in children it is difficult to note any increased risk in each of the potentially high-risk stratum, but children with short bowel syndrome appear to be at higher risk with the relative risk over 15 as compared with all patients in the denominator. Children with spleen disorders also had an elevated risk, with a relative risk of nearly 3.5. Since the desire was to develop a stratification or classification scheme for immunocompromised patients that could be applied to a number of indicators, results from other indicators were also considered. Consistency across indicators and modules is desired, and so in consideration of stratification of pediatric indicators, we also considered the impact of these comorbidities on an adult population. Some conditions that were rare in children are less rare in adults and the impact on these complications more apparent.

Literature based evidence specific to pediatric population

Post-operative abdominopelvic wound dehiscence is an issue of concern in the pediatric surgical population. Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. The incidence of post-operative wound dehiscence was investigated in pediatric patients in several studies (e.g., 1.25 per 1,000 discharges at 0-17 years, 1.74 at 18-44 years, 2.65 at 45-64 years, and 3.77 at 65 or more years).[10] HCUP data from 1997 showed a rate of 2.9 per 10,000 discharges for a broader definition of post-operative wound disruption (based on either a diagnosis code or a procedure code). Using HCUP data from 2000, a rate of 8 per 10,000 discharges was seen for the complication of postoperative wound dehiscence in pediatric patients 0-18 years of age.[11, 17] Additionally, it was found that this complication resulted in an increased mean length of stay (by 21.1 days) and $76,737 in increased charges in affected patients, with 5.7 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11] Sedman et al found a range of observed rates for post-operative wound dehiscence from 1.7 per 1,000 in 2002 to 1.2 per 10,000 in 1999 using NACHRI data (i.e., a slight downward trend over time).[12]

SELECTED INFECTION DUE TO MEDICAL CARE (PSI)

Indicator definition:

Number of patients with specific infection codes (see definition and exclusions below) per 1,000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of infection:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • Other infection (Infection, sepsis or septicemia following infusion, injection, transfusion, or vaccination) [999.3] • Infection and inflammatory reaction due to other vascular device, implant, and graft [996.62] Note: These codes identify a variety of infections, but primarily catheter and IV related infections.	a. All medical and surgical patients (defined by DRG), age 0-17 years, except exclusions (see below). b. Exclude patients with principal diagnosis code of 999.3 or 996.62. c. Stratify patients by three risk groups i. High risk: High risk immunodeficient patients (HIV, immune system disorders, transplant, short bowel syndrome, cancer, renal failure and severe malnutrition.) ii. Intermediate risk: Cystic fibrosis, Hemophilia, Intermediate risk immunodeficient patients (lupus, renal disease and other rare autoimmune, hepatic failure, cachexia, spleen disorders). iii. Low risk: All other patients d. Exclude patients with length of stay of less than 2 days. e. Exclude all newborns (born in-hospital) and neonates (age <28 days) transferred from an acute care facility. f. Exclude obstetric patients (MDC 14)

Rates based on year 2003 KIDs' Inpatient Database (per 1000):	
OVERALL	3.25
Age stratified rates:	
Neonate, < 2000g	9.69
Neonate, ≥ 2000g	1.29
29 days – 364 days	3.58
1 – 2 years	3.44
3 – 5 years	3.57
6 – 12 years	3.12
13 – 17 years	3.18

Clinical stratification	
High risk: High risk immunodeficient patients (HIV, immune system disorders, transplant, short bowel syndrome, cancer, renal failure and severe malnutrition.)	24.23
Intermediate risk: Cystic fibrosis, Hemophilia, Intermediate risk immunodeficient patients (lupus, renal disease and other rare autoimmune, hepatic failure, cachexia, spleen disorders).	7.61
Low risk: All other patients	1.68

Hospital type			
Children's		**Non-Children's**	
OVERALL	6.15	**OVERALL**	1.10
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g	19.75	**Neonate, < 2000g**	5.32
Neonate, ≥ 2000g	3.05	**Neonate, ≥ 2000g**	0.43
29 days – 364 days	7.00	**29 days – 364 days**	1.06
1 – 2 years	6.93	**1 – 2 years**	0.87
3 – 5 years	6.13	**3 – 5 years**	1.35
6 – 12 years	5.33	**6 – 12 years**	1.01
13 – 17 years	6.20	**13 – 17 years**	1.39
Clinical strata:		**Clinical strata:**	
Low Risk	25.88	**Low Risk**	17.26
Intermediate Risk	9.27	**Intermediate Risk**	3.82
High Risk	3.27	**High Risk**	0.68

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator will be included in the pediatric quality indicator set. Panelists rated this indicator favorably with indeterminate agreement for internal quality improvement, but did not recommend the indicator for comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Cancer, immunocompromised state and short bowel patients included.	Exclude patients with any code of immunocompromised state or cancer or short bowel syndrome.	Patients with these conditions tend to have long term indwelling catheters that are prone to infection.
Normal newborns included.	Exclude normal newborns.	Normal newborns do not typically have lines that would

		put them at risk for this complication.
Premature neonates. . .	Exclude newborns with a birth weight less than 500g.	Excluded from all indicators due to very high risk nature and bias related to delivery practices (i.e. attempting delivery vs. allowing fetal death).
No stratification.	Stratify by low birth weight neonate (2000 g or less) and other patients.	Small neonates are at higher risk for infection due to underdeveloped immune systems.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
High risk patients, with long term lines or immunocompromised state excluded.	High risk patients (those with long term lines and immunocompromised state) included and stratified.	Panelists felt that this indicator is most useful if high risk patients are included, since these patients are the patients for which interventions could be targeted.
Include all length of stay zero or one.	Exclude patients with length of stay of zero or one.	Admission patterns vary and these patients are unlikely to develop this complication during a short stay.
Exclude only normal newborns and those < 500 g.	Exclude all newborns and neonates transferred from another acute care facility.	Difficult to distinguish infection captured by this indicator from perinatally acquired infection. Consider newborn infections in a separate novel indicator in future.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason implemented
Separate vaccination and injection related infection from line infections.	Panelist suggested that vaccination and injection related infections are very different from line infections and should be removed from the indicator.	Not possible using codes, but most likely few cases are vaccination/injection related.

Clinical rationale

This indicator is intended to capture infections that are due to medical care, but are limited to those easily captured using administrative data. This indicator likely captures mostly line and other vascular access related infections. High quality care is likely to reduce the risk for this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the panel consisted of physicians: two general surgeons, a geriatrician, two adult hospitalists, an internist, and a nurse specialist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists rejected codes for "infection due to contaminated or infected blood or other substance" as they felt these complications were out of the control of the health care provider. This suggestion was implemented.
- Panelists rejected an exclusion of trauma patients, arguing that these patients should be tracked, but argued for the exclusion of immunocompromised patients. This suggestion was implemented.
- Panelists noted that not all infections are preventable and that these infections will be charted variably.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of ten pediatric clinicians, including one neonatologist, one infectious disease specialist, one ambulatory care pediatrician, one pediatric hospitalist, one pediatric cardiovascular surgeon, one pediatric oncologist, two pediatric surgeons, one pediatric interventional radiologist, and one pediatric critical care physician. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The panel felt that it was important to track line infections in all patients, even those at high risk in the pediatric population, including tracking immunocompromised patients and those with long-term lines. They requested that rates be available for high risk patients separately from low risk patients.
- Panelists suggested that vaccination and injection related infections are very different from line infections and should be removed from the indicator. However, it is likely that very few of the infections detected by the indicator are related to these procedures.

The same panel participated in a second round of rating, which included preliminary rating, followed by a conference call, and a final rating. The panel was identical except for the attrition of three panelists (pediatric cardiovascular surgeon, pediatric oncologist, pediatric hospitalist). The panel re-reviewed three other indicators. In the course of review the panel further suggested the following, in addition to the comments from the previous review:

- Panelists noted that the intermediate risk group used for stratification could not be comprehensive as many small patient groups are at higher risk of infection. However, they agreed that most of the important groups were included. They suggested that we also examine patients undergoing cardiovascular surgery and trauma. Risk adjustment approaches will account for differences in risk between trauma and cardiovascular surgery patients.
- Panelists also noted that line associated infections are already tracked at many hospitals. The clinical based data has been used with the administrative based data to confirm actual rates.

Post-conference call panel ratings

Question	Median	Agreement status

Overall rating – internal QI	7	Indeterminate agreement
Overall rating – comparative purposes	6.5	Indeterminate agreement
Not present on admission	7.5	Agreement
Preventability	7	Indeterminate agreement
Due to medical error	6	Agreement
Charting by physicians	6	Indeterminate agreement
Lack of bias	5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Not recommended

Empirical analyses to inform indicator definition

The following empirical analyses were completed after the initial panel review using the 2003 KIDs' Inpatient Database (KID).

Panelists suggested we stratify this indicator by risk. We examined the risk of this complication for several groups theorized to have higher risked. We the following to be at highly elevated risk: short bowel syndrome (RR=97.69), immunocompromised state (RR = 29.61), lymphosarcoma and reticolosarcoma (RR = 34.17), myeloid leukemia (RR = 38.69), monocytic leukemia (RR = 77.43), leukemia of unspecified cell type (RR=51.43). The following patients were at intermediate risk: cystic fibrosis (RR=8.81), hemophilia (RR=14.26), Hodgkin's disease (RR=10.49), other malignant neoplasms of lymphoid and histiocytic tissue (RR=17.00), lymphoid leukemia (RR=18.95), and all other cancer (RR=15.60).

