Development of Quality Metrics in Ambulatory Pediatric Cardiology

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ABSTRACT

The American College of Cardiology Adult Congenital and Pediatric Cardiology (ACPC) Section had attempted to create quality metrics (QM) for ambulatory pediatric practice, but limited evidence made the process difficult. The ACPC sought to develop QMs for ambulatory pediatric cardiology practice. Five areas of interest were identified, and QMs were developed in a 2-step review process. In the first step, an expert panel, using the modified RAND-UCLA methodology, rated each QM for feasibility and validity. The second step sought input from ACPC Section members; final approval was by a vote of the ACPC Council. Work groups proposed a total of 44 QMs. Thirty-one metrics passed the RAND process and, after the open comment period, the ACPC council approved 18 metrics. The project resulted in successful development of QMs in ambulatory pediatric cardiology for a range of ambulatory domains. (J Am Coll Cardiol 2017;69:541–55)

Congenital heart disease (CHD) is the most common birth defect in the United States, occurring in 40,000 of the 4 million live births a year, or nearly 1% of U.S. births. There are more than 35 types of CHD lesions. CHD affects patients across their lifespan, from fetus through adulthood. Patients also have unique and complex medical histories, including multiple interventional procedures and operations, which have rapidly changed and evolved in the past few decades. All of these issues make it difficult to create robust evidence to guide practice. Although the field of...
ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology
ACHD = adult congenital heart disease
ACPC = Adult Congenital and Pediatric Cardiology
ASO = arterial switch operation
CHD = congenital heart disease
KD = Kawasaki disease
QM = quality metric
RSV = respiratory syncytial virus
TGA = transposition of the great arteries
TOF = tetralogy of Fallot

Pediatric cardiology has advanced, with significant improvement in outcomes for children with CHD (1-5), data to guide clinical decisions are lacking in many areas of CHD care.

Consistent with the American College of Cardiology’s (ACC’s) aim to improve cardiovascular care, the ACC Adult Congenital and Pediatric Cardiology Council (ACPC) Leadership Council (6) recognized the need to develop quality metrics (QMs) to guide practice for pediatric cardiology, and, in particular, the ACPC recognized a void of QMs to guide ambulatory practice (7). This paper reviews the structure established to develop candidate QMs in 5 key areas, a summary of the published reports reviewed, and key issues considered during QM development.

METHODS

PROCESS OF MEASURE DEVELOPMENT: RAND-UCLA MODIFIED DELPHI PROCESS. On the basis of the success of the adult congenital heart disease (ACHD) group, the ACPC leadership and the Ambulatory Pediatric Cardiology group agreed to use similar methodology to develop metrics in ambulatory pediatric cardiology. The RAND-UCLA modified Delphi process (RAND process) (8,9) provided an opportunity to develop structure, process, or outcome metrics for multiple areas simultaneously, and included scoring for validity, thereby allowing development of measures with limited clinical evidence. Within the modified RAND-UCLA methodology is a process of developing quality measures without the need for expert consensus that can be used in situations where there is a paucity of evidence for care. The method consists of developing candidate QMs, and convening an expert panel to score the metrics for validity and feasibility. The metrics are scored by a panel of experts in 2 rounds: 1 alone and 1 in an in-person meeting, with the ability to discuss and refine the metrics before they receive a final score. Each metric is scored for both validity and feasibility on a scale of 1 to 9, with 9 being the most valid or most feasible. A candidate QM will pass, and be accepted as a final metric with a mean validity score of 7 to 9 and a median feasibility score of 4 to 9 without significant spread or dispersion among the scores (e.g., not all 1s and 9s). As each candidate QM is scored independently and there is no need to come to a consensus, there is less of a chance that the outcome will be biased by the input of a single member of a group.

The RAND-UCLA modified Delphi method has been used to develop and evaluate appropriate use and quality measures for many conditions. In cardiology, it has been used to develop QMs for the management of acute myocardial infarction and for percutaneous coronary intervention (10-12). Even in these more common conditions, the metrics are typically related to improving structure and process of care, rather than outcomes. However, in 1 Canadian study, it was estimated that if the QM benchmarks of 90% were met, there would be a 20% reduction in mortality from coronary heart disease conditions (10-13).

IDENTIFICATION OF 5 FOCUS AREAS. The Steering Committee selected 5 areas across a variety of domains to explore the usefulness of the process for various types of care; domains included both condition-specific and crosscutting clinical issues, and areas where guidelines existed, as well as areas with less evidence to guide practice. The 5 selected topic areas and their justification are:

1. Chest pain: Chest pain is a common symptom-based reason for referral to an outpatient pediatric cardiology clinic. There is little evidence and few guidelines to inform practice.
2. Infection prevention: Infection prevention is not lesion-specific and covers several topics, such as subacute bacterial endocarditis prophylaxis and asplenia prophylaxis, with various levels of evidence and recommendations.
3. Kawasaki disease: Kawasaki disease (KD) is a well-defined condition and had published guidelines for ambulatory care. Additionally, a guideline update was under development during the QM development process.
4. Tetralogy of Fallot: Tetralogy of Fallot (TOF) is the most common cyanotic heart disease and had been included in the metrics developed by the ACHD, providing an opportunity to develop metrics across the continuum of care, from pediatrics to adults. There are no published guidelines and little evidence to inform practice.
5. Transposition of the great arteries after arterial switch operation: Transposition of the great arteries (TGA) after arterial switch operation (ASO) is a well-defined and well-studied condition for which there are published data on longer-term outcomes, but no guidelines. The ACHD metric development effort also included TGA after atrial switch operation (performed more commonly in the past).

CREATION OF TEAMS TO DEVELOP CANDIDATE MEASURES. To develop the proposed candidate
metrics, volunteers were recruited through an open call to the ACPC Section in June 2012. In accordance with ACC policy, volunteers were required to disclose relevant conflicts of interest before participation.

Approximately 70 volunteers were assigned to 1 of the 5 groups. Teams reflected volunteer interest, represented a balance of various institutions and practice settings, and favored individuals practicing primarily in the ambulatory pediatric cardiology setting. In September 2012, teams convened via phone, were oriented to the project, and charged with reviewing relevant published reports and developing candidate QMs following the ACC/American Heart Association (AHA) template for Performance Measures (Online Appendix). Team members, directed by team leads, were expected to use their best judgment for decisions about scope and metric definition. For example, the condition-specific groups (TOF and TGA) were not required to develop common metrics, despite several similarities. For 9 months, advisors held a standing monthly call with team leaders, in addition to individual calls with team leads and members, as needed. The advisors were involved in refining and formatting of the metrics before they were finalized. Overall, 5 teams (1 per focus area) were established in June 2012 and asked to submit candidate metrics in June 2013 (Online Appendix).

