Abstract:

Unwanted variation in care is a challenge to high-quality care delivery in any health-care system. Across the Emergency Medical Services for Children (EMSC) continuum, there is wide variation in care delivery for which best practices have demonstrated opportunities to minimize that variation through clinical standards (evidence-based pathways, protocols, and guidelines for care). A model of development of clinical standards is delineated and tools used in that process are described. Implementation strategies for improving utilization are also described with clinical decision support tools being a promising strategy for accelerating uptake of guidelines. Critical to implementing guidelines through improvement science strategies is the ability to make iterative improvements directed by data and analytics. The progression of sophistication in a system's informatics and analytics capabilities is driven by a maturity of data reporting to analytics that drives decision support for implementing clinical standards. Integration of financial data into the clinical standards processes and analytics platforms is necessary to determine value of the work. Within the EMSC continuum, a number of initiatives will drive national clinical standards activities and are fueled by current pockets of successful development and implementation activities within organizations and systems.

Keywords:

Health care; evidence-based; quality; value

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Delivering Value Through Evidence-Based Practice

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Health care organizations and our health care system as a whole should be striving towards achieving high value. All stakeholders in health care delivery systems benefit from increased value including patients, providers, payers, and suppliers who reap benefit from a stable and well-supported system. As value is defined by outputs, measurement and outcomes are critical to demonstrating increased value and driving iterative improvement to achieve even greater value. The relationship of outcomes relative to cost may define value, and this has been popularized as a value equation where value is equal to quality over cost (dollars spent).[1,2]

Quality itself has been defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[3] Professional knowledge implies consideration for the best evidence to inform clinical decision-making based on studies and scientific literature with a goal of provision of the right care to the right child at the right time. Evidence-based practice should not be construed to imply that published or high quality scientific evidence is available to inform all clinical questions, rather, that an evidence-based model of care includes consideration for scientific evidence, physician clinical expertise, patient and family values and preferences, clinician preferences, and available resources contextualized to the specific clinical care question for which a recommendation will be derived.[4]

VARIATION AND THE EMERGENCY MEDICAL SERVICES FOR CHILDREN CONTINUUM

The Institute for Healthcare Improvement has suggested a triple aim framework for optimizing health system performance: (1) a better overall patient experience, (2) improving the health of a population, and (3) delivering care at a better value.[5] Application of the triple aim would be relevant for care delivered across the pediatric emergency medicine (emergency medical services for children or EMSC) care continuum. Although thought of as beginning in prehospital or hospital care, the EMSC continuum begins with an incident and involves potentially multiple care venues and providers with ultimate return of the patient to the community and their medical home (Figure 1).

Health care has become increasingly complex, and variation in care delivery has contributed to that complexity and potential gaps in quality. The understanding that unwanted variation is the enemy of quality has been attributed to W. Edwards Deming, statistician, professor, and expert in quality management,[6] and can be applied to any type of care delivery, including that within the EMSC continuum of care. Unwanted variation in health care can contribute to waste, inefficiency and ineffectiveness in providing diagnostic accuracy and therapeutic reliability. Several studies across the pediatric emergency care continuum have described wide variations in practice. In prehospital care, Shah and colleagues described the prehospital transport of 250 actively seizing children to 10 urban EDs in which a wide variation in delivery of medication routes for midazolam were noted with approximately half resulting in dosing errors.[7] Similar variation also has been noted in utilization patterns for trauma specialty care for children with moderate and severe injuries.[8] Although variation in care delivery for children treated in EDs has been well described,[4] the association between this variation with cost and quality is becoming increasingly highlighted. Data from the Pediatric Health Information System, a comparative pediatric database housed in the Children's Hospital Association, was used to assess the management of 3 pediatric conditions treated in 21 hospital EDs (ie, gastroenteritis, asthma, and simple febrile seizures). While wide variation in care was noted, higher costs were not associated with better quality.[9] ED based care also has implications on the quality of care delivered in inpatient settings. One study of children treated on inpatient units for bronchiolitis noted variations in diagnostic testing and management among 16 US hospitals that was unrelated to patient demographics or severity of illness.[10]

