Pediatr Drugs
DOI 10.1007/s40272-013-0042-4

LEADING ARTICLE

Pediatric Health Care Quality Measures: Considerations for Pharmacotherapy

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Abstract Measuring the quality use of medicines can be conceptualized as a mechanism for understanding appropriate use, underuse, overuse, or misuse. For pediatric pharmacotherapy, measuring the quality use of medicines requires awareness of the differences in health care between children and adults and the differences in the quality and quantity of science that supports evidence-based practice in pediatric health care compared with adult health care. Here we use the Pediatric Quality Measures Program that arose from the Children's Health Insurance Program Reauthorization Act in the United States to illustrate the challenges in developing quality measures of pediatric pharmacotherapy. The challenges are primarily twofold: (i) weak evidence base for the specific pharmacotherapy in children and (ii) limited data to calculate the measure. A weak evidence base must often be weighed against the importance of the topic if the quality measure is intended to address a known quality of care or public health problem. Limited data because of insufficient amount or inappropriate type will affect implementation of the measure and its eventual usefulness. Methods to meet these challenges often depend on the priorities of and the tools available to end users. Health information technology is emerging as a tool to improve quality measurement but presents additional challenges.

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Published online: 06 August 2013

1 Background

The appropriate use of prescription medicines is an important component of measuring quality of care delivered to children. In the United States (US), prescription medicines continue to account for a large part of pediatric health care [1–3]. Appropriate use of prescription medicines, sometimes called Quality Use of Medicines (QUM) or Rational Use of Medicines (RUM), can be conceptualized in multiple ways [4, 5]. One way to conceptualize QUM is to consider the type of therapy (e.g., antibiotic therapy), the time at which medications are ordered (e.g., on hospital admission), or the degree to which medications are integrated into overall care (e.g., as part of condition-specific action plans) [6, 7]. Another way to conceptualize QUM is as a mechanism for understanding appropriate use, underuse, overuse, or misuse [8, 9]. Underuse is the failure to provide a healthcare service when it would have produced a favorable outcome for a patient (e.g., missing a vaccination). Overuse occurs when a healthcare service is provided under circumstances where harm is likely to exceed the possible benefit (e.g., using an antibiotic to treat an upper respiratory viral infection or otitis media with effusion) [10]. Misuse occurs when an appropriate service has been selected but is applied incorrectly. Misuse may or may not result in harm to the patient (e.g., inappropriate dosing intervals for the correctly chosen medication).

Measuring QUM is also important for pediatric health care because key differences exist between pediatric health care and adult health care. Often referred to as the 'Four Ds', the key differences are developmental change, differential epidemiology, dependency on adults and other caregivers, and demographic patterns that differ between children and adults in the US [11]. Furthermore, measuring QUM for pediatric health care requires awareness of the

different quality and quantity of science that supports evidence-based practice in pediatric health care compared with adult health care. Less pediatric-focused research occurs [12, 13], and the quality of pediatric-focused research is lower [14]. Even for conditions where children experience 60 % of the disease burden, only 12 % of the clinical trials for drugs to treat those conditions focus on children [15]. Efforts are emerging worldwide to align the policies, generate scientific evidence, and implement programs to better deliver QUM to children [16, 17].

Here we use the recently enacted Children's Health Insurance Program Reauthorization Act (CHIPRA) [18] and the resultant Pediatric Quality Measures Program in the US to illustrate the challenges associated with developing evidence-based, health care quality measures related to pediatric pharmacotherapy.

1.1 CHIPRA

The passage of CHIPRA in 2009 signaled a new day for improving children's health care in the US. In addition to reauthorizing the Medicaid and Children's Health Insurance Program (CHIP) programs, which cover more than 43 million children, CHIPRA included provisions for identifying and developing health care quality measures for children [19, 20]. Previously, measuring and improving the quality of children's health care had received little attention in the US relative to the adult population [21]. CHIPRA required that the quality measures be applicable across all child and adolescent ages, across all care settings and providers, and across all types of healthcare services (e.g., prevention and health promotion, treatment and management of acute and chronic conditions). In addition, CHIPRA called for quality measures in the quality domains of access (e.g., availability of services, duration of insurance enrollment and coverage), patient and family centeredness, and 'most integrated health care settings' (e.g., medical home and care coordination).