TEAM DISCUSSIONS

The following is a discussion of the review of published studies, key decisions, and challenges for each of the teams. The teams were given the autonomy to perform a review of published data. The data focused on by the teams was primarily related to processes that would guide the ambulatory practice of pediatric cardiology.

CHEST PAIN. Review of published reports. Published studies of chest pain in children consist largely of retrospective cohort studies. Although chest pain is a common symptom in children, cardiac causes are rare (14-17) (Online Appendix). In a cohort of 3,700 patients with a median follow-up of 4.4 years, a cardiac cause was identified in 37 cases (1%), with no cardiac deaths (14). In a retrospective cohort of 484 patients ultimately diagnosed with cardiac conditions that could cause chest pain, 35% presented due to chest pain (18). Among these patients with actual cardiac conditions, the most common diagnosis made in the cardiology clinic was a coronary artery anomaly, with 70% presenting with exercise-induced chest pain (18).

Chest pain may be a presenting symptom of cardiomyopathy, which may be heritable. The electrocardiogram (ECG) can be abnormal in cardiac causes of chest pain (18-20), and has a high negative predictive value for hypertrophic cardiomyopathy, long QT syndrome, and Wolff-Parkinson-White syndrome (21). Coronary artery anomalies are the most common cardiac diagnosis to present with chest pain, which is typically exertional and can lead to sudden death (19,21-26). Echocardiography is the first-line modality for evaluation of coronary artery anomalies (27,28).

Key decisions. The candidate measures submitted for expert panel review were intended to reflect appropriate evaluation and testing on the basis of existing studies and expert opinions. Due to the rarity of positive findings, improved quality care and cost effectiveness may be reflected in the absence, rather than in the performance of further testing. Thus, instead of measuring the proportion of patients who received an appropriate test or documentation, several candidate metrics (no echocardiogram in pediatric patients with musculoskeletal chest pain, appropriate use of rhythm recording devices for chest pain, and use of exercise testing in musculoskeletal chest pain) evaluated the proportion of patients who had testing performed under inappropriate conditions. For these measures, optimal care would be reflected in a lower rather than a higher percentage of tests performed. However, this approach may be less feasible and lead to confusion when retrospectively applying QMs to clinical practice.

Challenges and barriers. Appropriate documentation of family history may be limited at the patient or family level, such as poor knowledge or recollection of family history. Laypersons may lack familiarity with diagnoses such as hypertrophic or dilated cardiomyopathy, and may use nonspecific terms such as enlarged heart or heart problems. At the physician and system level, limitations may include incomplete documentation, such as failure to report pertinent negatives on family history or to describe the context of the chest pain, particularly related to exertion. However, appropriate documentation is a component of quality patient care. Exertional chest pain may also be associated with musculoskeletal chest pain or exercise-induced asthma, and there may be disagreement at the physician level regarding the need for echocardiography in some cases (Online Appendix).

INFECTION PREVENTION. Review of published reports. Influenza vaccination. Current guidelines recommend seasonal influenza immunization (trivalent or quadrivalent) for all children over 6 months of age (29-32). This is particularly important for patients
with medical conditions including asthma, immunosuppression, neurological disorders, and hemodynamically significant cardiac disease, which increase the risk of complications from influenza, and conditions requiring long-term aspirin therapy (33,34). Children with cardiopulmonary disease, particularly those <1 year of age, have an increased rate of hospital admission, intensive care unit admission, and death due to influenza compared with healthy controls (33-35).

**Respiratory syncytial virus prophylaxis.** Prior guidelines recommended palivizumab prophylaxis for infants and children under the age of 24 months who had hemodynamically significant cyanotic or aca- notic CHD (36). This included patients receiving medications for congestive heart failure, as well as those with pulmonary hypertension. Palivizumab prophylaxis is effective in reducing hospitalization for respiratory syncytial virus (RSV) in patients with these underlying conditions (37). Of note, guidelines for RSV prophylaxis were updated by the American Academy of Pediatrics during the open comment period of this QM process (38).

**Hand Hygiene.** The potential for infection transmission via ambulatory care (39) and for inconsistent hand hygiene practice (40) have long been recognized (41) (Online Appendix). Infectious transmission risks modifiable by hand hygiene have been identified (39,42). However, some situations, such as waiting room exposures (42) and fomite transmission (43), may not be as modifiable by typical health care personnel hand hygiene. Experience with inpatient hand hygiene suggests that routine dissemination of guidelines may not make any measureable difference (44,45), with potential barriers including busy staff, limited infra- structure for systems change, and facilities designed without infection control in mind (42). Despite these limitations, outpatient hand hygiene is recommended in guidelines (45,46). Detailed data on particular hand hygiene products (soaps, alcohol based, chlorhexi- dine, among others) are available (46).

**Evaluation of splenic function in heterotaxy patients.** Patients with heterotaxy syndrome may have a variety of anatomic findings with respect to the spleen or absence thereof (47). The cardiac features in these patients cannot help predict splenic anatomy. However, the presence of splenic tissue does not rule out hyposplenism and the accompanying risk of infectious complications (48,49). Abdominal ultrasound, computed tomography (CT), or magnetic resonance imaging can assess splenic anatomy. Tests of splenic function may include assessment of the blood smear for Howell-Jolly bodies, quantification of pitted red blood cells (RBCs) by interference-contrast microscopy, and heat-damaged technetium-99m-labeled RBC scan (50,51). Importantly, both Howell-Jolly bodies and pitted RBCs can be seen in normal newborns up to 2 months of age. However, the absence of Howell-Jolly bodies does not rule out hyposplenism (52). Pitted RBC studies and heat-damaged technetium-99m-labeled RBC scans are more sensitive than peripheral blood smears only, and are widely endorsed as the best measures of splenic function, although availability of these tests may be limited and institution dependent (50,52,53).

