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Pediatric Patients in Diabetic Ketoacidosis: A Pathway to Improvement

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Abstract

Problem Statement: Pediatric patients in diabetic ketoacidosis (DKA) frequently present to non-pediatric specific care centers initially for medical management where providers may or may not be familiar with standards and treatment guidelines particular to this specialty population.

Purpose: The purpose of this project was to establish a pediatric DKA clinical pathway (CPW). Pediatric patients require precise treatments tailored to age and weight specifications. A pediatric DKA CPW identifies treatment order sets, goals, and outcomes customized to the patient's metabolic demand. Commonalities within a predictable course of treatment for patients with a shared clinical diagnosis result in accelerated care, improved patient outcomes, and healthcare organizational benefits.

Methods: A CPW to care for the pediatric patient in DKA is an evidence-based approach to the management of patients with a common diagnosis and predictable clinical course of care.

Inclusion Criteria: Pediatric patients less than 19 years of age presenting to the ED of a regional medical center and diagnosed with DKA are included in the study sample.

Analysis: Fisher Exact test analysis was used to compare order set usage pre- and post-intervention. Parametric independent t-test and non-parametric Wilcoxon tests were used to analyze Emergency Department LOS, overall total hospital LOS, and compare sample means pre and post CPW implementation. Statistical test selection was based on the ability to compare differences between two variables for the same subject. A p-value > 0.05 was considered statistically significant.

Pediatric Patients in Diabetic Ketoacidosis: A Pathway to Improvement

Diabetic ketoacidosis (DKA) is a prevalent condition seen throughout healthcare systems. Clinical pathways (CPW) optimize care by providing a standardized approach to the implementation of evidence-based practice guidelines for a group of patients with a shared diagnosis and predictable clinical course. Lack of standardization results in inconsistencies in care, which potentially result in patient complications.

Background

Approximately 34.2 million people (just over 1 out of every 10) are living with diabetes in America. Within this statistic, 210,000 are children and adolescents (Benoit et al., 2018; Centers for Disease Control and Prevention, 2020). Annually, 30.2 per 1,000 hospitalizations are related to DKA (Centers for Disease Control and Prevention, 2020). Approximately 4-8 per 1,000 hospitalizations are pediatric patients in DKA (Young, 2018). Pediatric patients in DKA present to regional medical centers for acute care. Educational and practice gaps often exist regarding adherence to pediatric DKA treatment guidelines, which differ from adult practice recommendations (Zee-Cheng et al., 2017).

Children have a higher metabolic rate, developing cerebral and autoregulatory mechanisms, and a larger surface area to body mass index ratio. The re-hydration of pediatric patients must consider all factors. Adults are typically re-hydrated with 1-2L of 0.9% NS regardless of age and weight. Children need to be re-hydrated using a weight-based protocol (typically 10-20mls/kg) plus maintenance fluids over 24-36 hours. Overhydration can lead to fluid volume overload. All DKA patients are at risk for cerebral edema, but that risk is greater in children. Insulin is not bolused in pediatric DKA patients as it is in adults due to the risk of rapid electrolyte shifting. Adult hyperglycemia protocols titrate insulin. Pediatric protocols usually

maintain insulin at a 0.1unit/kg/hr rate and use a two-bag fluid titration system to maintain a steady decline of blood sugars at a rate of 50-100 points per hour (Wolfsdorf et al., 2006).

Dehydration severity directly correlates with required insulin infusion length (Ronsley et al., 2018). Delayed treatment can lead to increased comorbidities at earlier stages in life including renal injury or failure, peripheral neuropathy, retinopathy, hyperlipidemia, stroke, heart disease, and mental illness (Premchand, 2017). The most severe complication of DKA is cerebral edema, which has a 25% mortality rate and 0.5-3% occurrence rate in DKA presentations (Ronsley et al., 2018). Permanent neurologic deficits are found in 5-25% of cerebral edema survivors (Ronsley et al., 2018). Inconsistencies in disease management have negative repercussions including irregularities in care, treatment timing variations, delays in interfacility transfer, and ultimately prolonged achievement of expected outcomes (Joyner Blaire et al., 2018). Any extension of a disease process impacts a variety of stakeholders including patients inflicted with the ailment and treatment facilities accruing costs.