To fulfill the CHIPRA goals, the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) (two agencies within the US Department of Health and Human Services), partnered to initially identify an 'initial core set' of quality measures for voluntary use by State Medicaid and CHIP programs. In this stage, 24 measures were identified, and the State programs have begun to use them to identify quality problems for their populations [22]. This set of measures included several related to the use of prescription medicines. Measures related to overuse were avoidance of antibiotics for otitis media with effusion and appropriate testing when prescribing antibiotics for streptococcal pharyngitis. Measures related to underuse were status of childhood and adolescent immunizations and follow-up care for children prescribed medication for attention deficit/hyperactivity disorder (ADHD). A measure related to misuse was the rate of pediatric central line-associated bloodstream infections in the neonatal and pediatric intensive care units.

Subsequently, AHRQ and CMS created the Pediatric Quality Measures Program (PQMP) to fill gaps left by the initial core set and to develop quality measures under all of the domains mandated by CHIPRA [23]. AHRQ awarded research grants to seven entities deemed 'Centers of Excellence' (COEs) that were collectively assigned 41 high priority topics for measure development. Many of the topics relate directly to underuse, overuse, or misuse of pediatric medicines (see Table 1). In addition, several topics relate indirectly to appropriate use of pediatric medicines. For example, one COE is developing a measure on the topic of inpatient safety, and another is working on medication reconciliation. Duration of insurance coverage and enrollment, another PMQP assignment, can also affect QUM because of its impact on access to child healthcare providers and on the ability for families to pay for medicines.

All of the topics assigned to the COEs present methodological challenges, which we highlight here using examples related to pediatric medicines. While the framework of underuse, overuse, and misuse works well for understanding QUM, each challenge points to important nuances for quality measure development in pediatric pharmacotherapy.

2 Methodological Challenges

2.1 Weak Evidence Base for Specific Pharmacotherapy in Children

Quality measures are "mechanisms that enable the user to quantify the quality of a selected aspect of care by comparing it to an evidence-based criterion that specifies what is better quality." [24]. Quality, according to the Institute of Medicine, is "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." [25]. However, the evidence base for the effectiveness of medicines for children and the amount of professional knowledge about the use of medicines for children are substantially less compared with adults [12, 13, 26]. Knowledge about high-quality practice can still form the basis for quality measures in this case, but the evidence must be carefully weighed.

If the evidence is insufficient or conflicting, quality measure developers must decide whether or how measure development should proceed. Often, quality measure developers will consult outside experts to weigh the

Table 1 Selected pediatric pharmacotherapy measures already identified or being developed as a result of the Children's Health Insurance Program Reauthorization Act

Category/topic	Status	Quality issue(s)
Prevention and health promotion		
Childhood and adolescent immunizations	ICS	Underuse – vaccines [44]
Dental care	PQMP assignment	Underuse – fluoride varnish [45]
Management of acute conditions		
Otitis media with effusion	ICS	Overuse – antibiotics [27]
Pharyngitis	ICS	Overuse – antibiotics without streptococcal testing
Management of chronic conditions		
Obesity	PQMP assignment[a]	Underuse – lipid-lowering and anti-hypertensive medications [46]
ADHD	PQMP assignment	Overuse and misuse – stimulant medications [47]
Adolescent depression	PQMP assignment	Underuse and misuse – antidepressant medications [48]
Asthma	ICS[b]	Underuse – inhaled corticosteroids [49]
	PQMP assignment	
Tobacco dependence	PQMP assignment[c]	Underuse and misuse – nicotine replacement, prescription medications (multiple) [50]
Sickle cell anemia	PQMP assignment	Underuse – hydroxyurea, penicillin prophylaxis [51]
		Underuse and misuse – pain medications [51]
Mental health of children in foster care	PQMP assignment	Overuse and misuse – antipsychotic medications [29]
Crosses multiple conditions or domains of care		
Medication reconciliation	PQMP assignment	Overuse and misuse [52]
Inpatient safety	PQMP assignment	Underuse, overuse, and misuse [53]
Enrollment/duration of insurance coverage	PQMP assignment	Underuse