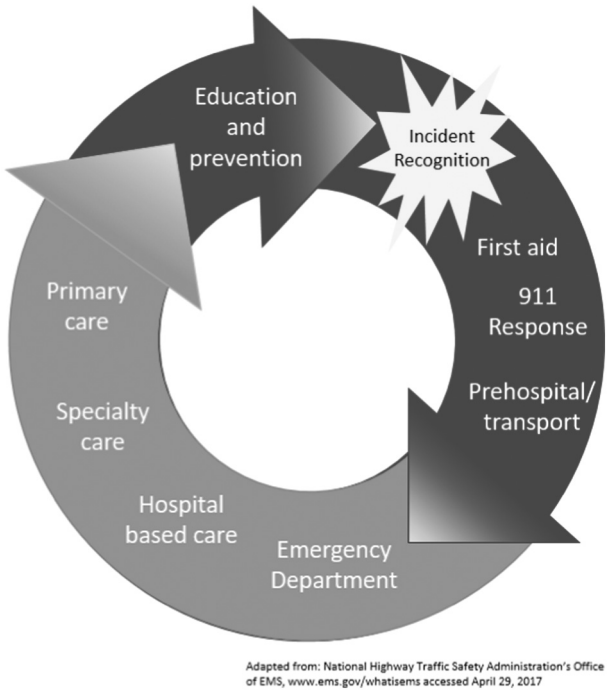

Figure 1. Emergency Medical Services for Children continuum of care.

CLINICAL STANDARDS IN EMSC

Because unwanted variation can exist anywhere in the continuum, a gap in quality can have the net effect of less than optimal outcomes for the child. Aligning care with clinical standards supported by systematic approaches to guideline development will improve the probability that patient populations will receive care based on the most current professional knowledge. Clinical guidelines serve to synthesize available evidence and bridge the gap between science and clinical practice; not through rigid protocol adherence but by a framework for care delivery, thus contributing to efficiency, cost containment, and improved patient outcomes.[11] Clinical standards may refer to pathways, protocols, evidence-based summaries, or full guidelines, and ideally are developed in a patient-/family- centric manner in order to address care across the continuum.

National attention for the need for evidence-based clinical standards for prehospital care has been growing despite the limited research on the direct benefits of existing prehospital evidence-based guidelines (EBGs), mostly because of the wealth of evidence to illustrate their contributions to

improved outcomes in other medical fields and other EMSC settings.[12-14] One pediatric study used improvement science methodology to improve adherence to national septic shock guidelines, consequently demonstrating improvement in process and outcome measures.[15] A study of over 180, 000 children with gastroenteritis found that hospitals adhering to published guidelines had 50% lower charges for ED or observation patients without adverse effects on other outcomes.[16] Guidelines for diagnosis and management of bronchiolitis both in the ED and across the hospital continuum have been associated with improved outcomes through decreases in utilization of unnecessary testing and interventions, including decreases in costs.[17-21]

Several organizations and systems have developed strategies for minimizing unwanted variation in clinical care by utilizing systematic approaches to development of evidence-based clinical standards. Concurrently, they have described improved processes and outcomes, many of which include reduced costs.[4,22-24] Thus, there is a plethora of experiential learning from clinical standards work that is applicable to the EMSC environment.

DEVELOPING CLINICAL STANDARDS: ONE MODEL

At Texas Children's Hospital/Baylor College of Medicine, the Evidence-Based Outcomes Center has had a decade of experience in the development and implementation of clinical standards. The core elements of systematic clinical standards development are described below and are applicable to any venue of care.