Problem Statement

The project site resides in a geographical location lacking a pediatric-specific emergency department. Though specialties exist, such as a pediatric intensive care unit, within local medical centers; initial patient encounters often occur with providers who are generalist rather than specialists trained and familiar with standards and treatment guidelines particular to a specialty population. It is imperative pediatric diabetic patients be managed with care adapted to age-specific guidelines, specifically exercising precision in delivering fluids, electrolytes, and medications proportional to body weight (Wolfsdorf et al., 2006). Children and adolescents differ from the adult population with a higher metabolic rate, developing cerebral and

autoregulatory mechanisms, and larger surface area to body mass index ratio (Wolfsdorf et al., 2006).

The site recently implemented a protocol for the initial medical management of pediatric patients in DKA, distinguishing their care from the adult population (B. Brown, personal communication, May 19, 2021). Through the development of a visual algorithm and CPW which includes all protocols designed for pediatric DKA treatment at this site, staff have a comprehensive view of overall standardized care from admission to discharge. Protocols included in the CPW include initial medical management, PICU management including care while on an insulin drip, and care once transitioned from intravenous insulin administration to subcutaneous administration. The complexity of DKA in a specialty population such as pediatric patients can create treatment delays due to hesitation among providers. Implementation of a clinical pathway for treatment provides a visual algorithm for reference facilitating treatment efficiency and nurse-efficacy (Teoule et al., 2019). CPWs seek to standardize care processes, contain cost, improve organizational productivity and adherence to standards while maximizing patient outcomes (Lawal et al., 2016).

The significant morbidity and mortality risk associated with treatment efficiency and a necessity for adherence to treatment guidelines by a cohort of providers including emergency medicine, pediatric specialists, and primary care providers have resulted in standardized treatment protocols, algorithms, and order sets utilized across North America (Ronsley et al., 2018). Considering statistics, it is imperative to standardize pediatric DKA treatment within a local facility to ensure standard work, adherence to current age-specific guidelines, and protocols.

Prompt diagnosis and implementation of care following up-to-date treatment protocols is key to overcoming DKA. Evidenced-based clinical pathways outline clear treatment guidelines specific to the presenting patient's needs (Lawal et al., 2016). Based on identified problems, the working PICOT was developed: In pediatric patients admitted to a regional medical center with DKA, how does a pediatric DKA CPW compare to care rendered before CPW implementation decrease emergency department (ED) length of stay (LOS) times over a three-month period?

- Population: Pediatric patients (specifically ages 18 years and under) in DKA admitted to a regional medical center
- Intervention: Implementation of a pediatric DKA CPW to include site-specific order sets, treatment guidelines, and algorithms for medical management (Du Z, 2019). Components of CPWs improve quality methodology, analysis of presenting disease severity, guideline compliance, reduction of readmission rates, and minimization of unnecessary lab testing (Baumer-Mouradian et al., 2019; Brober et al., 2020; Flood et al., 2019; Ilkowitz et al., 2016; Pruitt et al., 2019).
- Comparison: Care rendered before CPW implementation
- Outcome: Hospitalized LOS times and ED LOS times
- Time: Three-month period

Review of the Literature

A search of literature utilizing multiple databases including the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, Pubmed-Medicine, and Joanna Briggs Institute yielded 15 robust articles included in an evidence table. The literature was analyzed for the best interventions used to address hospital LOS in pediatric patients experiencing DKA (see Appendix A).

A CPW is a successful approach to care among patients with a shared diagnosis (Al Nemri et al., 2016; Askari et al., 2021; Du Z, 2019; Edholm et al., 2021; Rooholamini et al., 2017; Rotter et al., 2010; Shaffer & Dohar, 2020; Yang et al., 2016). A CPW is a multidisciplinary approach utilizing structured interventions to incorporate evidence-based practice standards for a specific diagnosis adapted at a particular site. It may be referred to interchangeably with terms such as care map, care model, or evidenced-based care and encompass several aspects including protocols, order sets, and guidelines into an all-encompassing care approach (Kinsman et al., 2010). CPW components include order panels, provider guidelines, nursing guidelines, order sets, and multidisciplinary approaches (Baumer-Mouradian et al., 2019; Flood et al., 2019; Ilkowitz et al., 2016; Zee-Cheng et al., 2017).