In order to further investigate the definition of immunocompromised state, we examined each of the following strata, which are associated with impaired immunity separately: HIV, primary immunodeficiencies, transplant, high risk cancer (leukemia, lymphoma), other cancers, lupus, other rare autoimmune diseases, juvenile rheumatoid arthritis, other rheumatoid arthritis, short bowel syndrome, renal conditions treated with immune suppressants, renal failure, hepatic failure, severe malnutrition, cachexia and spleen disorders.

We found that patients with rheumatoid arthritis were not at elevated risk for this complication (relative risk less than 1.4). Patients with spleen disorders had a slightly elevated risk (relative risk between 1.4 and 3). Patients with lupus, other rare autoimmune diseases, renal diseases, hepatic failure and cachexia had a moderately elevated risk (relative risk between 3 and 9). Patients with primary immunodeficiencies, all types of cancer, short bowel syndrome, renal failure, or severe malnutrition or having undergone a transplant procedure had a greatly elevated risk (relative risk above 9).

In a separate analysis, we examined the length of stay for patients with nosocomial infections given peer review comments on patients with short stays (length of stay of zero or one days). We found that almost 22% of the denominator patients had a length of stay of less than 2 days, but only 1.8% of numerator patients had a length of stay of less than 2 days.

Literature based evidence specific to pediatric population

Infections due to medical devices are of great concern to those caring for critically ill infants and children. These infections represent a significant iatrogenic problem in pediatric health care. Bloodstream infections associated with a central intravascular line were found to be the most common infection site in a sample of pediatric intensive care units between 1992 and 1997.[27] Guidelines have been published in an attempt to decrease the rates of intravascular catheter-related infections.[28, 29]

Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. This indicator was applied to pediatric hospital populations (e.g., 1.89 per 1,000 discharges at 0-17 years, 1.89 at 18-44 years, 2.50 at 45-64 years, and 1.66 at 65 or more years).[10] Miller and colleagues analyzed HCUP data from 1997 and found an incidence of "infection attributed to procedures" (999.3 alone) of 0.13 per 1,000 discharges among children aged 0-18 years.[17] In the HCUP data from 2000, using the current PSI definition, they found a rate of 1.3 per 1,000 discharges for "infection as a result of medical care".[11] Sedman et al found observed rates varying from 3.2 per 1,000 in 1999 to 4.0 per 1,000 in 2002 in the NACHRI database (i.e., a slight upward trend over time).[12] Additionally, Miller & Zhan found that this complication resulted in an increased mean length of stay (by 30 days) and $121,010 in increased charges in affected patients, with 2.2 times higher odds of in-hospital mortality (after adjusting for age, gender, expected payer, up to 30 comorbidities, and multiple hospital characteristics, including ownership, teaching status, nursing expertise, urban location, bed size, pediatric volume, coding intensity, ICU bed percentage, and surgical discharge percentage).[11]

TRANSFUSION REACTION (PSI)

Indicator definition:

Number of patients with transfusion reaction (see definition and exclusions below) per 1,000 eligible admissions (population at risk). See The Pediatric Quality Indicator Technical Specifications.

Definition of transfusion reaction:	**Definition of population at risk:** Patients eligible to be included in this indicator:
Secondary diagnosis code for: • ABO incompatibility reaction [999.6] • Rh incompatibility reaction [999.7] • Mismatched blood in transfusion [E876.0]	***a. All medical and surgical patients (defined by DRG), age 0-17 years, except exclusions (see below).*** ***b. Exclude patients with principal diagnosis code for transfusion reaction.*** ***c. Exclude all neonates.*** ***d. Exclude obstetric patients (MDC 14)***

Rates based on year 2003 KIDs' Inpatient Database (per 1000):

OVERALL	0.002
Age stratified rates:	
Neonate, < 2000g	
Neonate, ≥ 2000g	
29 days – 364 days	0.004
1 – 2 years	0.000
3 – 5 years	0.000
6 – 12 years	0.000
13 – 17 years	0.003

Hospital type			
Children's		**Non-Children's**	
OVERALL	0.002	**OVERALL**	0.000
Age stratified rates:		**Age stratified rates:**	
Neonate, < 2000g		**Neonate, < 2000g**	
Neonate, ≥ 2000g		**Neonate, ≥ 2000g**	
29 days – 364 days	0.000	**29 days – 364 days**	0.000
1 – 2 years	0.000	**1 – 2 years**	0.000
3 – 5 years	0.000	**3 – 5 years**	0.000
6 – 12 years	0.000	**6 – 12 years**	0.000
13 – 17 years	0.009	**13 – 17 years**	0.000

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator will be included in the pediatric quality indicator set. Panelists rated this indicator favorably, with agreement for internal quality improvement, and favorably with indeterminate agreement for comparative reporting purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Newborns included.	Exclude all newborns.	Empirical analyses revealed a high rate of "reactions" in uncomplicated newborns. These are likely miscoding of maternal-fetal ABO or Rh incompatibility The high rate of miscoding suggests lack of validity for this population.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional.		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to flag ABO and Rh incompatibility reactions. High quality care is likely to reduce the incidence of this complication.

Summary of AHRQ QI clinician panel reviews

This indicator was reviewed twice during our development of the Patient Safety Indicators, which included a clinical panel review. For this indicator the first panel (multispecialty) consisted of 5 clinicians: a critical care physician, an adult hospitalist, two specialized nurses, and an anesthesiologist. The second (surgery specialist) panel consisted of 6 clinicians: a spine surgeon, a pediatric neurosurgeon, a transplant surgeon, a urologist (female specialty), a colon and rectal surgeon, and an orthopedic surgeon. Both panels reviewed several other indicators. In the course of review the panels suggested the following:

- Panelists advocated for the inclusion of only ABO and Rh incompatibility reactions.
- Panelists argued that trauma patients should be included, despite the occasional deliberate use of mismatched blood.

Results of pediatric clinician panel review

This indicator was also reviewed, during the current development process by a panel of eleven pediatric clinicians, including one general pediatrician, one pediatric hospitalist, one pediatric critical care physician, one neonatologist, one pediatric infectious disease specialist, one pediatric hematologist/oncologist, one pediatric cardiothoracic surgeon, one pediatric emergency medicine specialist, on pediatric interventional radiologist, and two pediatric surgeons. In the course of review the panels suggested or noted the following:

- Panelists noted that some reactions may result from outpatient therapy. In order to track these complications, an area level indicator will be developed for this indicator, which includes principal diagnoses for transfusion reactions identified by this indicator, and which utilizes a population denominator. The area level indicator is intended to capture transfers and readmissions for transfusion reaction. It will be available in addition to this hospital-based indicator.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating – comparative purposes	8	Indeterminate agreement
Not present on admission	8	Agreement
Preventability	8	Agreement
Due to medical error	8	Agreement
Charting by physicians	8	Agreement
Lack of bias	7.25	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (+)

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

Prior to panel review, using the AHRQ QI definition applied to a pediatric population, we found that the rate of transfusion reaction was much higher in children than adults (more than 10 fold increase in children). We suspected that these cases may be in children undergoing “exchange transfusions” for severe hyperbilirubinemia. Analysis showed that none of these patients had a procedure code for an exchange transfusion. In order to better understand this increased rate we looked at DRGs for patients with transfusion reaction. All but two patients of 66 with transfusion reaction were neonates and most of those neonates were in a DRG for normal newborns and had a normal birthweight. Due to this information, we began to suspect miscoding as a cause for the higher rate in children. To verify we examined the secondary diagnosis and procedure codes for children with transfusion reaction. Most children had no diagnosis code that would suggest a severely ill infant that would have received a transfusion, and therefore truly seemed to be normal newborns. Many only had one diagnosis code for normal delivery in addition to the

transfusion reaction code. As a result, we concluded that these cases are most likely miscoding, perhaps of maternal-fetal Rh incompatibility.

Literature based evidence specific to pediatric population

Transfusion reactions due to ABO or Rh incompatibility remain a very rare but preventable patient safety issue in pediatrics. HCUP data from 1997 showed an event rate of 0.17 per 1,000 discharges for transfusion reaction among children 0-18 years of age, using a broader definition that included "other transfusion reaction."[10] Other groups have analyzed rates of this indicator using the publicly available indicator definition applied to a pediatric population; this definition differs slightly from the definition proposed above. The incidence of transfusion reactions was investigated in pediatric patients (e.g., 0.003 per 1,000 discharges at 0-17 years, 0.003 at 18-44 years, 0.006 at 45-64 years, and 0.005 at 65 or more years). [17] Using HCUP data from 2000, a rate of 0.006 per 1,000 discharges was seen. Given the rarity of this complication, Miller and Zhan were not able to determine whether it was associated with increased mean length of stay, mean hospital charges, or in-hospital mortality.[11]

ASTHMA ADMISSION RATE (PQI)

(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for asthma (see definition and exclusions below) per 100,000 population. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

All patients 2-17 years old with a principal diagnosis code for asthma.

- Extrinsic asthma (unspecified, with status asthmaticus, with acute exacerbation [493.00-2])
- Intrinsic asthma (unspecified, with status asthmaticus, with acute exacerbation [493.10-2])
- Chronic obstructive asthma (unspecified, with status asthmaticus, with acute exacerbation [493.20-2])
- Exercise induced bronchospasm [493.81]
- Cough variant asthma [493.82]
- Asthma (unspecified, with status asthmaticus, with acute exacerbation [493.90-2])

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates).