1. Selection of a clinical topic can be determined by both importance of outcomes (as defined by high prevalence, high rate of morbidity and mortality, resource intensiveness, or wide variation in care) and organizational readiness for improvement. Internal data can help identify importance quantitatively, especially when including cost of care for each disease process being considered for clinical standards. Simply defined, organizational readiness is the institutional member's commitment to the complex change that might ensue from development and implementation of the clinical standard;[25] they must value the development process as well as the potential in order to assure ongoing engagement for development, implementation, and sustainability.
2. Guideline development teams should be created with a multidisciplinary, "bottom up" approach to allow front line content experts rather than authoritative leaders to voice all opinions. Patient and family participation and feedback should be incorporated into the guideline development process in order to ensure that important clinical questions and outcomes to the patients and their families are considered.
3. Determining the scope of the clinical standard, along with patient inclusion criteria and exclusion criteria, is a prerequisite to identifying the important clinical questions to be addressed. Focused clinical questions should be brainstormed based on areas of variation in care, new research availability, areas with performance outcomes below benchmark, and/or identified patient care concerns. Clinical questions should be presented in Patient Intervention Comparison Outcome (PICO) format in order to ensure searchable keywords and specific recommendations (eg, in children with acute asthma in the ED [P], do anticholinergic agents [I] versus standard albuterol care [C] reduce admission rates [O]).[26] Patient-centered outcomes are preferred and should be rated on their degree of importance to the patient. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology currently utilizes 3 categories for outcome rating (critical, important but not critical, and limited importance). Outcomes of limited importance are not included in the development of the clinical standard as they should not have an effect on decision-making related to patient care.[27]
4. A systematic search for existing national guidelines and pertinent clinical research for each question should be completed using research databases, evidence-based practice websites, and professional organization websites (eg, American Academy of Pediatrics, Agency for Healthcare Research and Quality National Guideline Clearinghouse, or specialty specific professional societies pertinent to the guideline topic).
5. Existing guidelines and clinical research should be critically appraised utilizing an established appraisal method (eg, Texas Children's Hospital has implemented the use of Appraisal of Guidelines for Research and Evaluation II [AGREE II] and[28] GRADE methodologies for guidelines and clinical research, respectively[29]). With the review of evidence for each PICO question,

unambiguous practice recommendations will be developed that give guidance to clinicians on the care of the patient. Remarks outlining the values and preferences of the patients, families, and providers can be incorporated into recommendations, especially when the desired effects of an intervention are closely balanced with the undesired effects.[28] Where evidence is lacking, consensus amongst the guideline development team is needed with transparent statements to reflect the paucity of evidence.

Assessments of existing guidelines utilizing tools should be transparently demonstrated in the guideline. AGREE II is a 23-item instrument encompassing 6 domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. Each item is ranked on a 7-point Likert scale and the item ratings are used to formulate an overall rating of the guideline quality.[29] Ultimately, the guideline is either adopted, adopted with modifications (most common), or rejected. Other tools in addition to the AGREE II tool, such as the Institute of Medicine Standards for Developing Trustworthy Clinical Practice Guidelines, also exist.[30,31]

For each PICO question, studies should be critically evaluated as a body of evidence using an appraisal tool, such as GRADE.[32] GRADE is a widely adopted global tool that allows for a seamless, transparent process of translating the evidence into clinically useful practice recommendations. Each practice recommendation is categorized as strong or weak and is supported by high, moderate, low, or very low-quality evidence. Limitations in study design and execution, inconsistency between studies, indirectness between the PICO question and the studies, imprecision of the studies, and publication bias can lower the overall quality of evidence. Large estimates of treatment effect, evidence of a dose-response gradient, and plausible confounding that would increase confidence in an estimate of effect can raise the quality of evidence. The strength of the recommendation is "the extent to which we can be confident that adherence to the recommendation will do more than harm." It is formulated by weighing the risks versus the benefits of the intervention and by considering the patient/family values and preferences, quality of evidence, importance of the outcome, ease of implementation, costs, and resources.

IMPLEMENTATION OF CLINICAL STANDARDS

Implementation of clinical standards, described here briefly as the context in which guidelines are implemented, is broadly variable and literature for successful uptake specific to the EMSC continuum is limited. With rare exception, the entirety of guidelines or components of the guideline may represent the shared baseline by which a quality improvement (QI) initiative is driven. Nonetheless, opportunities in utilizing improvement methodologies such as the Model for Improvement with its embedded Plan-Do-Study-Act (PDSA) cycles are used at Texas Children's Hospital (TCH) as the method of choice, although many other methods are also incorporated.[33] Iterative improvements are discovered during the planning phase and multiple QI tools are utilized to understand the workflow, leverage points, metrics, and analytics to manage change and drive improvement in outcomes. The Agency for Healthcare Research and Quality suggests that a QI implementation team be comprised of individuals connected to or a part of hospital leadership, clinical experts in the intervention or disease process of focus, persons proficient in QI methodology, and influential personnel from the areas most affected by the change.[34] Critical to understanding the financial impact and value of clinical standards is the incorporation of finance team members into our implementation teams.