CPWs are primarily used in acute care hospital settings but have also been implemented in primary care settings including telehealth as tools to treat patient populations with common characteristics such as symptoms and diagnosis (Al Nemri et al., 2016; Askari et al., 2021; Baumer-Mouradian et al., 2019; Brober et al., 2020; Du Z, 2019; Edholm et al., 2021; Everette et al., 2021; Flood et al., 2019; Ilkowitz et al., 2016; Pruitt et al., 2019; Rooholamini et al., 2017; Rotter et al., 2010; Shaffer & Dohar, 2020; Yang et al., 2016; Zee-Cheng et al., 2017). Clinical pathways aid in protocol adherence, timeframes specific for clinical interventions, and management plans for specific diagnoses (Al Nemri, 2017; Lawal et al., 2016). Additional advantages include minimalization of side effects, prompt return of glycemic control, and decreased hospitalized LOS. Decreased LOS is a key indicator of intervention success as it typically indicates the achievement of treatment goals. Delayed treatment results in increased severity of ketoacidosis and further progression of the patient's acute emergent state (Raghupathy, 2015).

Pediatric DKA is a complex and multifaceted disease process requiring knowledge and expertise to deliver optimal care. CPWs promote standardization and timeliness of care, improved diagnostic effectiveness, patient education, and guideline compliance (Al Nemri et al., 2016; Askari et al., 2021; Du Z, 2019; Edholm et al., 2021; Rooholamini et al., 2017; Rotter et al., 2010; Shaffer & Dohar, 2020). Components of CPWs improve quality methodology, analysis of presenting disease severity, guideline compliance, reduction of readmission rates, and minimization of unnecessary lab testing (Baumer-Mouradian et al., 2019; Brober et al., 2020; Flood et al., 2019; Ilkowitz et al., 2016; Pruitt et al., 2019).

A quality improvement initiative conducted at a tertiary care hospital similar to the project site yielded positive results following the implementation of a pediatric DKA order set (Flood et al., 2019). Study results included improvements in DKA management coinciding with practice guidelines such as more appropriate intravenous fluid replacement rates, earlier potassium administration in intravenous fluids, and earlier initiation of dextrose-containing fluids (Flood et al., 2019). Another study evaluating quality outcomes following order set implementation for pediatric DKA validated that evidenced-based protocols and order sets generate positive clinical outcomes (Joyner Blaire et al., 2018).

Streamlining processes leads to improved standard work compliance and utilization of resources, which benefits healthcare organizations and patients by decreasing LOS (Al Nemri et al., 2016; Askari et al., 2021; Baumer-Mouradian et al., 2019, Ilkowitz et al., 2016, Rotter et al., 2010; Yang et al., 2016). CPWs designed and implemented specifically for pediatric patients in DKA lead to reductions in LOS (Al Nemri et al., 2016; Baumer-Mouradian et al., 2019; Ilkowitz et al., 2016). The benefits of the CPW application showed reductions in emergency department LOS for pediatric patients in DKA (Baumer-Mouradian et al., 2019). Specific benefits resulting

from pediatric DKA CPW application in practice include correction of dehydration within 48 hours; insulin drip initiation one hour after starting normal saline, which is compliant with treatment guidelines; appropriate fluid rates based on age and weight; standardized diabetes education; and provider adherence to guidelines (Al Nemri et al., 2016; Baumer-Mouradian et al., Flood et al., 2019, Ilkowitz et al., 2016, Rooholamini et al., 2017, Zee-Cheng et al., 2017).

Evidenced-based clinical pathways addressing fluid administration, electrolyte imbalance, and insulin administration increase provider adherence to recommended practice guidelines (Joyner Blaire et al., 2018). In a joint consensus statement, The American College of Endocrinology and American Diabetes Association supported intervention studies that resulted in evidenced-based CPWs, which yielded time-efficient improvements in physiologic improvements and cost markers (Joyner Blaire et al., 2018).

Theoretical Framework

The Modeling and Role Modeling Theory focuses on applying clinical practice based on awareness and knowledge of patient distinctiveness and uniqueness as guiding principles to care (Petiprin, 2020). This theory incorporates principles from Maslow's Theory of Hierarchy of Needs, Erikson's Theory of Psychological Stages, Piaget's Theory of Cognitive Development, and Seyle and Lazarus's General Adaptation Syndrome (Petiprin, 2020). The foundational concepts for nursing practice based on this theory include associations among basic need status, growth and development, and adaptive potential (Sappington & Kelley, 1996). An example of theory application is individualized care based on patient-specific developmental considerations such as anatomical, metabolic, and cognitive specificities of pediatric patients in diabetic ketoacidosis.