**Antibiotic prophylaxis (endocarditis, rheumatic fever, and asplenia or hyposplenism).** Current guidelines exist in the areas of endocarditis prophylaxis and rheumatic fever secondary prophylaxis, with both guidelines having been updated 7 years prior to this publication (54,55). In the case of endocarditis prophylaxis, the 2007 update to the guidelines included a marked decrease in the number of patients recommended to receive prophylaxis, limiting this to those cardiac conditions with the highest risk of adverse outcomes from endocarditis (55).

Children with asplenia or hyposplenism from any cause are known to have an increased risk of invasive pneumococcal disease, which is most significant until the age of 5 years (56). After 5 years of age, the utility of daily antibiotic prophylaxis against invasive pneumococcal disease is unclear (57), although some risk of sepsis persists indefinitely in individuals with asplenia (58). Recommendations differ between countries regarding discontinuation of routine anti- biotic prophylaxis; in the United States, prophylaxis is often recommended until 5 years of age, with subsequent discontinuation (56).

**Key decisions.** Endocarditis prophylaxis was a difficult topic for metric design. This was due to wide variability in published clinical adherence to the latest iteration of guidelines (59,60), as well as wide variability even among the team members. The team ultimately decided on 2 metrics for this topic. The first would assess the frequency of a documented recommendation for endocarditis prophylaxis before dental procedures in patients with single ventricle physiology, a group covered by the 2007 AHA guidelines (55). The second would assess the frequency of documented recommendation for endocarditis prophylaxis before dental procedures in patients with isolated bicuspid aortic valves, a group of patients not recommended to receive prophylaxis per the 2007 guidelines (55). Last, the hand hygiene metric was debated widely. The topic cannot be underestimated as a potential contributor to the health of patients, but the manner in which to measure the outcomes was unclear.
Challenges and barriers. Influenza vaccination for health care workers is already documented at most health care institutions, and likely will be the easiest of the 3 metrics to implement. The rheumatic fever secondary prevention metric may be more burdensome to some institutions compared with others, depending on the incidence of rheumatic fever in the region. The asplenia antibiotic prophylaxis metric may be troubled by several factors. First, there are differing opinions on how to diagnose poor splenic function, which may occur in the heterotaxy patient, even in the presence of a spleen or multiple spleens (56). Second, the overall number of patients will be relatively low, requiring several years of analysis to identify improvement. Last, the lack of a standard method to document the recommendations for antibiotic prophylaxis in the medical record may make assessment of metric adherence cumbersome.

Kawasaki Disease. Review of published reports. The team relied on a combination of existing guidelines and published papers as the rationale for QM recommendations (61–64) (Online Appendix). Two KD topics are particularly evolving, and had limited evidence and corroborating data. These topics include: 1) the categorization and treatment of coronary aneurysms; and 2) the use of echocardiography in following the disease process. Manlhiot et al. (62) described a classification system for coronary aneurysms solely on the basis of the z-score, and Sugahara et al. (64) demonstrated the value of warfarin in preventing myocardial infarction in patients with giant aneurysms. Scott et al. (63) considered the variability and Lowry et al. (61) considered the cost effectiveness of echocardiography in children with KD.

Key decisions. Because of the available comprehensive guidelines, the metrics included all phases of the disease pertinent to ambulatory pediatric cardiology, as well as each of the various risk categories, with particular focus on the high-risk patient with coronary aneurysms. Issues of data validity were particularly challenging for a variety of reasons. The 2004 AHA Scientific Statement is on the basis of level C evidence. The treatment of KD has evolved as well as has diagnostic testing. For example, some centers have replaced cardiac catheterization with advanced imaging modalities (CT, magnetic resonance angiography). Additionally, it is uncertain whether absolute coronary artery diameter or z-scores predict risk more accurately, a question complicated by variation in published formulas to calculate z-scores. Finally, as the AHA recommendations were in the process of being updated, the team aimed to propose metrics to reflect quality outpatient KD care sufficiently general and evidence-based to maintain validity in face of updated guidelines.

Challenges and barriers. Outpatient care of the KD patient is particularly suited to the use of QMs. The team was mindful of factors affecting implementation, including ease of data extraction in diverse pediatric cardiology practice settings, the evolving nature of the care and evaluation of this patient population, the difficulty in defining a single standard with which to evaluate coronary artery enlargement, and ongoing revision of the KD guidelines. Increasing the use of electronic medical records in the ambulatory setting, with the possibility of customizing encounter documentation for well-defined, unique populations, such as patients with KD, may make future implementation easier.

Tetralogy of Fallot. Review of published reports. ECG testing. Young patients with repaired TOF remain at risk for arrhythmias and sudden death, with a reported 1.5 to 4.5 deaths per 1,000 patient-years occurring 4 or more years after repair (65,66). Studies have reported prolonged QRS duration to be a risk factor for arrhythmias and sudden death (67–69). There is limited evidence regarding recommendations for ECG testing frequency.

Ambulatory ECG monitoring. Ambulatory ECG monitoring is more effective than a routine ECG for the detection of rhythm abnormalities, only some of which may be associated with symptoms. In addition, among patients in whom arrhythmias do occur and require therapy, ambulatory monitoring assists in decision making for therapeutic need and efficacy (65,66,70). However, there is no evidence on how often this monitoring should be performed.

Noninvasive imaging. Two-dimensional and Doppler echocardiography provide useful noninvasive methods for the detection of residual lesions, as well as assessment of right ventricle size, systolic pressure and function, and left ventricle function. Serial measurements can also be helpful in monitoring the progression of any residual lesions. The timing of such evaluations was debated, with no consensus reached on the frequency of follow-up testing (71). The right ventricle and great arteries become difficult to evaluate by echocardiography in older patients with increasing body size. Cardiac magnetic resonance (CMR) correlates well with clinical status, and has become the reference standard for evaluation of the right ventricle, particularly with regard to timing of pulmonary valve replacement. The indication for pulmonary valve replacement remains controversial, and makes timing of imaging difficult to establish. Available guidelines and publications did not
provide specific recommendations for the timing of imaging studies in children (65,71-73). Moreover, the need for general anesthesia in younger patients presents a limitation to the timing and frequency of performing CMR.

**Exercise testing.** Patients with repaired TOF are at long-term risk for exercise intolerance, arrhythmias, and sudden death due to residual defects, progressive right and left ventricular dysfunction, and myocardial scarring. Existing guidelines have endorsed the use of exercise testing for the follow-up of children and adults with TOF after repair (65,74). There is no consensus as to the frequency of routine testing.