Factors that influence implementation success of clinical standards have been described and include the following:[35-40]

1. Characteristics of the guideline that improve uptake:
- a low complexity guideline (ie, easy to understand and use)
- the scientific nature of the guideline being evidence-based rather than lacking a scientific basis
- development by the target group and stakeholders who will use it

2. Characteristics of the implementation strategies that improve success:
- multifaceted, intensive strategies involving system redesign

3. Characteristics of professionals that will decrease success:
- lack of familiarity or limited familiarity
- lack of agreement with the clinical standard
- younger age or less experience of the professional

4. Characteristics of patients that decrease uptake by the user:
- patients who perceive no need for guideline recommendations or reject them

- patients with comorbidities

5. Environmental characteristics that decrease success:
- limited time and personnel resources
- limited perceived support from peers or superiors

CLINICAL DECISION SUPPORT

Clinical decision support (CDS) built within the electronic medical record (EMR) is a powerful means to leverage guideline uptake. CDS encompasses a variety of approaches to provide clinicians, staff, patients, and other users with timely, relevant information that can improve decision making, prevent errors, and enhance health and health care.[41] Qualitative research has defined 3 categories of CDS: (1) Alerting CDS: alerts and reminders that fire to deliver information and interrupt workflow; (2) Workflow CDS: eases data entry, documentation, and resource location, and (3) Cognitive CDS: provides a patient management and planning overview.[42] CDS tools and interventions include computerized alerts and reminders, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools.[41] CDS tools allow for dissemination of the right information to the right people at the right time. At TCH, we offer our clinicians a plethora of CDS tools, including algorithms, evidence-based order sets, suggestion records, interdisciplinary plans of care (IPOCs), best practice alerts (BPAs), and navigators. Suggestion records use discrete variables from the patient chart to promote the use of evidence-based order sets by passively suggesting targeted order set use to the ordering clinician on the order entry screen. Interdisciplinary plans of care display goal-driven interventions for the entire care team. Best practice alerts are pop-ups that prompt a clinician to address an issue before continuing and can be programmed with hard stops.

Algorithms or flowcharts provide a visual representation of the practice recommendations. Evidence-based order sets allow for timely application of evidence at the bedside. Orders that are supported by evidence can be defaulted and orders that are not supported by evidence are intentionally omitted or listed last on order lists if minimal evidence supports their use. For example, chest radiographs for bronchiolitis are not offered on ED-based bronchiolitis order sets, and generic oral antibiotic choices are listed first on options for community- acquired pneumonia order sets and other ED- based infectious disease related order sets. Order sets may have hyperlinks to resources (eg, clinical standard, algorithm, or other pertinent internal or external resources) to provide transparency to CDS. In addition, clinical and information services governance structures at Texas Children's Hospital prohibit consensus- or silo-based order set builds if an existing evidence-based order set exists.

The implementation of evidence-based order sets, clinical guidelines, and QI interventions driven by a CDS tool for early recognition of severe sepsis and septic shock at our institution led to an improvement in a number of quality metrics. The trigger tool, designed as a hard stop alert, had an 81% sensitivity and 99.9% negative predictive value.[43] After implementation of the protocol, measurement of impact compared to baseline data revealed significant improvements in time from triage to first bolus (decrease from a median of 56 to 22 minutes) and triage to first antibiotics (decrease from a median of 130 to 38 minutes).[44]

ANALYTICS

As with all quality improvement initiatives such as the sepsis example above, measurement is critical to defining success. This would include demonstration of clinical, operational, and financial measures (including process and outcome measures for those domains) for quantifying value in clinical standards work. The science of informatics (data plus meaning), as it relates to pediatrics, must target population health (including ED care within a continuum) It must simultaneously address the rising costs associated with implementation and maintenance of computerized systems of care coordination, while at the same time contribute towards excellence in patient care.[45] Analytics (data plus information) plays a key role in predictive assessment, clinical decision support, and various patient throughput measures.[46] To illustrate this, an initiative to create and implement clinical standards for asthma included EMSC related activities comprised of prehospital and hospital based interventions that included early steroid delivery; standardization of scoring scales and pathways linking protocols for care; standardization of first line, adjunct, and second line therapies; standardization of asthma action plans; and control medication for persistent asthma from any acute venue of care including emergent care settings. One