[a] This assignment is about measuring body mass index and arranging follow-up treatment, if necessary

[b] This measure is about rates of visits to emergency departments for asthma

[c] This measure is a component of a larger assignment to develop measures of well adolescent care

ADHD Attention deficit/hyperactivity disorder, *ICS* Initial Core Set of child health care quality measures, *PQMP* Pediatric Quality Measures Program

relative lack of scientific evidence against the importance of the topic. The importance of the topic may reflect organizational priorities, the need for public reporting, the need to address a known quality of care problem, or a combination of these and other factors.

For the COEs developing measures to assess the use of pediatric medicines, the impact of insufficient evidence depends on the measure topic. For the topic of otitis media with effusion, clear evidence exists that antibiotics do not provide benefit to the vast majority of patients in the long term [27]. The challenges for this topic relate to proper diagnosis (validating the measure denominator), to antibiotics usage for other reasons (identifying exclusions to the measure numerator), and to identification of that small percentage of patients for whom antibiotics might actually be appropriate.

For the topic of antipsychotic medications in the foster care population, a comprehensive evidence base for what, when, why, how, and for whom the antipsychotic medications should be prescribed does not exist [28, 29]. Still, antipsychotic medications for foster care children are being prescribed at high rates in the US, rates that are thought to be disproportionate to the burden of mental or behavioral health conditions in this population [30]. For this topic, the challenge is to develop a measure that allows for flexible practice but identifies cases where more information is

needed. The purpose of the measure or set of measures would be to provide a mechanism for better understanding the circumstances under which antipsychotic medication prescribing might occur and for identifying which cases might be flagged for further evaluation. In addition, a measure might assess whether a child on antipsychotics was receiving adequate clinical management [31, 32].

In cases where limited scientific evidence leads to clinical uncertainty, a more holistic approach that takes into account patient characteristics, prevention, and public health priorities may be preferable. For example, counseling to prevent tobacco dependence in children or adolescents is another COE topic for which the scientific evidence to support the measure may be limited relative to its importance for public health [33].

2.2 Limited Data to Calculate the Measure

While CHIPRA calls for measures intended for public and private programs broadly, the primary focus of the PQMP has been to develop measures for State Medicaid and CHIP programs. Together, these programs serve more than 43 million low income and medically needy children and adolescents ages 0 to 20 years in the US [34]. Measures for State Medicaid and CHIP programs predominantly depend on claims data submitted as part of the billing process rather than on clinical data generated by physicians and by other clinicians as part of the care delivery process [35]. For many of the COE measure topics, however, clinical data generated at the point of care may be the desired or only source of data that can supply enough granular information to support calculation of the measure. For example, measures of appropriate use of pain medications for children with sickle cell anemia may depend on the type of medication, on whether a care plan was discussed with the patient/family, on communications with pharmacies, or on care coordination with emergency rooms or with other healthcare providers. Much of this information may not be reflected in the claims data available to the State Medicaid or CHIP program. Of the initial core set of 24 CHIPRA measures, 10 measures include specifications for only administrative data, 11 measures include specifications for both administrative and medical record data, one measure includes specifications for only medical record data, and one measure is based on a patient survey [36].

3 Meeting the Challenges

3.1 Focusing on the Purpose of Measurement

The impact of the challenges described earlier depends on the purpose of the measure itself. If the purpose of the measure is to satisfy public reporting requirements by States, then overcoming the challenge of data availability at the State level becomes paramount. If the purpose of the measure is to improve quality at the level of an individual hospital, then the challenge of data availability may be less problematic. A hospital may currently collect or may be able to change the way it collects data to generate the information needed to calculate the measure. Similarly, if the purpose of the measure is to improve quality at the level of the individual clinician, the challenge of data availability is likely to be less consequential as long as the data needed are accessible in the medical record and the data can be transmitted back to the clinician in an actionable way. The challenge of insufficient scientific evidence is likely to affect all measures related to pediatric medicines regardless of the level of reporting or of the level of intended quality improvement. If the scientific evidence supporting a measure is too weak, providers are unlikely to accept the measure.