**Genetic testing.** Long-standing support for identifying the underlying genetic cause of CHD in a patient with a cardiac lesion has been advocated by the ACC, AHA, and the American Academy of Pediatrics (AAP) (75). Such a discovery might shed light on other organ system involvement that may require surveillance, provide prognostic information, and enable counseling regarding recurrence risks. Patients with TOF have associated genetic syndromes or chromosomal anomalies in approximately 25% of cases, with over 15% of cases having the 22q11.2 deletion (76-78) (Online Appendix). At least 6% of patients with TOF and no additional arch anomalies have the 22q11 deletion (79). In addition, clinical assessment for phenotypic signs of 22q11 deletion may be subtle and can be difficult to identify in affected patients, especially in neonates (80,81). Moreover, there are published reports suggesting an increased morbidity and mortality risk in patients with CHD who have this genetic abnormality (82-84).

**Key decisions.** Given the challenges related to lack of evidence and guidelines, the team chose to extrapolate from existing adult guidelines where available, and to build measures around existing published data where possible. Measures with no sufficient supporting evidence in existing published reports were eliminated from consideration (Online Appendix).

**Challenges and barriers.** The obvious challenge faced by the team was the lack of evidence or consensus to guide care delivery for patients with TOF after surgical correction, especially in the area of ambulatory pediatric cardiology. Efforts of the team exposed key deficiencies in the available published data and highlighted important areas where more research is needed, especially in the area of testing intervals and utility.

**Transposition of the great arteries. Review of published reports.** **Periodic ECGs, ambulatory ECG monitoring, and exercise tests.** TGA/ASO patients are at risk for ischemia, arrhythmia, and sudden cardiac death (SCD). The risk of tachyarrhythmia increases with age, and is related to myocardial infarction occurring secondary to coronary artery obstruction (85-89). SCD occurs in 0.3% to 0.8% of TGA/ASO patients (86,90-94). Exercise testing has been proposed as a useful adjunct to anatomic and SCD risk assessment. Exercise testing may help determine the hemodynamic significance of a particular structural problem (95). In general, patients with normal structure and normal coronary arteries have a normal cardiopulmonary response to exercise after the ASO, and are at low risk for SCD (96). There is no consensus or guidance related to the frequency of ECG testing, ambulatory ECG monitoring, or exercise stress tests.

**Echocardiography.** Midterm and long-term complications of the ASO include neoaortic regurgitation, aortic root dilation, supravalvar pulmonary stenosis, and supravalvar aortic stenosis (91,97-105). Aortic root dilation occurs in at least two-thirds of TGA/ASO patients with freedom from aortic root dilation at 10 years of 51% (105,106). The median time from ASO to the development of aortic root dilation is 6 years, with a shorter time to aortic root dilation in patients with a history of ventricular septal defect and pulmonary artery banding (105) (Online Appendix).

Approximately 10% to 15% of TGA/ASO patients develop supravalvar pulmonary stenosis by 20 years after ASO. Pulmonary stenosis is the most frequent reason for reintervention (87). The majority of TGA/ASO patients have normal ventricular function. However, mild left ventricular dysfunction can develop (ejection fraction 30% to 45%) secondary to coronary artery stenosis (98).

**Advanced imaging.** During the ASO the coronary arteries are translocated. A risk factor for SCD is coronary artery ischemia (107). Echocardiography can be used to identify anatomic changes following the ASO, but may not be sufficient for assessing abnormalities in coronary artery perfusion (108). Current ACC/AHA guidelines describe use of advanced imaging (e.g., CMR, CT, cardiac catheterization) as a Class IIa recommendation for evaluating anatomy and hemodynamics at 5, 10, and 15 years after ASO (1). The ACC/AHA Class I recommendation is for at least 1 cardiac angiogram to be performed during adulthood if the coronary arteries cannot be evaluated non-invasively (65).

**Periodic neurodevelopmental assessment.** Children with TGA/ASO are at risk for poorer neurodevelopmental outcomes (109-111). Furthermore, infants undergoing the ASO who experience transient post-operative seizures are at even greater risk of poor neurodevelopmental outcomes (112-115). By
adolescence, children with TGA/ASO are at risk for lower academic achievement, and poorer visual spatial skills, memory, attention, and executive functioning (111). Current guidelines recommend routine and periodic neurodevelopmental screening during childhood, following the ASO procedure (116).

**Regular health surveillance of body mass index, arterial pressure, and lipid profile.** Children with CHD are at risk for acquired heart disease, deconditioning, and metabolic syndrome. Children who have had surgical manipulation of the coronary arteries, such as TGA/ASO patients, are at greater risk for coronary artery occlusion and ventricular dysfunction in later childhood, and may be at increased risk for atherosclerosis as adults (111,117-119). Weight, blood pressure, and cholesterol are among the modifiable risk factors and, when controlled, may help to improve long-term outcomes among TGA/ASO patients. Current recommendations encourage all children undergo routine measurement of body mass index and blood pressure at each clinic visit. Lipid screening should begin at 9 years of age (120).

**Exercise recommendations.** TGA/ASO patients are at risk for early cardiovascular disease (119). Although TGA/ASO patients with variant coronary artery anatomy are at greatest risk for impaired aerobic capacity and arrhythmia. According to the Bethesda criteria, only individuals with ventricular dysfunction, symptomatic arrhythmia, or severe anatomic abnormalities are restricted from competitive sports (121).

**Transition of care plan.** Improvement in health outcomes includes ensuring TGA/ASO patients receive medically and developmentally appropriate care. (121) The American Academy of Pediatrics recommends all adolescents have an individual transition plan, and transition of care from the pediatric to the adult provider take place between 18 and 21 years of age (121-122). Patients with a history of TGA/ASO should have a written transition plan created during adolescence (104,123-125).

**Instructions regarding reproductive health.** At the present time, there are no formal guidelines regarding the reproductive counseling of individuals with TGA. Most long-term complications of the ASO procedure are well tolerated during pregnancy, and the recurrence risk of TGA is low (89,126,127).

**Key decisions.** The team activities were enhanced by the inclusion of TGA in existing guideline documents for both pediatric and adult care, and by TGA/ASO being a well-defined and well-studied population that had been included in standard definitions in high-risk pediatric populations.