Exclude patients with any diagnosis for cystic fibrosis, chronic lung disease of prematurity, anomalies of upper respiratory system, congenital cystic lung, anomalies of the lungs and accessory lobes, anomalies of respiratory system, including mediastinal cysts and pleural anomalies, tracheoesophageal fistula, esophageal atresia and stenosis, ciliary dismotility syndrome and vascular ring/sling.

Rates based on year 2003 KIDs' Inpatient Sample(per 100,000):

OVERALL	177.9
Age stratified rates:	
2 years	624.1
3 – 5 years	270.4
6 – 12 years	157.2
13 – 17 years	68.3

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably with agreement for internal quality improvement within an area and favorably with indeterminate agreement for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 2 – 17	Pediatric age range. Lower age limit changed from zero to two, since diagnosis in younger children may be difficult to distinguish from bronchospasm.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
All complicated patients included.	Exclude patients with cystic fibrosis, chronic lung disease of	Patients with respiratory disorders may have complications

	prematurity, anomalies of upper respiratory system, congenital cystic lung, anomalies of the lungs and accessory lobes, anomalies of respiratory system, including mediastinal cysts and pleural anomalies, tracheoesophageal fistula, esophageal atresia and stenosis, ciliary dismotility syndrome and vascular ring/sling.	requiring admission.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
Only asthma codes including in numerator.	Include codes for bronchospasm and wheezing in numerator.	Panelists felt that these codes are more likely to represent first presentation (e.g., not preventable) or other conditions.

Clinical rationale

This indicator is intended to identify hospitalizations for asthma, where asthma is identified as the principal reason for hospitalization. Guidelines outline maintenance therapy, including drug treatments, which may reduce the incidence of acute exacerbations requiring hospitalization.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from indicators developed independently by John Billings[30] and Weissman and colleagues[31] after favorable evaluation by physician panels.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The panel advocated excluding patients with cystic fibrosis and anomalies of the respiratory system as these patients represent highly complicated cases that may require hospitalization. This exclusion was added to the definition.
- The panel discussed adding codes for bronchospasm and wheezing, but agreed that these should not be added, as panelists felt that these may be more likely to

represent a first presentation (that would not be avoidable) or conditions other than asthma.

- Panelists expressed concern that certain patients may be less likely to seek timely care regardless of access to quality care. These patients may present with advanced disease. Panelists argued, as for all potentially preventable hospitalizations, that this indicator be adjusted for socioeconomic status and that differences in cultural groups be considered when analyzing results.
- Panelists also noted that areas with hospitals that have short stay units or similar practice patterns (e.g. holding patients in the ER instead of admitting) may appear to have lower rates without actually having higher quality of care. Given data limitations, no changes to the indicator definition could be made to address this issue. However, users of the indicator could explore admitting patterns with additional data.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI area	8	Agreement
Overall rating – comparative purposes	7	Indeterminate agreement
Access to quality outpatient care	7	Indeterminate agreement
Charting by physicians	8	Indeterminate agreement
Lack of bias	5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (-)

Literature based evidence

Numerous studies have shown that asthma hospitalization rates are associated with socioeconomic factors, including median household income (at the area level) and lack of insurance (at the individual level).[31] A study of asthma hospitalization rates in California in 1993 (ages 0-64) found that areas with median household incomes under $35,000 had hospitalization rates that were 1.5 times higher than areas with higher median incomes.[32] In Boston, in 1992, age and gender standardized hospitalization rates (all ages) were correlated with percentage poverty in an area (r=0.68), percentage holding a bachelor's degree (r=-0.61), and income (r=-0.51).[33] Within New York City in 1994, asthma hospitalization rates were negatively correlated with a zip code area's median household income (r=-0.67), and positively correlated with the percentage of minorities in the population (r=0.82).[33] These findings confirm an earlier study by Billings et al.,[30] who reported 6.4-fold variation in asthma hospitalization rates (age 0-64) at the zip code level in New York City in 1988, with 70% of this variation explainable by the percentage of households with annual income below $15,000. Millman et al.[34] reported that low-income zip codes had 5.8 times more asthma hospitalizations per capita (age 0-64) than high-income zip codes in 11 states in 1988. Using New York State data, Lin et al showed that hospitalization rates were higher in areas with higher poverty, unemployment, minority populations, and lower education levels.[35] Even in England, 45% of the variation in asthma hospitalization rates across 90 family health services authorities in 1990-95 was attributable to socioeconomic factors, plus the availability of secondary care.[36] To our

knowledge, only one study has reported partial correlations;[37] it found that in New York City, the percentage of African-American residents (age 0-34) was the strongest predictor, and median household income was the next strongest predictor, of asthma hospitalization rates.

The observation that asthma admission rates are higher in areas with low socio-economic status (SES) has led some researchers to hypothesize that lack of access to care, or poor quality outpatient care, may lead to higher admission rates. Although analyses of the National Health and Nutrition Examination Survey found that Medicaid enrollment and Spanish language preference were associated with inadequate asthma therapy, these deficiencies in care were not directly linked to hospitalizations in children.[38] Studies from other settings have shown that African-American asthmatics tend to have fewer scheduled primary care visits, and more hospitalizations and emergency room visits, than White asthmatics.[39, 40] African-Americans' use of asthma medications in children may also be less consistent with current practice guidelines.[41]

Few studies have directly linked high-quality processes of outpatient care with lower hospitalization rates at either the area or the individual level. An in-depth study of asthma treatment practices in New Haven, Boston, and Rochester found that the community with the highest asthma hospitalization rate (Boston) also had lower use of inhaled anti-inflammatory agents and oral steroids. The threshold for admission also appeared to be lower in Boston, as fewer of the admitted children were hypoxemic, relative to the other cities.[42] One case control study from a large health maintenance organization established that not having a written asthma management plan was a strong risk factor for asthma hospitalization in children (after adjusting for severity of asthma), but the use of anti-inflammatory medications was not.[43] More recent studies have confirmed that continuity of care with the same provider and a comprehensive asthma care program decrease the risk of ED visits and hospitalization for asthma. The risk of hospital admission was lower when clinical pathways were used for asthmatic children in ERs of Australian hospitals.[44] In another Australian study, having a written asthma action plan contributed to a reduction in hospital and emergency department attendance.[45]

With patient and parent education, good medical therapy, and outreach programs, adverse outcomes for children can be reduced considerably.[43, 46] For example, Medicaid HMO enrollees had higher age-gender-race adjusted asthma hospital discharge rates than Medicaid recipients enrolled in primary care case management program under fee-for-service reimbursement.[47] On the other hand, experience with Child Health Plus (CHPlus), a health insurance program providing ambulatory and ED coverage for uninsured and low-income children (0-13 years) in New York, suggests that some access-improving interventions do NOT reduce asthma hospitalization rates. Visit rates, follow-up visits, and total visits to primary care providers were significantly higher during CHPlus than before enrollment. There was no significant association between CHPlus coverage and ED visits or hospitalizations for asthma, although specialty utilization increased .[48]

DIABETES SHORT-TERM COMPLICATIONS ADMISSION RATE (PQI)
(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for diabetes short-term complications (ketoacidosis, hyperosmolarity, coma) (see definition and exclusions below) per 100,000 population. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

All patients 6-17 years old with a principal diagnosis code for ketoacidosis, hyperosmolarity or coma.

- Diabetes with ketoacidosis (includes type II and type I, stated as uncontrolled and not stated as uncontrolled [250.1x])
- Diabetes with hyperosmolarity (includes type II and type I, stated as uncontrolled and not stated as uncontrolled [250.2x])
- Diabetes with other coma (includes type II and type I, stated as uncontrolled and not stated as uncontrolled [250.3x])

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates)

Rates based on year 2003 KIDs' Inpatient Sample(per 100,000):

OVERALL	30.7
Age stratified rates:	
6 – 12 years	22.9
13 – 17 years	41.3

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated this indicator favorably with agreement for internal quality improvement within an area but rated the indicator less favorably for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 6 – 17	Pediatric age range. Lower age limit increased to six years to reduce the incidence of first time presentations included in numerator.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional.		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
Uncontrolled diabetes code in separate complimentary indicator.	Uncontrolled diabetes included in numerator.	Panelists felt that this code is likely to represent high quality care, with appropriate intervention for uncontrolled diabetes.

Indicator status summary

Based on the evidentiary base and the pediatric clinician panel review, this indicator will be included in the pediatric quality indicator set. For details of the panel discussion see below.

Clinical rationale

This indicator is intended to identify hospitalizations for diabetic ketoacidosis, coma, and hyperosmolarity. With good disease management, these complications are avoidable.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from an indicator developed by John Billings[30] and colleagues after favorable evaluation by a physician panel.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- The panel discussed the possibility of adding a code for uncontrolled diabetes, as is included in the Healthy People 2010 indicator. Panelists felt that admissions with this code may actually be indicative of good care, indicating an attempt to pinpoint reasons for uncontrolled diabetes that may be unrelated to medical care (e.g. social factors). This code was not added to the definition.
- It would be most desirable to eliminate admissions for initial diagnoses; however, it is not possible to do so given coding constraints. Panelists felt that a relatively high age lower limit (as the 6 year age limit) would aid in reducing the number of first time presentations captured by this indicator.
- Panelists expressed concern that certain patients may be less likely to seek timely care regardless of access to quality care. These patients may present with less controlled disease. Panelists argued, as for all potentially preventable hospitalizations, that this indicator be adjusted for socioeconomic status and that differences in cultural groups be considered when analyzing results.