The Model and Role Modeling Theory proves applicable since it incorporates psychological stages and cognitive developmental principles. The Modeling and Role Modeling Theory is a suitable theoretical conceptual basis for implementing standard work to treat pediatric patients in DKA presenting to a healthcare system with a common diagnosis and predictable course of care.

Project Purpose, Objectives, Expected Outcomes

The purpose is a quality improvement project to determine if the implementation of a CPW for the treatment of pediatric patients in DKA would cause a reduction in emergency department LOS. The objective is to use a pediatric CPW on all qualifying patients presenting to a regional ED for treatment of DKA. Qualifying criteria for patients include those under 19 years of age with an admitting hospital diagnosis of DKA. Expected outcomes include a reduction in the time pediatric patients spend in a non-pediatric specific ED with facilitated transfer to the pediatric intensive care unit and decreased ED LOS.

Project Design

This project was implemented at a health system in the southeastern United States, which is a regional hub of a larger healthcare system serving the South Carolina Midlands spanning to the coastal borders of North and South Carolina (McLeod Health, 2021). As of 2018, 13.5% of Florence County is diagnosed with diabetes according to the United States Diabetes Surveillance System (Centers for Disease Control and Prevention, 2021). In a calendar year, the project site serves approximately 77,000 emergency department patient encounters, 1,800-1,850 pediatric admissions, and 150-175 pediatric DKA admissions (McLeod Health, 2018; S. Roland, personal communication, May 24, 2021).

At a macro-level, the project site is a healthcare organization comprised of seven hospital facilities. It is the centralized hub of the healthcare organization. At the micro-level is the ED, which is a level two trauma center, serving and receiving patients from all aspects of the healthcare system. This department serves all ages and disseminates care to neonatal, pediatric, adult, and geriatric specialty areas. The project site contains a children's hospital consisting of a pediatric intensive care unit (PICU), pediatric medical/surgical floor, neonatal intensive care unit (NICU), and newborn nursery.

The facility recently expanded its ED from 40 to 77 acute care treatment rooms. The expanded department is designed to serve 109,500 patients per year compared to the 77,000 patients per year served prior to 2021. Annually, 30.2 per 1,000 hospitalizations are related to DKA (Centers for Disease Control and Prevention, 2020). Approximately 4-8 per 1,000 hospitalizations are pediatric patients in DKA (Young, 2018). Approximately 1-10% of established pediatric diabetics and 15-67% of new-onset pediatric diabetics will present to an ED setting in DKA within a calendar year (Young, 2018).

The implementation of a CPW was feasible given the already established protocols dedicated to treating pediatric patients in DKA at the project site. A CPW incorporated all resources dedicated at the project site already in existence and utilized for patient care into a visual clinical algorithm. Clinicians can visualize the overall clinical course. The population included all patients less than nineteen years of age with ICD-10 codes E10.1 (Type 1 diabetes mellitus with ketoacidosis) and E11.1 (Type 2 diabetes mellitus with ketoacidosis). This is a quality improvement project designed to increase the utilization of existing protocols for the treatment and care of pediatric patients in DKA.

Implementation Plan

CPW design and implementation are based on the Model for Improvement (MFI) which is a quality improvement approach (Agency for Healthcare Research Quality, 2013). The MFI was developed by the Institute for Healthcare Improvement in 1996 and uses a rapid cycle process called Plan Do Study Act (PDSA). Through this process, small aspects are impacted, which ultimately culminates in effective change throughout an organization (Agency for Healthcare Research Quality, 2013).

Specifically, initial steps were made through educational sessions with clinical staff in the ED. The clinical pathway for the treatment of pediatric patients in DKA was presented in an algorithm format. The goal was to increase the utilization of the pediatric protocol for initial management in the ED. Staff were educated on what next steps in the clinical course look like should the patient progress beyond initial management while still housed in the ED.

Clinicians in the PICU were presented and educated on the CPW. PICU education focused specifically on the PICU protocol portion of pediatric DKA treatment, but also include an overview of the CPW as a whole. Educational sessions progressed through all points of care for pediatric patients in DKA. Once staff members were educated, the project progressed to the Do stage of the PDSA process. The Study process occurred concurrently with this step as data is collected on qualifying patients. Re-education sessions occurred during these steps, which is the Act portion of the PDSA cycle. The rapid and repetitive process of PDSA provided the basis for the MFI implementation-based plan.