**Challenges and barriers.** Potential challenges with implementation of these metrics include limited resource availability. Although routine echocardiograms and lipid panels can be performed in the majority of children, comprehensive neurodevelopmental and adult congenital resources may be limited (128). Identifying appropriate QMs for complex cases of TGA presents an additional opportunity. Standardized practices for how to address common complications following the ASO are also needed.

## Evaluating and Reviewing Candidate Quality Metrics

Each of the 5 teams reviewed the available published reports and deliberated the key issues, as outlined previously. After deliberations, the team leaders submitted proposed QMs for further consideration, as described in the following sections.

### Convening of the Expert Panel

In accordance with the RAND process, an expert panel was appointed on the basis of nominations from a broad range of stakeholders. The 9-member panel (and 1 facilitator) is shown in **Table 1**. Stakeholders were permitted to nominate individuals who had been team leads or members of teams to develop candidate measures. Panel members received 44 (10 chest pain, 8 infection prevention, 8 KD, 6 TOF, and 12 TGA ASO), candidate metrics in July 2013, and were asked to score each measure for validity and feasibility, according to the RAND process (13). All metrics were scored independently by each panelist for validity and feasibility on an ordinal scale of 1 to 9.

### Table 1

**ACPC Ambulatory QMs Expert Panel Meeting, October 3–4, 2013, ACC Heart House, Washington, DC**

<table>
<thead>
<tr>
<th>Society/Organization</th>
<th>Panelist</th>
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<tbody>
<tr>
<td>American Academy of Pediatrics (Cardiology and Cardiovascular Surgery)</td>
<td>David Danford, MD, FACC</td>
</tr>
<tr>
<td>American Board of Pediatrics</td>
<td>Daphne Hsu, MD, FACC</td>
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<tr>
<td>American College of Cardiology</td>
<td>Jane Newburger, MD, FACC</td>
</tr>
<tr>
<td>American Heart Association (Cardiovascular Disease in the Young)</td>
<td>Lloyd Tani, MD, FACC</td>
</tr>
<tr>
<td>Asia Pacific Pediatric Cardiology Society</td>
<td>Y. F. Cheung, MD</td>
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<tr>
<td>AEPC</td>
<td>AEPC’s representative was unable to participate in the Expert Panel process due to an unexpected scheduling conflict.</td>
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<tr>
<td>Canadian Pediatric Cardiology Association</td>
<td>Andrew Mackie, MD</td>
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<tr>
<td>Facilitator</td>
<td>Roberta Williams, MD, MACC</td>
</tr>
<tr>
<td>Mended Little Hearts (Medical Advisory Board)</td>
<td>Paul Matherne, MD, FACC</td>
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<tr>
<td>National Pediatric Cardiology (Quality Improvement Collaborative)</td>
<td>Jeffrey Anderson, MD, MBA, FACC</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Roy Jedeikin, MD, FACC</td>
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ACPC = Adult Congenital and Pediatric Cardiology; AEPC = Association for European Pediatric Cardiology; QM = quality metric.
TABLE 2 Measures With Validity and Feasibility Scores