Post-conference call panel ratings – Diabetes

Question	Median	Agreement status
Overall rating – internal QI area	7	Agreement

Overall rating – comparative purposes	6	Indeterminate agreement
Access to quality outpatient care	7	Indeterminate agreement
Charting by physicians	8	Agreement
Lack of bias	7	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Not recommended

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

Type I and Type II diabetes have differing risk of acute complications and incidence in the pediatric population. Type II is expected to vary systematically by area leading to more bias potentially. We examined the relative incidence of Type I and Type II in this indicator. If Type II diabetes were frequent enough, a stratified rate may be in order. Over 95% of cases were due to Type I diabetes. Further, a handful of "Type II" cases (14) occurred in children under 5 years of age, and may be miscoded, since this type of diabetes is extremely rare in this age group. Based on this information, stratification was not recommended, and the age range for the indicator was implemented as 6 years and above.

Literature based evidence

Precipitating events leading to admission may include physiologic causes, as discussed above, or the cessation of treatment due to access to care or non-compliance issues. Evidence that such causes are or are not due to access to care contributes to the construct validity of this indicator. However, such evidence has not been strongly shown. Access to care in relation to admissions has been explicitly studied and reported. Weissman[31] found that uninsured patients had a higher risk of admission for DKA and coma than privately insured patients (age 0-64) (adjusted O.R. 2.18 – 2.77). Two studies of ACSC indicators reported validation work for diabetes independent of measure sets. Millman et al.[34] reported that low-income zip codes had 4.1 times more diabetes hospitalizations per capita (age 0-64) than high-income zip codes in 11 states in 1988. Billings et al.[30] found that low-income zip codes in New York City (where at least 60% of households earned less than $15,000 in 1988, based on adjusted 1980 Census data) had 6.3 times more diabetes hospitalizations per capita (age 0-64) than high-income zip codes (where less than 17.5% of households earned less than $15,000). Household income explained 52% of the variation in short term diabetes complication hospitalization rates at the zip code level. These findings suggest that this indicator may be a marker for poor access to outpatient care.

DEHYDRATION ADMISSION RATE (PQI)

(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for dehydration (see definition and exclusions below) per 100,000 population.

Included admissions:

All patients 0-17 years old with a principal diagnosis code for hypovolemia [276.5].

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates)

Exclude patients with any diagnosis code for immunocompromised state.

Rates based on year 2003 KIDs' Inpatient Sample(per 100,000):

OVERALL	
Age stratified rates:	
0 – 30 days	
31 days – 364 days	
1 – 2 years	
3 – 5 years	
6 – 12 years	
13 – 17 years	

Status summary. Based on current evidence base and the pediatric panel literature review, this indicator was eliminated from further review. A subset of patients were added to the indicator for gastroenteritis admission.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range
Immunocompromised patients included.	Immunocompromised patients excluded.	Immunocompromised patients are more likely to develop complications requiring hospitalization.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
Patients with principle diagnosis of dehydration in separate indicator.	Patients with principle diagnosis of dehydration and a secondary diagnosis of gastroenteritis included in the numerator (gastroenteritis indicator).	Panelists felt that this change more accurately reflected gastroenteritis hospital admissions and that other types of dehydration admissions were not important.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to identify hospitalizations for dehydration, where dehydration is identified as the principal reason for hospitalization. Many cases of dehydration can be treated in an outpatient setting effectively with early identification, oral rehydration therapy and IV fluids.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from an indicator developed by John Billings[30] and colleagues after favorable evaluation by a physician panel.

Literature based evidence

We found little literature on admission for dehydration as an ambulatory care sensitive condition indicator. Millman et al.[34] reported that low-income zip codes had 2.1 times more dehydration hospitalizations per capita (age 0-64) than high-income zip codes in 11 states in 1988. Billings et al.[30] found that low-income zip codes in New York City (where at least 60% of households earned less than $15,000 in 1988, based on adjusted 1980 Census data) had 2.0 times more dehydration hospitalizations per capita (age 0-64) than high-income zip codes (where less than 17.5% of households earned less than $15,000). Household income explained 42% of the variation in dehydration hospitalization rates at the zip code level. These findings suggest that this indicator may be marker for poor access to outpatient care.

In a before and after study conducted on the effectiveness of a clinical pathway for gastroenteritis in the emergency department of the Children's Hospital at Westmead, the admission rate was reduced from 20.0% in 1996 to 9.1% in 1999 ($P < 0.05$) without adverse sequelae.[44] This finding is consistent with the hypothesis that timely and effective care for gastroenteritis reduces the severity of dehydration and hence the risk of hospitalization.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists suggested that this indicator be combined with the gastroenteritis indicator. That indicator will now include patients admitted with a principal diagnosis of dehydration and a secondary diagnosis of gastroenteritis as well as patients with a principal diagnosis of gastroenteritis. Before this recommendation, there was a separate indicator for dehydration. The combination of the dehydration and gastroenteritis indicators allowed for gastroenteritis patients to be more fully captured in one indicator. Patients admitted for dehydration that is not due to gastroenteritis will no longer be captured.

Empirical analyses to inform indicator definition

The following empirical analysis aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

We examined the secondary diagnosis codes for patients in the numerator to better understand the clinical mixture of this indicator. We found that approximately half of the diagnosis codes were related to gastroenteritis, supporting the panelists' suggestion to change the gastroenteritis admission rate indicator and remove the dehydration indicator from consideration.

GASTROENTERITIS ADMISSION RATE (PQI)

(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for gastroenteritis (see definition and exclusions below) per 100,000 population. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

All patients 3 months - 17 years old with a principal diagnosis code for gastroenteritis OR a principal diagnosis of dehydration accompanied by a secondary diagnosis of gastroenteritis.

Enteritis due to:

- Rotavirus [008.61]
- Adenovirus [008.62]
- Norwalk virus [008.63]
- Other small round virus [008.64]
- Calicivirus [008.65]
- Astrovirus [008.66]
- Enterovirus, not elsewhere classified [008.67]
- Other viral enteritis [008.69]
- Other organism, not otherwise specified (viral) [00.88]
- Infectious colitis, enteritis and gastroenteritis not otherwise specified [009.0]
- Colitis, enteritis, and gastroenteritis of presumed infectious origin [009.1]
- Infectious diarrhea [009.2]
- Diarrhea of presumed infectious origin [009.3]
- Other and unspecified noninfectious gastroenteritis and colitis [558.9]

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates)

Exclude patients with any diagnosis code for bacterial gastroenteritis and gastrointestinal abnormalities.

Rates based on year 2003 KIDs' Inpatient Sample(per 100,000):

OVERALL	180.80
Age stratified rates:	
61 days – 364 days	1029.94
1 – 2 years	672.01
3 – 5 years	164.86
6 – 12 years	67.15
13 – 17 years	32.44

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably with indeterminate agreement for internal quality improvement but rated the indicator less favorably for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
Patients with principle diagnosis of dehydration in separate indicator.	Patients with principle diagnosis of dehydration and a secondary diagnosis of gastroenteritis included in the numerator.	Panelists felt that this change more accurately reflected gastroenteritis hospital admissions.
No specific exclusion for bacterial gastroenteritis	Exclude patients with any diagnosis code for bacterial gastroenteritis.	Bacterial gastroenteritis may require hospitalization, despite high quality outpatient care.
Age range 0-17	Age range 3 mo.-17 years.	Infants 2 months or younger often better managed as inpatients.
Include gastrointestinal abnormalities.	Exclude patients with any diagnosis codes of gastrointestinal abnormalities.	Gastrointestinal abnormalities may cause diarrhea that may mimic infectious diarrhea.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
Include patients with immunocompromised state.	Exclude patients with immunocompromised state.	Patients are not at higher risk for being admitted.

Clinical rationale

This indicator is intended to identify hospitalizations for gastroenteritis, where gastroenteritis is identified as the principal reason for hospitalization. Timely and effective care for gastroenteritis, such as oral rehydration therapy, may reduce the need for hospitalization.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from an indicator developed by John Billings and colleagues after favorable evaluation by a physician panel.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists suggested that this indicator include patients admitted with a principal diagnosis of dehydration and a secondary diagnosis of gastroenteritis as well as patients with a principal diagnosis of gastroenteritis. Before this recommendation, there was a separate indicator for dehydration. The combination of the dehydration and gastroenteritis indicators allowed for gastroenteritis patients to be more fully captured in one indicator.
- Panelists agreed that patients with immunocompromised state should be excluded since these patients may be at increased risk for complications due to gastroenteritis, requiring hospitalization.
- Panelists argued that patients two months of age or less should not be included since they felt that these patients have less reserves to cope with gastroenteritis / dehydration or additional underlying illness and are often best managed in an inpatient setting.
- Panelists expressed concern that certain patients may be less likely to seek timely care regardless of access to quality care. These patients may present with advanced disease. Panelists argued, as for all potentially preventable hospitalizations, that this indicator be adjusted for socioeconomic status and that differences in cultural groups be considered when analyzing results.
- Panelists also noted that areas with hospitals that have short stay units or similar practice patterns (e.g. holding patients in the ER instead of admitting) may appear to have lower rates without actually having higher quality of care. Given data limitations, no changes to the indicator definition could be made to address this issue. However, users of the indicator could explore admitting patterns with additional data.