Measures, Tools, and Data Plan

The project measure for determining CPW effectiveness was ED LOS, overall total hospital LOS, and provider adherence to CPW guidelines measured using order set utilization. ED LOS is defined as the time a patient spends in the ED from admission to transfer. It is

essential pediatric patients be managed with consideration to age and weight (Wolfsdorf et al., 2006). At the project site, ED encounters are in a non-pediatric specialized ED, which encounters approximately 150-175 pediatric patients in DKA per year (McLeod Health, 2018; S. Roland, personal communication, May 24, 2021). By decreasing ED LOS, patients are moved to the PICU sooner, which is a specialized area designed to care for this population.

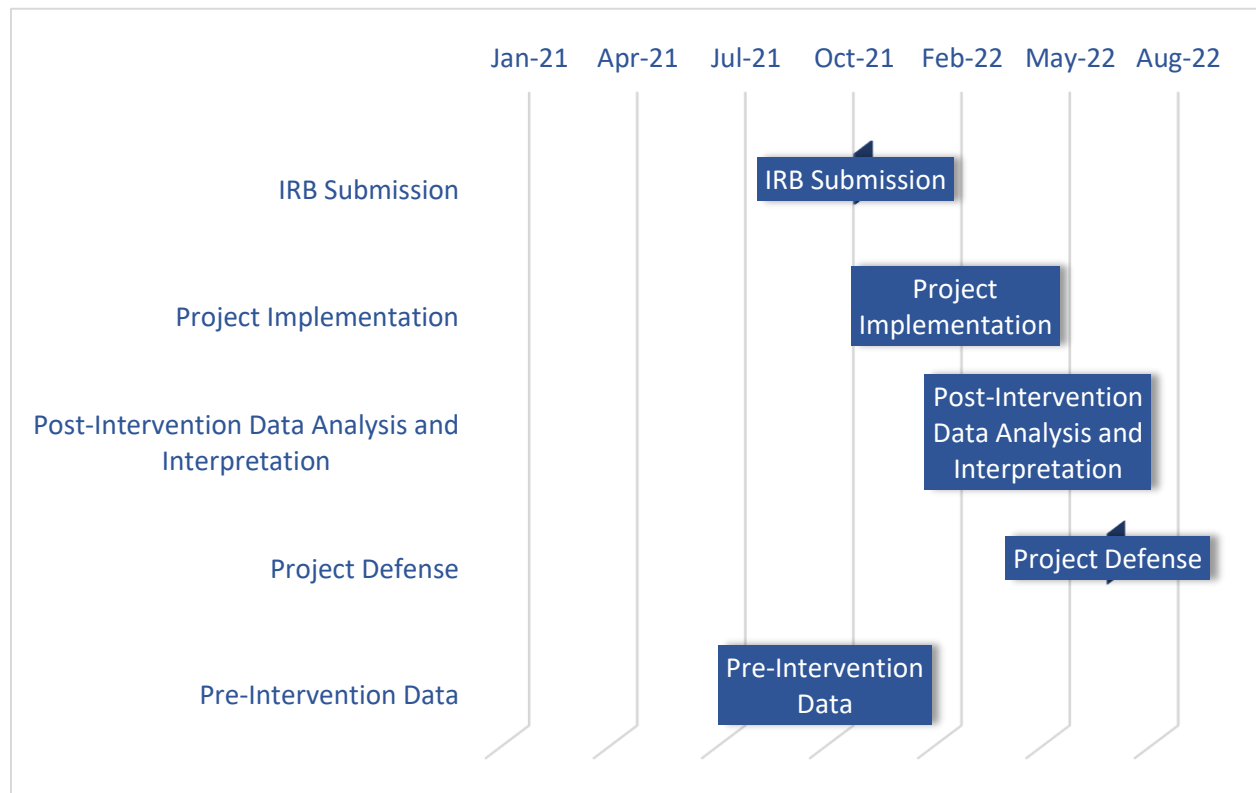
Project costs were minimal since systems and processes already established were utilized for CPW implementation. The systems and processes include documentation using an electronic medical record, utilization of order sets, and patient transition processes. Contributions to the project's success included staff buy-in and physician acceptance of a CPW.

Parametric independent t-test and non-parametric Wilcoxon test were used to compare sample means pre- and post-intervention. Fisher Exact test analysis was used to compare provider order set utilization pre- and post-intervention group. These statistical tests were selected because they allowed a comparison of the difference between two variables for the same subject. A p-value > 0.05 was considered statistically significant. Monthly updates and progress were presented to the project committee.