<table>
<thead>
<tr>
<th></th>
<th>Score Round 1</th>
<th>Score Round 2</th>
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<th>Final Pass</th>
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<tr>
<td></td>
<td>Validity</td>
<td>Feasibility</td>
<td>Validity</td>
<td>Feasibility</td>
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<tr>
<td>A. Chest pain</td>
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<tr>
<td>Chest pain: family history</td>
<td>8.0 (5-8), 0.8</td>
<td>8.0 (6-9), 0.7</td>
<td>7.0 (6-8), 0.6</td>
<td>8.0 (6-9), 0.7</td>
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<tr>
<td>Palpation of the chest wall in evaluation of chest pain</td>
<td>8.0 (3-9), 1.4</td>
<td>8.0 (7-9), 0.8</td>
<td>8.0 (5-9), 1.1</td>
<td>8.0 (6-9), 1.0</td>
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<tr>
<td>ECG for chest pain</td>
<td>8.0 (5-9), 1.0</td>
<td>9.0 (8-9), 0.3</td>
<td>7.0 (4-9), 1.3</td>
<td>9.0 (8-9), 0.4</td>
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<tr>
<td>No echocardiogram in pediatric patients with musculoskeletal chest pain</td>
<td>7.0 (1-9), 1.3</td>
<td>7.0 (1-9), 2.2</td>
<td>8.0 (6-9), 0.6</td>
<td>4.0 (2-7), 1.2</td>
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<tr>
<td>Echocardiogram for exertional chest pain</td>
<td>8.0 (3-9), 1.4</td>
<td>8.0 (3-9), 1.9</td>
<td>8.0 (5-8), 0.3</td>
<td>6.0 (4-8), 1.2</td>
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<tr>
<td>Appropriate use of rhythm recording devices for chest pain</td>
<td>7.0 (1-8), 1.1</td>
<td>8.0 (1-9), 1.7</td>
<td>7.0 (7-9), 0.6</td>
<td>7.5 (5-9), 0.9</td>
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<td>Utilization of EST in musculoskeletal chest pain</td>
<td>8.0 (1-9), 1.1</td>
<td>8.0 (1-9), 2.0</td>
<td>8.0 (8-9), 0.2</td>
<td>8.0 (3-9), 1.4</td>
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<tr>
<td>Appropriate use of EST in patients with exertional chest pain</td>
<td>8.0 (1-9), 1.7</td>
<td>8.0 (1-9), 1.3</td>
<td>7.0 (6-9), 0.7</td>
<td>7.0 (5-8), 0.8</td>
</tr>
<tr>
<td>Chest pain: history of fever</td>
<td>6.0 (2-9), 2.3</td>
<td>7.0 (5-9), 1.1</td>
<td>4.0 (2-6), 1.0</td>
<td>8.0 (3-9), 1.3</td>
</tr>
<tr>
<td>Chest pain: history of KD</td>
<td>7.0 (5-9), 1.2</td>
<td>8.0 (6-9), 0.8</td>
<td>6.0 (1-8), 1.8</td>
<td>8.0 (6-9), 1.0</td>
</tr>
<tr>
<td>B. Infection prevention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotic prophylaxis in patients with heterotaxy and asplenia</td>
<td>8.0 (7-9), 0.7</td>
<td>7.0 (4-9), 1.3</td>
<td>8.0 (7-9), 0.7</td>
<td>7.0 (5-9), 0.9</td>
</tr>
<tr>
<td>Adherence to bacterial endocarditis prophylaxis guidelines in patients with congenital heart disease</td>
<td>8.0 (5-9), 1.0</td>
<td>8.0 (5-9), 1.0</td>
<td>7.0 (1-9), 1.6</td>
<td>8.0 (4-9), 1.7</td>
</tr>
<tr>
<td>Recommendation against bacterial endocarditis prophylaxis in patients with bicuspid aortic valve</td>
<td>8.0 (6-9), 0.7</td>
<td>8.0 (5-9), 0.9</td>
<td>8.0 (7-9), 0.4</td>
<td>8.0 (2-9), 1.3</td>
</tr>
<tr>
<td>Influenza vaccination compliance of health care personnel</td>
<td>8.0 (6-9), 0.7</td>
<td>6.0 (2-9), 1.4</td>
<td>8.0 (8-9), 0.4</td>
<td>7.0 (3-9), 1.0</td>
</tr>
<tr>
<td>Adherence to recommended regimens of secondary prevention of rheumatic fever in patients with a previous history of rheumatic fever</td>
<td>9.0 (3-9), 0.7</td>
<td>8.0 (3-9), 1.2</td>
<td>9.0 (7-9), 0.4</td>
<td>9.0 (6-9), 0.7</td>
</tr>
<tr>
<td>Recommendation for palivizumab administration</td>
<td>8.0 (5-9), 1.0</td>
<td>7.0 (5-9), 1.1</td>
<td>9.0 (7-9), 0.7</td>
<td>8.0 (7-9), 0.9</td>
</tr>
<tr>
<td>Hand hygiene</td>
<td>8.0 (5-9), 1.3</td>
<td>4.0 (1-6), 2.0</td>
<td>8.0 (7-9), 0.8</td>
<td>2.0 (1-4), 1.0</td>
</tr>
<tr>
<td>Recommendation of influenza vaccination</td>
<td>8.0 (3-9), 1.4</td>
<td>8.0 (6-9), 1.2</td>
<td>5.0 (3-9), 1.9</td>
<td>8.0 (2-9), 1.4</td>
</tr>
<tr>
<td>C. KD</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Aspirin therapy in acute/subacute phase KD</td>
<td>8.0 (3-9), 1.1</td>
<td>8.0 (6-9), 1.1</td>
<td>9.0 (8-9), 0.3</td>
<td>9.0 (6-9), 0.8</td>
</tr>
<tr>
<td>Appropriate follow-up without aneurysms in acute and subacute phases of KD, echocardiogram at 3 weeks</td>
<td>8.0 (3-9), 1.1</td>
<td>8.0 (3-9), 1.2</td>
<td>8.0 (7-9), 0.6</td>
<td>8.0 (6-9), 0.9</td>
</tr>
<tr>
<td>Appropriate consideration and evaluation of fever in acute and subacute phases of KD</td>
<td>8.0 (3-9), 1.1</td>
<td>7.0 (5-9), 1.1</td>
<td>8.0 (7-9), 0.6</td>
<td>8.0 (6-9), 0.9</td>
</tr>
<tr>
<td>Appropriate care in low-risk patients (no therapy or restrictions) following subacute phase of KD</td>
<td>8.0 (5-9), 0.7</td>
<td>8.0 (6-9), 0.9</td>
<td>8.0 (7-9), 0.4</td>
<td>8.0 (7-9), 0.7</td>
</tr>
<tr>
<td>Appropriate stress evaluation of KD patients with coronary artery aneurysms</td>
<td>8.0 (6-9), 0.8</td>
<td>8.0 (7-9), 0.8</td>
<td>8.0 (7-9), 0.4</td>
<td>9.0 (8-9), 0.4</td>
</tr>
<tr>
<td>Appropriate counseling regarding myocardial infarction in KD patients with giant coronary artery aneurysms</td>
<td>8.0 (7-9), 0.7</td>
<td>8.0 (6-9), 1.0</td>
<td>9.0 (8-9), 0.3</td>
<td>9.0 (7-9), 0.6</td>
</tr>
<tr>
<td>Complete initial echo evaluation of coronary arteries in KD</td>
<td>8.0 (5-9), 1.2</td>
<td>8.0 (5-9), 0.9</td>
<td>8.0 (7-9), 0.6</td>
<td>8.0 (6-9), 0.7</td>
</tr>
<tr>
<td>Appropriate discussion of preventative care in KD patients with aneurysms</td>
<td>7.0 (5-9), 0.9</td>
<td>7.0 (5-9), 1.2</td>
<td>7.0 (1-9), 1.7</td>
<td>3.0 (1-7), 1.4</td>
</tr>
<tr>
<td>D. TOF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual echocardiogram</td>
<td>8.0 (3-9), 1.6</td>
<td>9.0 (6-9), 0.7</td>
<td>7.0 (3-8), 1.3</td>
<td>7.0 (4-9), 1.0</td>
</tr>
<tr>
<td>Genetic testing</td>
<td>7.0 (5-9), 1.1</td>
<td>7.0 (4-9), 1.3</td>
<td>8.0 (7-9), 0.7</td>
<td>8.0 (6-9), 0.7</td>
</tr>
<tr>
<td>CMR imaging</td>
<td>7.0 (3-9), 1.3</td>
<td>8.0 (6-9), 0.8</td>
<td>7.0 (5-9), 1.0</td>
<td>8.0 (6-9), 1.0</td>
</tr>
<tr>
<td>Post-operative outpatient visits</td>
<td>8.0 (3-9), 1.4</td>
<td>9.0 (3-9), 1.7</td>
<td>7.0 (3-9), 1.9</td>
<td>6.0 (1-9), 2.7</td>
</tr>
<tr>
<td>ECG testing</td>
<td>8.0 (3-9), 1.6</td>
<td>9.0 (6-9), 0.7</td>
<td>6.0 (3-9), 2.1</td>
<td>7.5 (5-9), 1.1</td>
</tr>
<tr>
<td>Ambulatory ECG monitoring</td>
<td>6.0 (5-9), 1.2</td>
<td>8.0 (6-9), 0.8</td>
<td>5.0 (2-8), 1.4</td>
<td>7.0 (1-9), 1.4</td>
</tr>
</tbody>
</table>