Post-conference call panel ratings – Gastroenteritis

Question	Median	Agreement status
Overall rating – internal QI area	7	Indeterminate agreement
Overall rating – comparative purposes	6	Indeterminate agreement
Access to quality outpatient care	6	Indeterminate agreement
Charting by physicians	7	Agreement
Lack of bias	4	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Not recommended

Literature based evidence

No published studies have specifically addressed the relationship of the gastroenteritis hospitalization rate to quality of outpatient care. John Billings' original study from New York reported 1.87-fold variation in gastroenteritis hospitalization rates for ages 0-64, with a coefficient of variation of 0.438 and 22% of variance explained by household income.[30] Millman et al.[34] reported that low-income zip codes had 1.9 times more pediatric gastroenteritis hospitalizations per capita than high-income zip codes in the same 11 states in 1988. Similarly, a retrospective analysis of the 1995-96 cohort of infants born in Western Australia showed that aboriginal infants were hospitalized for gastroenteritis 8 times more frequently, and readmitted 2.7 times more frequently than

their non-Aboriginal peers.[49] These findings suggest that this indicator may be marker for poor access to outpatient care.

In a before and after study conducted on the effectiveness of a clinical pathway for gastroenteritis in the emergency department of the Children's Hospital at Westmead, the admission rate was reduced from 20.0% in 1996 to 9.1% in 1999 ($P < 0.05$) without adverse sequelae.[44] This finding is consistent with the hypothesis that timely and effective care for gastroenteritis reduces the need for hospitalization.

BACTERIAL PNEUMONIA ADMISSION RATE (PQI)

(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for bacterial pneumonia (see definition and exclusions below) per 100,000 population. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

All patients 3 mo. – 17 years old with a principal diagnosis code for bacterial pneumonia.

Pneumonia due to:

- Pneumococcus [481]
- H. influenzae [482.2]
- Streptococcus unspecified [482.30]
- Group A streptococcus [482.31]
- Group B streptococcus [482.32]
- Other streptococcus [482.39]
- Bacterial pneumonia NOS [482.9]
- Mycoplasma [483.0]
- Clamydia [483.1]
- Other specified organism [483.8]
- Broncopneumonia, organism unspec [485]
- Organism unspecified [486]

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates).

Exclude patients with any diagnosis code for sickle cell anemia, HB-S disease, cystic fibrosis, immunocompromised state (ie. Organ transplant, bone marrow or stem cell transplant, HIV or AIDs, humoral immunodeficiencies, deficiencies of cell-mediated immunity, other specified and unspecified immunodeficiency), chronic lung disease of prematurity, anomalies of upper respiratory system, congenital cystic lung, anomalies of the lungs and accessory lobes, anomalies of respiratory system, including mediastinal cysts and pleural anomalies, tracheoesophageal fistula, esophageal atresia and stenosis, ciliary dismotility syndrome and vascular ring/sling.

Rates based on year 2003 KIDs' Inpatient Sample(per 100,000):

OVERALL	
Age stratified rates:	
3 mo – < 1 year	
1 – 2 years	
3 – 5 years	
6 – 12 years	
13 – 17 years	

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is not recommended for inclusion in the pediatric indicator set. Panelists disagreed regarding the usefulness of this indicator.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 3 mo. – 17	Pediatric age range. Lower range raised to reflect standard practice of admitting very young infants.
Exclude patients with sickle cell anemia and related diseases.	Exclude patients with cystic fibrosis, immunocompromised state, anomalies of upper	Patients are at higher risk for developing complications with pneumonia requiring

	respiratory system, congenital cystic lung, anomalies of the lungs and accessory lobes, anomalies of respiratory system, including mediastinal cysts and pleural anomalies, tracheoesophageal fistula, esophageal atresia and stenosis, ciliary dismotility syndrome and vascular ring/sling.	hospitalization.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional.		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to capture cases of hospitalization, where bacterial pneumonia is identified as the primary reason for the hospitalization. Bacterial pneumonia is for the most part treatable with antibiotics, and timely and appropriate treatment may reduce the need for hospitalization. Patients who are more likely to develop complications requiring hospitalization despite good quality outpatient care are excluded, including those with sickle cell diseases, cystic fibrosis, immunocompromised state, and anomalies of the respiratory system.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from an indicator developed by Weissman et al. [31] after favorable evaluation by a physician panel.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists expressed concern that certain patients may be less likely to seek timely care regardless of access to quality care. These patients may present with advanced disease. Panelists argued, as for all potentially preventable

hospitalizations, that this indicator be adjusted for socioeconomic status and that differences in cultural groups be considered when analyzing results.

- Panelists also noted that areas with hospitals that have short stay units or similar practice patterns (e.g. holding patients in the ER instead of admitting) may appear to have lower rates without actually having higher quality of care. Given data limitations, no changes to the indicator definition could be made to address this issue. However, users of the indicator could explore admitting patterns with additional data.
- Ideally, bacterial pneumonia could easily be distinguished from viral pneumonia in pediatric patients, since viral pneumonia is largely seen as less preventable. However, since it is not standard practice to culture the respiratory tract in children (due to the difficulty of obtaining material), this indicator will invariably pick up some viral pneumonias in addition to unspecified and specified bacterial pneumonia.

Post-conference call panel ratings – Pneumonia

Question	Median	Agreement status
Overall rating – internal QI area	6	Disagreement
Overall rating – comparative purposes	6	Disagreement
Access to quality outpt care	6.5	Indeterminate agreement
Charting by physicians	7	Indeterminate agreement
Lack of bias	5	Indeterminate agreement
Final recommendation	Not recommended for internal QI or comparative purposes.	

Literature based evidence

We found little literature on admission for pneumonia as an indicator of access to quality outpatient care. Millman et al.[34] reported that low-income zip codes had 5.4 times more pneumonia hospitalizations per capita (age 0-64) than high-income zip codes in 11 states in 1988. Billings et al.[30] found that low-income zip codes in New York City (where at least 60% of households earned less than $15,000 in 1988, based on adjusted 1980 Census data) had 5.4 times more pneumonia hospitalizations per capita (age 0-64) than high-income zip codes (where less than 17.5% of households earned less than $15,000). Household income explained 53% of the variation in pneumonia hospitalization rates at the zip code level. In a Swedish study using hospital episode statistics and population census data, deprivation was associated with increased admission rates for all respiratory infections and all age-groups. The greatest effect was among those 0-4 years of age, who had admission rates 91% higher in the most deprived areas compared to the least deprived.[50]These findings suggest that this indicator may be marker for poor access to outpatient care.

Numerous studies among adults have shown that influenza vaccination and pneumoccccal vaccination reduce hospitalization rates for pneumonia and influenza.[50-56] We are not aware of any evidence linking reduced pneumonia hospitalization rates among children to specific improvements in the process of care, although it is certainly plausible that timely initiation of outpatient antibiotics may obviate the need for

hospitalization. Supportive evidence comes from Washington,[57] who found that African-American children admitted to US hospitals for pneumonia were less likely to require bronchoscopy or mechanical ventilation, and hence less sick at presentation, than white children.

PERFORATED APPENDIX ADMISSION RATE (PQI)

(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for perforated appendix (see definition and exclusions below) per 100 admissions for appendicitis within an area. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

All patients 1-17 years old with any diagnosis code for perforation or abscess of appendix.

- Acute appendicitis with generalized peritonitis [540.0]
- Acute appendicitis with peritoneal abscess [540.1]

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates).

Rates based on year 2003 KIDs' Inpatient Sample(per 100):

OVERALL	31.36
Age stratified rates:	
1 – 2 years	69.21
3 – 5 years	51.79
6 – 12 years	31.90
13 – 17 years	25.53
Rates by type of hospital:	
Children's hospitals	39.25
Non-children's hospitals	28.61
Unknown	34.34

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably with indeterminate agreement both internal quality improvement within an area and for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 1– 17	Pediatric age range. Lower age range set to 1 year, given difficulty in diagnosing appendicitis in infants.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional.		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to identify cases of perforated appendix. Timely identification of appendicitis may avert perforation.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from an indicator developed by Weissman[31] and colleagues after favorable evaluation by a physician panel.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our all-age indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists expressed concern that certain patients may be less likely to seek timely care regardless of access to quality care. These patients may present with rupture. Panelists argued, as for all potentially preventable hospitalizations, that this

indicator be adjusted for socioeconomic status and that differences in cultural groups be considered when analyzing results.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI area	7	Indeterminate agreement
Overall rating – comparative purposes	7	Indeterminate agreement
Access to quality outpatient care	6	Indeterminate agreement
Charting by physicians	8	Agreement
Lack of bias	7	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Acceptable (-)

Literature based evidence

In the seminal study of this topic, Braveman et al. examined the likelihood of ruptured appendix among adults 18 to 64 years old who were hospitalized for acute appendicitis in California from 1984 to 1989. After controlling for age, sex, psychiatric diagnoses, substance abuse, diabetes, poverty, race or ethnic group, and hospital characteristics, ruptured appendix was more likely among both Medicaid-covered and uninsured patients with appendicitis than among patients with private capitated coverage (OR 1.49 and 1.46, 1.39 to 1.54, respectively).[58]