Timeline / Gantt Chart

As part of CPW implementation, educational sessions were held to instruct medical staff on the importance of CPW understanding and adherence. Educational sessions were provided to clinical staff including nurses and physicians in the ED, PICU, and general pediatric floor. Sessions included CPW presentation, explanation, and reference to existing corresponding order sets. Attendance was optional, but encouraged and available to all shifts over a four-week timeframe. Decreased hospitalized LOS and ED LOS were presented as a goal of CPW implementation.

Data was monitored through chart audits by the project chair. Data was collected four-months prior to CPW implementation; September-December and four-months post intervention; January-April. Based on the average number of pediatric DKA cases seen yearly at the project site, approximately 39 patient charts were expected to be available in the four-month time frame before CPW implementation and 39 patient charts in the four-month time frame post CPW implementation. The electronic medical record utilized tracks bed movement and allowed audits of unit-specific LOS based on patient bed movement. LOS times were collected and logged for statistical analysis.



Budget

Project costs were minimal since systems and processes already established were utilized for CPW implementation. The electronic medical record (EMR) Cerner Millennium is in practice at the project site and utilized at no additional cost to extract patient data. Microsoft Excel,

Intellectus Statistics, and SAS Statistical programming were used to perform statistical analysis of data at no additional cost.

Protection of Human Subjects

Ethical aspects of implementing a CPW included using evidence-based practice and research to provide up-to-date care at the highest level of quality possible. To study the implementation of a CPW for pediatric DKA relevant, modern research was presented proving CPWs as the best option to decrease ED LOS. Potential conflicts of interest included research bias to drive success and the possibility of the Hawthorne effect. Patient data privacy and confidentiality was maintained through password-protected databases and devices which stored identifiable information. Institutional Review Board (IRB) approval was not required and IRB exemption was granted by the project site deeming the intervention a quality improvement effort.

Results

Table 1: Frequency distribution of utilization by pre and post intervention

Order Set Utilization	Pre		Post		P value Fisher Exact
	N	%	N	%	
ED Peds DKA Age					
No	27	90.0	22	75.9	0.1806
Yes	3	10.0	7	24.1	
Peds PICU DKA					
No	11	36.7	12	41.4	0.7925
Yes	19	63.3	17	58.6	
PEDS Pediatric Diabetes Floor					
No	29	96.7	29	100	1.0
Yes	1	3.3	0	0	

PEDS PICU Pediatric Diabetes Transition Orders					
No	30	100	28	96.6	0.4915
Yes	0	0	1	3.4	
ED DKA Treatment					
No	20	66.7	18	62.1	0.7892
Yes	10	33.3	11	37.9	

Table 1 showed frequency distribution of utilization by pre and post intervention. The result revealed pre- and post-intervention group analysis of order set usage using a Fisher Exact test did not yield statistical significance; however clinical significance is noted. 24.1% of pediatric patients received initial ED medical management using the appropriate ED Peds DKA order set post intervention compared to 10% of patients’ pre-intervention.

Table 2: N, Mean, SD for LOS and Total LOS by pre and post intervention

Variables	Pre-Intervention		Post-Intervention		P value T-Test/Wilcoxon
	N	Mean	N	Mean	
Emergency Department LOS	26	3.88	24	4.31	0.4483/0.2128 0.2655/0.3033
	2.19		1.67		
Total Hospital LOS	30	50.81	29	59.18	
	23.26		33.22		

Table 2 showed n, mean, and SD of ED LOS and total hospital LOS by pre and post intervention. The result indicated the mean LOS was 3.88 hours pre-intervention and 4.31 hours for post-intervention. In addition, the mean total hospital LOS for pre was 50.82 hours compared to 59.18 hours post. Parametric independent T-test and non-parametric Wilcoxon test did not yield statistical significance of P-value<0.05 in ED LOS or total hospital LOS. Data limitations include a small sample size and a difference in seasonal presentation of the disease. The pre-

intervention group was measured September-December and the post-intervention group was measured January-April.