Continued on the next page

EXPERT PANEL MEETING AT HEART HOUSE. The Ambulatory Pediatric Quality Metrics Steering Committee members, advisors, facilitators, and expert panel convened on October 3 and 4, 2013, for a 1.5-day meeting at ACC Headquarters (ACC Heart House) (Table 1). At the meeting, panelists were given a summary of first-round ratings for each metric and how he or she had rated the metric in
TABLE 2 Continued

<table>
<thead>
<tr>
<th>Score Round 1</th>
<th>Score Round 2</th>
<th>RAND</th>
<th>Final Pass</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Validity</strong></td>
<td><strong>Feasibility</strong></td>
<td><strong>Validity</strong></td>
<td><strong>Feasibility</strong></td>
</tr>
<tr>
<td>E. Transposition of the great arteries (arterial switch)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least 1 echocardiogram in the first year of life, after ASO, that reports on LV function, aortic root dimension, degree of AI, patency of systemic and pulmonary outflows, branch pulmonary artery stenosis, and coronary arteries</td>
<td>9.0 (7–9), 0.7</td>
<td>9.0 (6–9), 0.6</td>
<td>9.0 (8–9), 0.2</td>
</tr>
<tr>
<td>Periodic echocardiogram after infancy after ASO</td>
<td>9.0 (7–9), 0.8</td>
<td>9.0 (6–9), 0.8</td>
<td>8.0 (5–9), 1.3</td>
</tr>
<tr>
<td>Neurodevelopmental assessment after ASO</td>
<td>7.0 (1–9), 1.9</td>
<td>6.0 (1–9), 1.4</td>
<td>8.0 (6–9), 0.8</td>
</tr>
<tr>
<td>A patient after ASO should undergo regular surveillance of body mass index and arterial pressure</td>
<td>7.0 (5–9), 1.2</td>
<td>9.0 (8–9), 0.9</td>
<td>7.0 (5–9), 1.2</td>
</tr>
<tr>
<td>Assessment of lipid profile by 11 yrs of age</td>
<td>8.0 (5–9), 1.3</td>
<td>8.0 (6–9), 1.0</td>
<td>7.0 (3–9), 1.7</td>
</tr>
<tr>
<td>Patients after ASO should be provided with information outlining exercise recommendations</td>
<td>6.0 (4–9), 1.3</td>
<td>7.0 (5–9), 1.3</td>
<td>8.0 (6–9), 0.9</td>
</tr>
<tr>
<td>Transition of care: patients with ASO (at 18 yrs of age or older) with documented transition of care in the past 2 yrs</td>
<td>7.0 (1–9), 1.3</td>
<td>6.0 (1–9), 1.7</td>
<td>8.0 (7–9), 0.5</td>
</tr>
<tr>
<td>Patients after ASO should be provided with age-appropriate reproductive health counseling on sexual health, contraception, and pregnancy beginning early adolescence</td>
<td>6.0 (1–8), 1.3</td>
<td>6.0 (1–9), 1.2</td>
<td>5.0 (1–7), 1.4</td>
</tr>
<tr>
<td>A patient after ASO should undergo periodic ECGs</td>
<td>6.0 (2–9), 1.7</td>
<td>9.0 (6–9), 0.7</td>
<td>5.0 (2–7), 1.2</td>
</tr>
<tr>
<td>A patient after ASO should undergo periodic Holter monitoring after the ASO</td>
<td>6.0 (3–9), 1.2</td>
<td>7.0 (6–9), 0.9</td>
<td>4.0 (2–6), 0.9</td>
</tr>
<tr>
<td>A patient after ASO should have at least 1 stress test by age of 11 yrs</td>
<td>6.0 (4–9), 0.9</td>
<td>8.0 (6–9), 0.9</td>
<td>4.5 (1–6), 1.3</td>
</tr>
<tr>
<td>Advanced imaging (MRI, CT, CATH) after ASO between 7 and 11 yrs of age</td>
<td>6.0 (3–9), 1.2</td>
<td>8.0 (6–9), 0.8</td>
<td>4.0 (1–7), 1.7</td>
</tr>
</tbody>
</table>

Values are median (range), mean absolute deviation.
AI = aortic insufficiency; ASO = arterial switch operation; CATH = cardiac catheterization; CMR = cardiac magnetic resonance; CT = computed tomography; ECG = electrocardiogram; EST = exercise stress test; KD = Kawasaki disease; LV = left ventricular; MRI = magnetic resonance imaging; TOF = tetralogy of Fallot.

comparison to the group. Before the second and final round of scoring, each metric was discussed individually.

OPEN COMMENT PERIOD AND STEERING COMMITTEE APPROVAL. In previous ACPC metric initiatives, the ACPC Section review process required input from ACPC Section members, the ACC/AHA Task Force on Performance Measures, and allied specialty societies. The metrics were posted on the ACC website and comments were solicited from all members. Following a 4-week open comment period, all comments were reviewed by the Steering Committee.

STEERING COMMITTEE MODIFICATIONS. Open comments were solicited for the metrics approved through the RAND process. Of the 27 types of comments resulting from the open comment period, 10 were submitted for discussion to the steering committee. This was done when changes could not be easily made to the metric to improve clarification, when the published data were not sufficiently conclusive, or when the objections raised by practicing pediatric cardiologists would obviate the potential benefit of metric implementation. In the chest pain group, there were several comments on the need for exercise testing, and the metrics were deferred. For the infection prevention group, there were several comments on the metric for subacute bacterial endocarditis prophylaxis for single ventricle. The definition of single ventricle was thought to be ambiguous, and the committee decided to defer the metric. Similarly, there were new guidelines in process for RSV prophylaxis, and the metric was deferred. In the KD group, comments were received about using the z-score as a definition of giant aneurysm; the metric was formulated such that the reference can be updated, and the metric was accepted with minor modification. For the TOF group, during the open comment period, a Journal of the American Society of Echocardiography paper on multimodality imaging guidelines for patients with repaired TOF recommended echocardiography for routine surveillance annually until 10 years of age, and then every 2 years afterward as a class IC recommendation (129). The frequency of performing
TABLE 3 Approved Measures