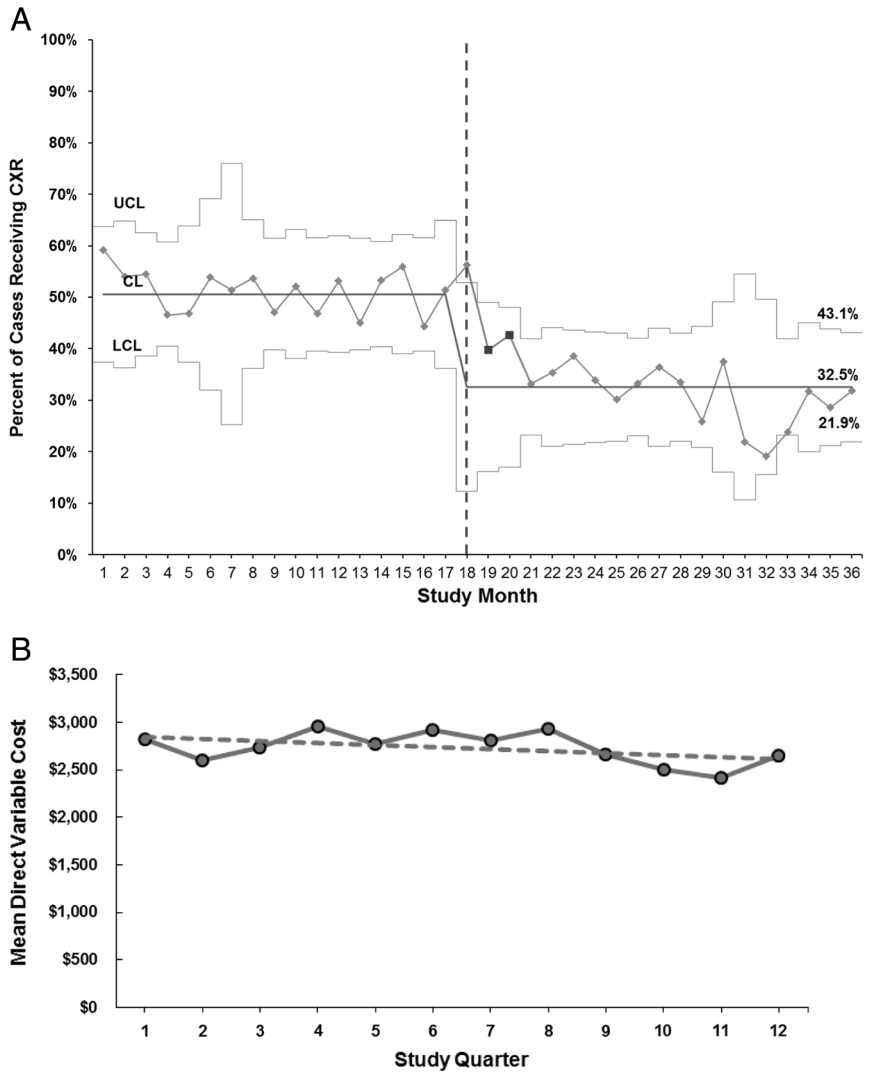

Figure 2. A, Percentage of acute asthma patients receiving a chest radiograph. This Statistical Process Control (SPC) P-chart illustrates the reduction in emergency center (EC), inpatient, and observation acute asthma patients receiving chest radiographs before and after QI intervention strategies aligned with an asthma guideline of care (dashed vertical green line). Approximately 60% of patients received a chest radiograph in Project Month 1, while approximately 32% of patients received a chest radiograph at the end of the project period. Currently, 28% of acute asthma patients receive chest radiographs. The SPC chart was generated with the QI Macros package (KnowWare Intl, Inc) for MS Excel. UCL = upper control limit; CL = control limit; LCL = lower control limit. B, Mean variable direct costs for asthma care. Average direct variable costs for acute asthma patients were computed and plotted for project quarters 1–12. All patients in the cohort included in this chart were clinical standards compliant. Linear regression analysis (dashed line) shows a decrease in cost over time (slope = negative) of 12% ($345.30). (Of note, an increase in margin contribution occurred in this same time period from an average loss to a positive contribution not shown here.) Courtesy of Travis L. Rodkey, PhD, Outcomes Analyst.