Several more recent studies have focused on the pediatric population. Using hospital discharge data from Washington state, Bratton et al. found that the risk-adjusted odds ratio for complicated disease (perforation or peritoneal abscess) among children with Medicaid as the primary payer was 1.3 (95% CI: 1.2-1.4). The risk of complicated disease for children without any medical insurance was not significantly elevated. Children who received care in centers with >10 000 annual admissions had a 1.8-fold increased odds of perforation, compared with children treated at smaller facilities. Patients initially managed in the emergency department were less likely to have complicated disease, compared with children who were referred from an office practice (OR: 0.7; 95% CI: .7-.8).[59] This last finding was confirmed by a study of both children and adults from San Diego, which reported that patients with appendicitis directly admitted from outpatient sources were 1.62 (95% CI: 1.28-2.05) times more likely to have rupture than were those admitted through the hospital ED.[60] Guagliardo et al. analyzed acute appendicitis cases from California and New York (4-18 years of age) and identified several independent risk factors for rupture in California: Hispanic ethnicity (OR=1.30, 95% CI: 1.14-1.48), public insurance (OR=1.29, 95% CI: 1.14–1.46), self-pay (OR=1.36, 95% CI: 1.07–1.74), median zip code <$25,000 (OR=1.22, 95% CI: 1.03–1.45), and non-ED referral (OR=1.15, 95% CI: 1.02–1.30). In New York, Hispanic ethnicity, insurance, and low income were not associated with rupture, but African-American race and non-ED referral were associated with rupture (OR=1.28, 95% CI: 1.05–1.57).[61] Finally, Ponsky et al. reviewed data on children aged 5 to 17 years from 36 pediatric hospitals, and found that Asian and black children were more likely to have appendiceal rupture than white children (OR=1.66, 95% CI: 1.24-2.23; OR=1.13, 95% CI, 1.01-1.30). Children with public insurance had a greater risk of rupture than children with private insurance

(OR=1.48; 95% CI 1.34-1.64), as did children who were self-insured (OR=1.36; 95% CI, 1.22-1.53). Hospital experience, defined by the volume of appendectomies performed, was not associated with appendiceal rupture rate (r = 0.03; P = .86) regardless of adjustments for race, sex, age, and insurance status.[62]

Another study in a pediatric population examined reasons for delay to surgery and insurance status in a New York pediatric population through retrospective chart review. They noted that Medicaid or uninsured children had both a higher perforation rate and a longer duration of symptoms before presenting to a health care professional as compared to HMO or private fee for service insured children. There were no differences between the types of insurance in the time to surgery after presentation.[63] Unfortunately the authors did not analyze how much of the variance in perforated appendix could be explained by delays in seeking care. Based on Maryland Medicaid claims and hospital discharge data for children from 1989 to 1994, the probability of ruptured appendicitis was inversely related to age (OR = 0.86, 95% CI 0.81-0.91), white race (OR = 0.35, 95% CI 0.17-0.71) and preventive care visits (OR = 0.19, 95% CI 0.05-0.77).[64] In this model, the number of preventive care visits may serve as a marker for access to care.

Weissman et al., in their analysis of avoidable hospitalizations, found that the uninsured had a relative risk of 1.14-1.20 of admission for ruptured appendix after adjusting for age and sex (age 0-64). Medicaid patients had a relative risk of .45-.58, suggesting that in at least this case, Medicaid patients are not at increased risk for ruptured appendix.[31]

URINARY TRACT INFECTION ADMISSION RATE (PQI)

(AREA LEVEL INDICATOR)

Indicator definition:

Number of patients admitted for urinary tract infection (see definition and exclusions below) per 100,000 population. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

All patients 3 mo. - 17 years old with a principal diagnosis code for urinary tract infection.

- Chronic pyelonephritis without lesion of renal medullary necrosis [590.00]
- Chronic pyelonephritis with lesion of renal medullary necrosis [590.01]
- Acute pyelonephritis without lesion of renal medullary necrosis [590.10]
- Acute pyelonephritis with lesion of renal medullary necrosis [590.11]
- Renal and pernephric abscess [590.2]
- Pyeloureteritis cystica [590.3]
- Pyelonephritis, unspecified [590.80]
- Pyelitis or pyelonephritis in diseases classified elsewhere [590.81]
- Infection of kidney, unspecified [590.9]
- Acute cystitis [595.0]
- Cystitis, unspecified [595.9]
- Urinary tract infection, site not specified [599.0]

Exclude patients transferring from another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates)

Exclude patients with any diagnosis of immunocompromised state (ie. Organ transplant, bone marrow or stem cell transplant, HIV or AIDs, humoral immunodeficiencies, deficiencies of cell-mediated immunity, other specified and unspecified immunodeficiency) or kidney/urinary tract disorders (e.g. chronic pyelonephritis, vesicoureteral reflux, congenital anomalies of urinary system, renal agenesis or dysgenesis, cystic kidney disease, exstrophy of bladder, atresia and stenosis of bladder neck, obstructive defects of renal pelvis and ureter, other anomalies of urinary system).

Rates based on year 2003 KIDs' Inpatient Sample(per 100,000):

OVERALL	52.28
Age stratified rates:	
3 mo. – < 1 year	410.34
1 – 2 years	74.50
3 – 5 years	38.61
6 – 12 years	26.16
13 – 17 years	34.93

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. Panelists rated the indicator favorably with indeterminate agreement for internal quality improvement within an area but rated the indicator less favorably for comparative purposes.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 3 mo. – 17	Pediatric age range. Age range raised to 3 months to reflect standard practice of admitting young infants.

All patients included.	Exclude patients with any diagnosis of immunocompromised state or kidney/urinary tract disorders (e.g. chronic pyelonephritis, vesicoureteral reflux, congenital anomalies of urinary system, renal agenesis or dysgenesis, cystic kidney disease, exstrophy of bladder, atresia and stenoosis of bladder neck, obstructive defects of renal pelvis and ureter, other anomalies of urinary system).	Patients are at higher risk for developing complications with urinary tract infection requiring hospitalization.

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional.		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator is intended to identify hospitalizations for urinary tract infection, where UTI is identified as the principal reason for hospitalization. Many cases of UTI can be treated in an outpatient setting effectively with early identification and appropriate antibiotic treatment, and will not progress to pyelonephritis. Patients who are more likely to develop complications requiring hospitalization despite good quality outpatient care are excluded, including those with, immunocompromised state, and anomalies of the urinary tract and kidneys.

This indicator was developed as part of the Prevention Quality Indicator measure set, and is adapted from an indicator developed by John Billings[30] and Weissman[31] and colleagues after favorable evaluation by a physician panel.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is a Prevention Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of eleven pediatric clinicians, including two ambulatory care pediatricians, one ambulatory care pediatric nurse practitioner, one family practitioner, one pediatric hospitalist, one pediatric emergency medicine physician, two pediatric pulmonologists, one pediatric endocrinologist, and two pediatric surgeons. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists expressed concern that certain patients may be less likely to seek timely care regardless of access to quality care. These patients may present with advanced disease. Panelists argued, as for all potentially preventable hospitalizations, that this indicator be adjusted for socioeconomic status and that differences in cultural groups be considered when analyzing results.
- Panelists also noted that areas with hospitals that have short stay units or similar practice patterns (e.g. holding patients in the ER instead of admitting) may appear to have lower rates without actually having higher quality of care. Given data limitations, no changes to the indicator definition could be made to address this issue. However, users of the indicator could explore admitting patterns with additional data.
- Panelists noted that practice patterns regarding evaluation for causative factors such as urinary tract malformations vary from hospital to hospital and may affect rates. Some hospitals always evaluate patients in-hospital, and when excludable abnormalities are found, these patients will be excluded. In other areas, this evaluation is done on an outpatient basis and therefore the patient will be included in the indicator, despite having an excludable comorbidity.

Post-conference call panel ratings – UTI

Question	Median	Agreement status
Overall rating – internal QI area	7	Indeterminate agreement
Overall rating – comparative purposes	6	Indeterminate agreement
Access to quality outpt care	6	Indeterminate agreement
Charting by physicians	7	Indeterminate agreement
Lack of bias	5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (-)	Comparative purposes: Not recommended

Literature based evidence

We found little literature on admission for urinary infection as an indicator of access to quality outpatient care. Millman et al.[34] reported that low-income zip codes had 2.8 times more UTI hospitalizations per capita (age 0-64) than high-income zip codes in 11 states in 1988. Billings et al.[30] found that low-income zip codes in New York City (where at least 60% of households earned less than $15,000 in 1988, based on adjusted 1980 Census data) had 2.2 times more UTI hospitalizations per capita (age 0-64) than high-income zip codes (where less than 17.5% of households earned less than $15,000). Household income explained 28% of the variation in UTI hospitalization rates at the zip code level. These findings suggest that this indicator may be marker for poor access to outpatient care.

Although there is ample literature indicating that most adolescents and adults with urinary tract infections can be safely managed with outpatient antibiotics, we are not aware of any evidence linking reduced UTI hospitalization rates among children to specific improvements in the process of care.

CRANIOTOMY MORTALITY RATE (IQI)

Indicator definition:

Number of deaths per 100 patients undergoing craniotomy. See The Pediatric Quality Indicator Technical Specifications.

Included procedures:

All patients 0-17 years old in a craniotomy DRG.