<table>
<thead>
<tr>
<th>Chest pain</th>
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</thead>
<tbody>
<tr>
<td>Chest pain: family history</td>
<td></td>
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<tr>
<td>ECG for chest pain</td>
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<tr>
<td>Echocardiogram for exertional chest pain</td>
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<tr>
<td>Infection prevention</td>
<td></td>
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<tr>
<td>Antibiotic prophylaxis in patients with heterotaxy and asplenia</td>
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<td>Influenza vaccination compliance of health care personnel</td>
<td></td>
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<tr>
<td>Adherence to recommended regimens of secondary prevention of rheumatic fever in patients with a previous history of rheumatic fever</td>
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<tr>
<td>KD</td>
<td></td>
</tr>
<tr>
<td>Aspirin therapy in acute/subacute phase KD</td>
<td></td>
</tr>
<tr>
<td>Appropriate follow-up without aneurysms in acute and subacute phases of KD</td>
<td></td>
</tr>
<tr>
<td>Appropriate consideration and evaluation of fever in acute and subacute phases of KD</td>
<td></td>
</tr>
<tr>
<td>Appropriate care in low risk patients (no therapy or restrictions) following subacute phase of KD</td>
<td></td>
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<tr>
<td>Appropriate stress evaluation of KD patients with coronary artery aneurysms</td>
<td></td>
</tr>
<tr>
<td>Appropriate counseling regarding myocardial infarction in KD patients with giant coronary artery aneurysms</td>
<td></td>
</tr>
<tr>
<td>Complete initial echo evaluation of coronary arteries in KD</td>
<td></td>
</tr>
<tr>
<td>TOF</td>
<td></td>
</tr>
<tr>
<td>Genetic testing in patients with TOF</td>
<td></td>
</tr>
<tr>
<td>TGA after ASO</td>
<td></td>
</tr>
<tr>
<td>At least 1 echo in the first yr of life, after ASO that reports on LV function, aortic root dimension, degree of AI, patency of systemic and pulmonary outflows, branch pulmonary artery stenosis, and coronary arteries</td>
<td></td>
</tr>
<tr>
<td>Neurodevelopmental assessment after ASO</td>
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<tr>
<td>Assessment of lipid profile by 11 yrs of age</td>
<td></td>
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<tr>
<td>Transition of care: patients with ASO (at ≥18 yrs of age) with documented transition of care in the past 2 yrs</td>
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</tr>
</tbody>
</table>

Details of current quality metrics available at the Adult Congenital and Pediatric Cardiology Quality Metrics webpage (30). Abbreviations as in Table 2.

The process was successful in developing metrics in ambulatory pediatric cardiology. The results at each stage of the process were analyzed both quantitatively and qualitatively. Table 2 summarizes the validity and feasibility scores after each round of the RAND process, and the final outcome after the open comment period. Table 3 illustrates the final metrics retained in each domain. The teams developed a total of 44 candidate metrics in the 5 domains. Of these, 31 passed the modified RAND-UCLA process, and the ACPA Council finally approved 18 in March 2014. Among the final list of 18 measures, 3 related to chest pain, 2 to infection prevention, 7 to KD, 4 to TGA, and 1 to TOF (Central Illustration). In total, 17 metrics were related to care process and only 1 related to a clinical outcome modifiable by care. The overall final retention rate from the generation of candidate metrics to the list of approved metrics varied from 17% to 88%, with a median of 33%. The highest overall retention rate occurred with the KD measures, which were created in a well-defined area with existing clinical practice guidelines, whereas the lowest was seen in the TOF group, with greater diversity and few, if any, pre-existing practice standards.

**DISCUSSION**

This process demonstrates successful development of metrics in ambulatory pediatric cardiology using the RAND methodology across 5 domains, facilitated by the ACPA Section and Leadership Council structure. This facilitated process proved more successful than previous efforts. Before this process, the Pediatric Cardiology Ambulatory Practice group had difficulty developing measures for many practice areas due to lack of evidence or consensus. In comparison, whereas prior efforts had been tedious, the facilitated process on the basis of the RAND methodology allowed measures directly related to pediatric cardiology care to be developed more expeditiously.

Linking the RAND process to the prior inclusive ACPA approval process was also beneficial. There was active participation to refine key definitions and openly identify areas of disagreement. Inspection of Table 2 reveals that the largest attrition occurred not from the RAND panel scores related to feasibility and validity, but during the step from the RAND rating to Steering Committee approval after the open comment period. The open comment period created an inclusive process, and allowed both widespread agreement of face validity and careful consideration of unintended consequences before approval.

The Steering Committee had anticipated that the development of QMs would be easier when guidelines existed, and wanted to see if the process could also be successful in other areas, given how few guidelines exist for ambulatory pediatric cardiology. The process demonstrated successful development of metrics across a wide range of domains. The KD group, which had published guidelines, was most successful, with an 88% retention rate and 7 approved measures,
including 1 outcome measure. The infection prevention group also had guidelines, but there were new guidelines in development for RSV prophylaxis, resulting in loss of several measures during the open comment period. This example highlights the dynamic relationship between guideline revisions and QM development. In the TGA group, because the ASO was relatively new, there was more applicable evidence to draw from, even in the absence of guidelines, making metric development easier. In contrast, for both chest pain and TOF, lack of evidence made measure creation more difficult and validity more difficult to assess.

In conclusion, the ACPC Section and Leadership Council used a facilitated RAND process to create a set of QMs for ambulatory pediatric cardiology that was more successful than prior attempts. Creation of this set of metrics is an important first step toward facilitating quality improvement for ambulatory pediatric cardiology. It is important to emphasize that the approved metrics still require testing and, in particular, some of the process measures require further testing to link to improved clinical outcomes. The ACPC Quality Network is expected to support this testing. These metrics should be useful to guide self-assessment and quality improvement at the provider, hospital, or health care system level. As noted previously, in accordance with the 2008 ACC/AHA Classification of Care Metrics, these QMs are for quality improvement, and do not meet the process or specifications of formal performance measures (7). The Steering Committee and the ACPC Section and Leadership Council would like to thank the numerous pediatric cardiologists and other volunteers who made this project successful.

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REFERENCES


KEY WORDS chest pain, congenital heart disease, infection prevention, Kawasaki disease, tetralogy of Fallot, transposition of the great arteries

APPENDIX For expanded Methods and References sections, please see the online version of this article.