component of the bundle driven by the ED is illustrated in Figure 2A, where efforts to decrease orders for unnecessary chest radiographs was targeted. Comprehensive guidelines for care were implemented with education, CDS, dashboard dissemination, and enhanced communication strategies that included components pertinent to the ED. As this bundle of activities aligned with the asthma guideline also included inpatient, critical care, and outpatient activities, the resultant decreases in length of stay, reductions in unnecessary test ordering, reductions in readmissions, and other improvements in clinically relevant quality metrics led to a decrease in cost of care for the population of thousands of children with asthma treated in our enterprise and is demonstrated in Figure 2B.

In order to support the analytics capabilities necessary to demonstrate improvements from

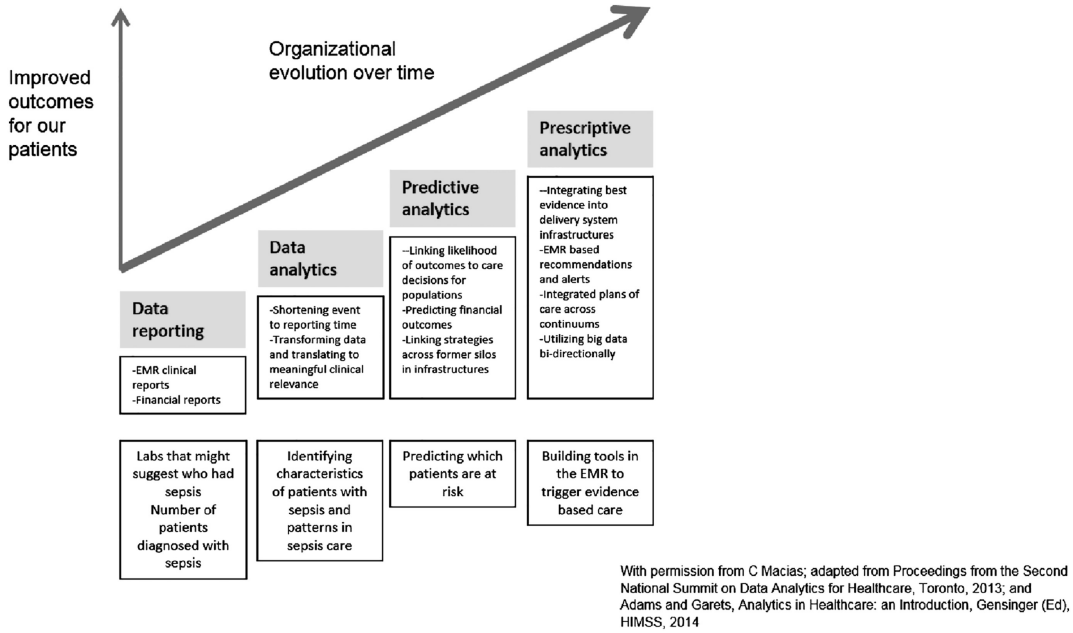

Figure 3. Maturity of informatics and analytics.

clinical standards, health care systems must drive increasing sophistication in informatics and analytics. To meet this demand, data systems must move from simple data gathering and reporting, as can be done from a patient EMR report at the bedside, to aggregating and analyzing data in populations or themes (data analytics), to predicting patients at risk (predictive analytics), or linking health observation with health knowledge to influence clinical decisions (prescriptive analytics or clinical decision support).[47] (See Figure 3). Although many EMRs are developing analytics platforms that embed some of these capabilities into their existing workflows, robust analytics must still overcome gaps in interoperability and the sharing of data between relevant health care systems to track data related to the health of a population. Guidelines developed along a patient- centric model ideally would be able to track metrics across systems, such as EMSC entities; however, current limitations in technology and culture for data sharing provide restrictions for understanding the complete value of clinical standards implemented across a system. Nonetheless, demonstrations of improvements in value likely understate the true impact across an entire health care system. At Texas Children's Hospital, the integration of data across multiple entities linked to our institution (eg, health plan data, pediatric practice data, hospital data, and prehospital data) can be housed in our Enterprise Data Warehouse (EDW) to encompass the EMR, financial information and staffing data, and other sources of data across its infrastructure. Future integration of health information exchanges, government hosted databases, and other big data sources will aid in providing analytics support for identifying opportunities for driving, assessing impact, and iterating quality improvement initiatives driven by clinical standards.