- Craniotomy, Age 0-17 <003>
- Intracranial Vascular Procedure with Principal Diagnosis of Hemorrhage <528>
- Ventricular Shunt Procedures with Complications and Comorbidities <529>
- Ventricular Shunt Procedures without Complications and Comorbidities <530>
- Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex Central Nervous System Principal Diagnosis <543>

Exclude patients transferring to another institution, MDC 14 (pregnancy, childbirth, and puerperium), or MDC 15 (newborns and neonates).

Exclude patients with a principal diagnosis of head trauma.

Exclude newborns with a birthweight of less than 500 grams.

Stratify into major risk groups by type of surgery: 1) Major craniotomies (tumors, epilepsy, vascular malformation and aneurysms) 2) craniosynostosis, 3) hydrocephalus (endoscopic third ventriculostomies, shunt procedure), 4) Chiari malformations

Rates based on year 2003 KIDs' Inpatient Sample(per 100)*

OVERALL	
Age stratified rates:	
Neonate, < 2000g	
Neonate, ≥ 2000g	
29 days – 364 days	
1 – 2 years	
3 – 5 years	
6 – 12 years	
13 – 17 years	

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this indicator is recommended for inclusion in the pediatric quality indicator set. However, further redefinition and consultation with specialists is required before this indicator can be implemented. Panelists rated this indicator favorably, with agreement for both for quality improvement and comparative uses.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
All ages	Age 0 – 17	Pediatric age range

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented

All craniotomies examined together.	Stratify into major risk groups by type of surgery: 1) Major craniotomies (tumors, epilepsy, vascular malformation and aneurysms) 2) craniosynostosis, 3) hydrocephalus (endoscopic third ventriculostomies, shunt procedure), 4) Chiari malformations.	Risk of mortality varies greatly by type of procedure.

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator was developed as part of the Inpatient Quality Indicator measure set. The indicator includes all DRGs for craniotomy in children, and excludes head trauma patients, as in previous coding conventions these patients were assigned to separate DRGs. This exclusion maintains consistency in the denominator group over time.

Results of pediatric clinician panel review

This indicator was not reviewed as part of our AHRQ QI indicator development process, since it is an Inpatient Quality Indicator with a strong evidentiary base in the literature.

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of twelve pediatric clinicians, one pediatric critical care specialist, one pediatric hospitalist, one pediatric anesthesiologist, one pediatric hematologist/oncologist, one pediatric cardiologist, two pediatric surgeons, one pediatric neurosurgeon, one pediatric urologist, two pediatric cardiovascular surgeons, and one neonatologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- At the onset of the review, this indicator was not stratified, and all patients undergoing any type of craniotomy were combined into one rate. Panelists argued that in order for this indicator to be fair due to case mix differences and useful for quality improvement the indicator should be stratified by four major risk groups, as outlined above. Panelists felt that this would be more informative, since different craniotomy procedures have vastly different risks for mortality.
- Panelists noted that risk adjustment is an important factor for this indicator. We will apply a general risk adjustment derived from administrative data, although it will likely not be tailored specifically to this indicator.

Post-conference call panel ratings

Question	Median	Agreement status
Overall rating – internal QI	8	Agreement
Overall rating - comparative	8	Agreement

Not present on admission	N/A	N/A
Preventability	7	Indeterminate agreement
Due to medical error	5.5	Indeterminate agreement
Charting by physicians	9	Agreement
Lack of bias	5.5	Indeterminate agreement
Final recommendation	Internal QI: Acceptable (+)	Comparative purposes: Acceptable (-)

Empirical analyses to inform indicator definition

The following empirical analyses aided in formulating the definition for this indicator. Analyses were conducted using the 2000 Nationwide Inpatient Sample.

This indicator includes procedures of varying complexity and risk. To better understand the breakdown we conducted a series of analysis. First we examined the risk of mortality for procedures associated with the DRG 003 (the only DRG in use in 2000 for the pediatric population). As anticipated, mortality rates varied widely, from no mortality for relatively simple procedures, to over 18% mortality. Also of note is that DRG 3 had a much higher % of ventricular shunt placements and revisions (25% in DRG3 versus 7% in DRG1 and 0.6% in DRG2). These procedures have lower mortality, in general, than other craniotomy procedures, especially in the pediatric population (just 0.77%). This analysis underscored the need for risk adjustment beyond the basic DRG and existing comorbidity adjustment for this indicator (in adults this adjustment is accomplished using APR-DRGs).

Panelists suggested stratification as one technique to account for different risk. Analyses were undertaken to explore the correct stratification. First we explored morality rates for pediatric craniotomy by principal diagnosis (4-digit) and procedure code, excluding procedures with fewer than 20 cases in the denominator. Due to the relative infrequency of some procedures we ran this analysis using three years of NIS data.

An attempt to classify cases according to risk strata included the following classification

1. any procedure with fewer than 5 cases in the three-year window (2000-02) was assigned to risk category 0
2. any procedure with no deaths was assigned to risk category 0
3. procedures with at least 5 cases and at least 1 death were assigned to risk categories 1-4 based on relative risk of mortality (roughly four equal groups)
4. any diagnosis-procedure combination with at least 20 cases was re-assigned to a new risk category if the relative risk was higher or lower than the original risk category (if the risk category was the same then the diagnosis was ignored)
5. In some cases diagnosis codes resulted in re-assignment. For example, procedure code 01.18 OTHER BRAIN DX PROCEDURE is assigned to risk category 4, unless it is associated with diagnosis codes 348.2x PSEUDOTUMOR CEREBRI or 996.2x MALFUN NEURO DEVICE/GRAF, in which case it is re-assigned to risk category 3.

A second set of groupings was calculated using specific diagnosis and procedure codes, based on panelist recommendations and a review of the ICD-9-CM codes.

For each stratum and each procedure code the raw rate and relative risk of mortality was calculated.

As a result of these analyses we found that the strata recommended by the panelists were too broad to differentiate risk of mortality. Further analyses and consultation with specialists will be required to define strata.

Literature based evidence

Most of the evidence for this indicator is based on several studies in adult populations. These studies found that providers who perform more than 30 procedures annually have lower mortality than those performing fewer procedures.[65, 66] In another study, adult patients who were referred to a large medical center for treatment of subarachnoid hemorrhage were less likely to die early, younger, and had fewer severe indications, including lower clinical grade, prevalence of coma, and diastolic blood pressure.[67]

***Pediatric-specific evidence*.** Only one relevant study has focused on the pediatric craniotomy population. A cross-sectional study of pediatric craniotomies for brain tumors, based on the Nationwide Inpatient Sample (i.e., administrative data) for 1998-2000, reported that adjusted mortality was significantly lower at high-volume hospitals than at low-volume hospitals (e.g., 2.3% at hospitals with 4 or fewer annual admissions versus 1.4% at hospitals with more than 20 annual admissions). There was a nonsignificant trend toward lower mortality after surgery performed by high-volume surgeons.

Empirical analyses have shown that a disproportionate percentage of children who undergo craniotomy have a primary indication of hydrocephalus or another defect requiring shunt placement to relieve intracranial pressure. Shunt placement is associated with a substantially lower probability of post-craniotomy mortality, such that it accounts for about 25% of all craniotomies, but only about 4% of post-craniotomy deaths.

PEDIATRIC HEART SURGERY MORTALITY RATE (IQI)

Indicator definition:

Number of in-hospital deaths in patients undergoing surgery for congenital heart disease per 100 patients. See The Pediatric Quality Indicator Technical Specifications.

Included admissions:

Discharges with a procedure codes for surgical intervention for congenital heart disease in any field or non-specific heart surgery in any field with a diagnosis code of congenital heart disease in any field.

Age less than 18 years old.

Exclude:
a. MDC 14 (pregnancy, childbirth and pueperium)
b. patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization
c. patients with septal defects (4P) as single cardiac procedures without bypass
d. heart transplant
e. premature infants with PDA closure as only cardiac procedure
f. age less than 30 days with PDA closure as only cardiac procedure
g. missing discharge disposition
h. transferring to another short-term hospital

Rates based on year 2003 KIDs' Inpatient Sample (per 1000):

OVERALL	46.66
Age stratified rates:	
Neonate, < 2000g	152.70
Neonate, ≥ 2000g	144.74
29 days – 364 days	39.09
1 – 2 years	21.14
3 – 5 years	12.53
6 – 12 years	11.77
13 – 17 years	9.57

Status summary. Based on the current evidence base, from the pediatric literature review, pediatric panel review, and empirical analyses, this is recommended for inclusion in the pediatric indicator set.

Changes from AHRQ QI Implemented Prior to Pediatric Panel Review

AHRQ QI definition	Pediatric indicator definition	Reason implemented
None.		

Changes Implemented to Pediatric Indicator as a Result of Pediatric Panel Review

Pre-panel definition	Post-panel indicator definition	Reason implemented
No additional		

Changes considered, but not implemented

AHRQ QI definition	Pediatric indicator definition	Reason not implemented
None.		

Clinical rationale

This indicator was developed as part of our Inpatient Quality Indicator measure set and is based on an indicator developed by Kathy Jenkins and colleagues. Dr. Jenkins developed this indicator based on physician input and empirical analyses.[68] Unlike other Inpatient Quality Indicators, this indicator also includes a tailored risk adjustment system, which estimates risk for patients based on procedure.