3.2 Enabling Measurement Through Health Information Technology

Health information technology (health IT) has been shown to increase quality of care when implemented well [37, 38]. The promise of health IT for quality measurement lies in its potential to automate (i) the process of finding data relevant to a measure, (ii) the calculation of the measure, and (iii) the provision of feedback to clinicians or to others who may need to act on the measure results. To date, quality measurement, particularly in cases where clinical data are required, has relied on human abstractors examining medical records and deciding whether to include individual patients in the measure numerator and/or the denominator. With health IT, it may be possible for a computer to perform the same functions more efficiently. In addition, measure results could be tied to other automated functions such as computerized clinical decision support, where a clinician could improve performance on a measure seamlessly and in real time.

Health IT-enabled quality measurement, however, presents unique challenges. Traditional measure specifications that provide instructions for human abstraction of medical records (paper or electronic) do not contain the level of specificity required for computerized, automated abstraction. For example, to determine appropriate use of stimulant medications for ADHD requires accurate diagnosis of ADHD, the names of acceptable medications, knowledge that the medications are not being prescribed for other purposes, and appropriate follow-up management. A human abstractor is likely to make numerous heuristic decisions about whether the numerator and denominator criteria are satisfied depending on information contained in handwritten (or typed, free text) clinic notes, on documentation of communications with teachers and parents, on

results from questionnaires, and on information about scheduled appointments.

For a computer to replicate these decisions, each decision needs to be completely and unambiguously described, needs to include appropriate standardized terminologies, and needs to connect to other decisions by formal, computer-interpretable logic statements. The data need to be available to the computer in predictable, valid locations. Highly structured clinical documentation aids computer processing such as automated quality measurement but presents challenges to clinical workflow [39]. Freely written clinical documentation may be transformed into computer-interpretable information using techniques such as natural language processing. However, such techniques remain largely in the research domain and are not yet widely implemented [40].

In the US, efforts are underway to increase the adoption of electronic health records (EHRs) and to use health IT to improve the quality of health care. Most prominent is the 'Meaningful Use' EHR incentive program from CMS, which provides incentive payments to eligible professionals and hospitals who care for patients under the Medicare and Medicaid public insurance programs to adopt, implement, and meaningfully use EHRs [41]. To date, CMS has processed more than US$14 billion in payments as part of the EHR incentive program, which includes payments to more than 270,000 eligible professionals and to more than 3,500 eligible hospitals [42]. Among other actions, clinicians use certified EHR technology to electronically prescribe medications, to connect to other clinicians for coordinated care, and to report on clinical quality measures. Several of these clinical quality measures relate to medications in terms of patient safety and appropriate management, including medications to treat childhood conditions [43]. Examples of childhood conditions for which medication-related clinical quality measures are included in the 'Meaningful Use' EHR incentive program are asthma, ADHD, and upper respiratory infections (avoidance of antibiotics).

4 Summary

Quality measures for pediatric pharmacotherapy can be divided into measures that assess overuse, underuse, or misuse of medicines. Challenges to developing quality measures for pediatric pharmacotherapy include limitations of the scientific evidence and limitations to the data that are available to measure implementers. The CHIPRA Pediatric Quality Measures Program in the US endeavors to address these challenges as it develops measures for more than forty pediatric topics. Health IT may emerge as a useful tool to enhance quality measurement as adoption of EHRs increases.

Acknowledgments The authors are employed by the US Department of Health and Human Services. The views expressed here are those of the authors and do not necessarily represent the views of the US Federal Government. No sources of funding were used to assist in the preparation of this review. The authors have no conflicts of interest that are directly relevant to the content of this review. The authors would like to thank Dr. Francis Chesley for his thoughtful input during preparation of this manuscript.

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