When assessing the impact on quality of evidence-based guidelines and other clinical standards products clinical outcomes as illustrated above are important, but these may be linked to financial outcomes to establish value. At Children's Hospital of Pittsburgh, a hospital aim to integrate actionable analytics into the broader framework of disease management targeted an existing appendicitis guideline (preoperative and postoperative phases) as its initial project. A self-service web-based tool provided measurement to provide clinical leaders and administrators analytics accessible in their offices or at the point-of–care. These interventions for guideline-driven care across the care continuum led to a 25% reduction in the median length of stay of patients with appendicitis, and also a significant decrease in the controllable (direct) cost per case. This illustrates that collection, analysis, and timely dissemination of accurate clinical and throughput data aligned with clinical pathways changed behavior and improved care outcomes.[48] Across the Texas Children's Hospital continuum, from ED to inpatient units to discharge, the total cost savings across a subset of 21 diseases for which guidelines were available in fiscal year 2016 was a net difference of $33.5 million in variable direct costs, or the costs directly attributable to the additional burden of care for

the patient calculated relative to the personnel time and resources consumed.

SUMMARY AND FUTURE DIRECTIONS

Clinical standards drive value in health care by improving quality of care: removing unwanted variation in a system drives reductions in waste, minimizes error, and improves throughput. Systematically developed guidelines can be implemented effectively utilizing best evidence for leveraging known enablers and eliminating barriers to adoption. Across the EMSC continuum, wide variations in practice have demonstrated opportunities for clinical standards to improve value. These strategies may include system- based clinical decision support and local analytics platforms to drive iterative improvement centered on such a shared baseline of care.

Across the EMSC continuum, we anticipate a continued growth in clinical standards activities and improvement science initiatives to develop and implement them as stakeholders demand greater transparency in data, and attribution models for best practices illustrate new opportunities for spread. Efforts to support prehospital clinical standards development and implementation have been driven and supported by a number of agencies such as the National Highway Traffic Safety Administration, the Health Resources Services Administration through the EMSC program, the Federal Interagency Committee on EMS, and the National EMS Advisory Council. Strategies included the creation of a prehospital guidelines consortium, the development, promotion and implementation of prehospital evidence-based guidelines, education and research on prehospital evidence-based guidelines, and standardization of evaluation methods for prehospital evidence-based guidelines.[41] The greatest potential for establishing value of clinical standards in prehospital work will likely emerge from standardization of evaluation strategies to link outcomes to local, regional, state, and federal efforts at implementing pediatric prehospital evidence-based guidelines.

The EMSC federal program has recently supported a conversion of its coordinating center to one embedded in improvement science (EMSC Innovation and Improvement Center), of which its initiatives includes efforts to minimize unwanted variation in care (www.EMSCImprovement.center). One such initiative includes a partnership with the American Academy of Pediatrics for development of national ED- based evidence-based pathways. To date, these have included publically accessible pathways for septic shock, bronchiolitis, and community acquired pneumonia.[49]Hospital-based efforts are currently limited by gaps in data sharing across institutions to evaluate outcomes and costs related to implementation of these pathways. However, local implementation of these and other evidence-based clinical standards products will likely continue to describe the value of clinical standards in pockets across the EMSC continuum. The Pediatric Initiative for Clinical Standards (PICS), now in its second year, is moving from its development of hospital-based guidelines activities within this consortium of children's hospitals to a phase of data collection on quality metrics in order to demonstrate value in clinical standards implementation that will include components of ED based care.

Although limitations to big data sharing will continue to limit the nation's ability to demonstrate the aggregate value in clinical standards across the EMSC continuum, demonstrated successes in defining value for components of the system will fuel more comprehensive and widespread approaches to development and implementation. Ultimately, these patient centric approaches to clinical standards work will continue to drive improved outcomes of care, a better patient experience, and decreased costs of care–achieving the triple aim.

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