Results of pediatric clinician panel review

As part of the current pediatric indicator development process, this indicator was reviewed by a panel of twelve pediatric clinicians, one pediatric critical care specialist, one pediatric hospitalist, one pediatric anesthesiologist, one pediatric hematologist/oncologist, one pediatric cardiologist, two pediatric surgeons, one pediatric neurosurgeon, one pediatric urologist, two pediatric cardiovascular surgeons, and one neonatologist. The panel reviewed several other indicators. In the course of review the panel suggested the following:

- Panelists noted that the validity of this indicator lays primarily in the ability to risk adjust the measure. The panelists were presented with one system, the RACHS risk adjustment system, developed by Kathy Jenkins and colleagues, and panelists discussed the use of other clinically based systems, such as Aristotle. They recommended that the relative performance of risk adjustment feasible with administrative data be evaluated.

Literature based evidence

This indicator was developed as part of our Inpatient Quality Indicator measure set and is based on an indicator developed by Kathy Jenkins and colleagues. Dr. Jenkins developed this indicator based on physician input and empirical analyses.[68] Unlike other Inpatient Quality Indicators, this indicator also includes a tailored risk adjustment system, which estimates risk for patients based on procedure.

The evidence for the validity of this indicator comes from two sources. First, three studies (including one that used prospectively collected clinical data) have reported an association between hospital volume and mortality following pediatric cardiac surgery. Using a multivariate model that included age, complexity category, and four comorbidities, Hannan et al.[69] found 8.26% risk-adjusted mortality at hospitals with fewer than 100 cases per year, versus 5.95% at higher volume hospitals (an effect limited to surgeons who performed at least 75 cases per year). Two other studies using hospital discharge data from California and Massachusetts found similar effects of hospital volume .[68, 70] The consistent association between volume and risk-adjusted mortality supports the validity of both measures of performance, and is consistent with the hypothesis that more experience leads to improved technical skills and better outcomes. Other studies from single centers have confirmed this hypothesis by demonstrating improvements in mortality over time for a variety of procedures.[71-73]

The second source of evidence is that cardiopulmonary bypass or aortic cross-clamp time has been repeatedly associated with postoperative mortality, adjusting for a variety of patient characteristics.[74-77] This relationship has been demonstrated not just for the Fontan procedure, but also for the Norwood procedure for hypoplastic left heart syndrome. [78] Experienced surgeons and surgical teams should be able to reduce cardiopulmonary bypass or aortic cross-clamp time, thereby improving postoperative mortality. It should be noted that patient-level reduction in mortality does not necessarily correspond with provider-level mortality. It is unknown how implementing these processes of care would actually affect provider-level mortality rates.

Conclusion

The dedicated research effort described in this report tailors the AHRQ QIs specifically for pediatric populations, and offers an example of developing pediatric indicators using routinely collected inpatient data. These indicators will be released as the AHRQ Pediatric Quality Indicator set to provide a tool for screening for quality of care for the millions of hospitalized children each year, as well as for assessing the rate of potentially preventable hospitalizations. The potential uses of the indicators span many arenas, from public health to internal quality improvement.

Consistent with previous indicator sets, each of the thirteen provider-level indicators is particularly applicable to quality improvement efforts. Hospitals may use existing data to identify indicators with higher than expected rates, flagging potential quality concerns. These areas of concern may be investigated further in order to identify the underlying cause of the poorer than expected performance. In some cases, incorrect coding practices may be identified, in other cases closer examination of system-level factors may be in order. Interventions may be devised to improve performance, and hospitals may track their own performance over time to identify areas of improvement.

The ability to track quality of care for a wide range of patients is an important consideration for quality improvement. Community hospitals, who admit nearly 2/3 of pediatric cases, may not treat a substantial number of patients with some specialized conditions. As a result, indicators that only apply to such conditions (e.g., cancer, cardiothoracic surgery, cystic fibrosis, neonatal surgeries) may not be as useful for non-children's hospitals. All but two of the thirteen selected provider-level measures are cross-cutting, applying to children admitted for a variety of procedures and/or conditions. Pediatric heart surgery mortality and volume may be more applicable to children's hospitals than community hospitals, although some community hospitals perform less complex heart surgeries. For indicators where hospital case mix is expected to vary, stratification is available to allow a hospital with a more complex case mix to examine rates by risk groups separately and pinpoint quality concerns further.

Given the historical use of the AHRQ QIs, the provider-level indicators are also likely to be used for inter-hospital comparisons. In anticipation of this potential application, each indicator was assessed for overall usefulness for two dimensions, internal quality improvement and comparative purposes. Ten of the provider level indicators were rated by panelists as useful for inter-hospital comparisons. These ratings provide additional information to policy makers selecting indicators for inter-hospital comparisons. Of course additional factors may also influence the selection of indicators, and risk adjustment for case mix will remain an important consideration.

Existing risk adjustment strategies for pediatric patients were not suitable for use with the Pediatric QIs. Most available schemes apply to specific clinical groups and utilize clinical data not available in administrative databases. The APR-DRGs, used for risk adjustment for the AHRQ Inpatient Quality Indicators, has considered pediatric populations when

developing algorithms. However, APR-DRGs are not suitable for adjusting for complications since complications are part of the adjustment algorithm (resulting in over-adjustment). As a result, we investigated alternative risk adjustment strategies, and identified three important risk adjustment factors: 1.) reason for admission (including principal procedure) 2.) comorbidities and 3.) age and gender. Using a modified-DRG risk adjustment combined with comorbidity adjustment based on the AHRQ Clinical Classification System (CCS) and age and gender adjustment, the AHRQ PedQIs include a novel and specialized risk adjustment system. Using Present on Admission (POA) data from New York and California, potential comorbidities were explored to minimize bias from complications being mislabeled as comorbidities. However, this system is only a first step in the development of pediatric-specific risk adjustment. Both the DRG and CCS system may prove to be too broad in some pediatric applications, grouping together important co-morbidities or procedures with many low-risk conditions.

Another approach to accounting for case mix is stratification. The original AHRQ QIs tended to use exclusion of high risk groups and risk adjustment to account for difference in case mix. However, since children are generally healthy, the high risk groups offer the best option for intervention. Stratification allows hospitals to identify which segment of the pediatric population accounts for any elevation in rates, creating more user-friendly indicators. Tailored stratification schemes are available for six complications indicators: Accidental puncture and laceration, decubitus ulcer, iatrogenic pneumothorax, postoperative hemorrhage and hematoma, postoperative sepsis, selected infection due to medical care.

Despite these efforts to account for risk, we anticipate that further research on pediatric risk adjustment will be important for targeting quality improvement appropriately. Certainly no risk adjustment system can account for all differences in risk and comparison between hospitals must be pursued with this caveat. Comparisons between similar types of hospitals, such as comparing tertiary care children's hospitals with other children's hospitals, will further facilitate fair comparisons between hospitals.

In addition to the provider-level indicators, the PedQIs also include five area level indicators. These indicators track potentially preventable hospitalizations, and allow policy makers to target specific groups that appear to be developing more severe disease requiring hospitalization. Higher than anticipated rates may reflect poor access to care (e.g., from lack of insurance or too few primary care physicians), barriers to timely care (e.g., clinics that require daytime appointments), barriers to adherence to medical advice (e.g., language barriers), cultural influences that preclude seeking early treatment, or higher prevalence of poor health behaviors (e.g., smoking). Interventions may address any of these factors.

Area level indicators are prone to bias due to cultural factors that may be outside of a health systems control. For instance, an area with a high number of illegal immigrants may have patients presenting with more advanced disease, because patients delay seeking care for fear of deportation. In addition, factors such as smoking or obesity may be more prevalent in certain areas. Panelists felt that risk adjustment should include these factors.

Since we cannot directly adjust for these factors, we have applied adjustment for socioeconomic status as a proxy. However, risk adjustment for socioeconomic groups may mask true differences in access to good quality care. For this reason it is recommended that risk adjusted rates be considered alongside raw unadjusted rates.

Future directions

The current PedQI indicator set and accompanying risk adjustment are only the initial step in pediatric indicator development. These indicators extend our previous indicator development efforts, but the eighteen indicators do not address some important areas of inpatient pediatric care, such as neonatal intensive care. A second phase of development will examine novel indicators based on administrative data, building from published literature and nominations from clinical and other professional organizations.

Along with the expansion of the indicator set, the Pediatric QIs will benefit from additional validation efforts. As the indicators are utilized, needed improvements to the indicators will be illuminated. Chart review efforts will provide better information on the sensitivity and specificity of the indicators, and may guide further the most appropriate applications of the indicators. Validation efforts may also demonstrate the usefulness of the indicators for facilitating quality improvement. Finally, further investigation and refinement of the risk adjustment system will be essential both for quality improvement and comparative reporting efforts.

Application of the indicator set requires high quality data. Currently few data standards exist for pediatrics, and since pediatric data in general does not fall under the auditing authority of the Centers for Medicare and Medicaid Services (CMS), variation in coding practices is of particular concern. Implementation of data standards for pediatrics would aid in further development and utility of the AHRQ Pediatric QIs. In addition, expansion of data sets to include data elements such as “present on admission,” linked data sets, or limited clinical data, such as laboratory or pharmacy data, would also allow for improvement in the sensitivity and specificity of existing indicators and the expansion of the indicator set to include indicators targeted to important clinical groups, such as asthma patients and special need children.

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