Discussion

Overall, though the pediatric DKA CPW did not yield statistical significance in terms of measurable outcomes, clinical significance was demonstrated through improved provider compliance to evidenced-based age-specific order sets. The pediatric DKA CPW implemented included five order-sets specific to the project site. Initial medical management in the ED by a designated order-set for pediatric patients in DKA served as the newest established portion of the overall CPW. When initially designed order set ED Peds DKA Age ≤ 14 years old and ≤ 40 kgs, was created for patients age 14 and under. Prior to CPW implementation, the order set was modified to include patients >30 days to 18 years old. Educational sessions included updates; however, during statistical analysis it was noted that order-set titles were not updated in the EMR. An order-set updated and intended to include ages >30 days to 18 years old was titled for ≤ 14 years old and ≤ 40 kgs. This could contribute to provider confusion and decreased utilization.

ED LOS and total hospital LOS were increased post-intervention which was not an expected outcome. Influential variables on project statistical significance could include seasonal disease presentation, staff CPW knowledge specifically related to an increased volume of transient agency staff, and overall hospital bed flow.

The future direction of the project is based in quality improvement. Through standardization of evidenced-based practices, provider compliance, and staff knowledge pediatric patients suffering DKA will continue to receive excellent care.

Conclusion

In conclusion, CPWs do not always yield statistical significance. However, their usage can attribute to clinical significance which benefits the healthcare organization, providers, and ultimately patient care. Standardization of healthcare practices provides a roadmap for guidance to providers regardless of disease complexity. LOS fluctuates and is impacted by a variety of attributes. Pediatric DKA is a complex and life-threatening disease process that impacts many. Endeavors to continue quality improvement will benefit those impacted by the dreadful disease.

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Appendix

Evidence Table

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 1: Du Z, Sun X. (2019). Clinical pathway for the community-level management of patients with type 2 diabetes</p> <p>Evidence Level I - Randomized Controlled Trial</p> <p>Quality A High - Sufficient sample size for the study design. The purpose is clearly stated. Findings are relevant to the topic.</p>	<p>Design: Randomized Controlled Trial</p> <p>Sample: 264 patients with type 2 diabetes mellitus (T2DM) at Weifang Community Health Service Center. 132 patients were randomized into the clinical pathway (CPW) intervention group. The remaining 132 patients were randomized into the control group.</p> <p>Setting: Weifang Community Health Service Center in Shanghai, China</p> <p>Framework: Not discussed</p> <p>Measures: (1) Biometrics including BMI, waist circumference, and hip circumference (2) Blood glucose (3) Hemoglobin A1C (4) Triglyceride levels (5) Blood pressure</p> <p>Analysis Plan: Excel 2013 was used to perform statistical analysis. Quantitative and qualitative data were expressed as mean +/- standard deviations. Independent sample t-tests compared intervention and control groups.</p> <p>Procedure: Implementation of an electronic clinical pathway as a management intervention for patients</p>	<p>Conclusion Validity: Good. Limitations listed. Results are statistically meaningful.</p> <p>Internal Validity: Provider training not addressed</p> <p>External Validity: China has standardized health care, which expands to public hospitals and community primary medical institutions. Given this healthcare structure, results may not be generalizable to other countries with different health systems.</p> <p>Construct Validity: Fair. Generalizability may be limited due to regional differences.</p> <p>Reliability: The process for randomization was not discussed.</p> <p>Precision: P<0.5 was considered statistically significant.</p>	<p>BMI, waist circumference, hip circumference, blood glucose, hemoglobin A1C, and triglyceride levels were significantly lower in the intervention group (p<0.5). No significant differences were noted in blood pressure between groups.</p>	<p>A comparison of relevant markers within the patients with T2DM showed significant changes after the implementation of a CPW for medical management of T2DM at a community health service center in Shanghai, China.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
	<p>with T2DM at Weifang Community Health Service Center. Chinese Type 2 Diabetes Prevention and Treatment Guidelines guided the electronic CPW design. Over 1 year, patients with T2DM were randomized into control and intervention groups for evaluation of a CPW for T2DM medical management.</p>			

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 2: Rotter, T., Kinsman, L., Jamesm, E., Machotta, A., Willis, J., Snow, P., & Kugler, J. (2010). Clinical pathways: effects on professional practice, patient outcomes, length of stay, and hospital costs</p> <p>Evidence Level I - Systematic Review and Meta-Analysis</p> <p>Quality C Low quality - Little evidence with inconsistent results. Vague conclusions</p>	<p>Design: Systematic Review and Meta-Analysis</p> <p>Sample: 3,000 published studies were screened. After applying inclusion criteria, 27 studies were included with a total of 11,398 participants.</p> <p>Setting: General acute care, Intensive care unit (ICU), Emergency Department (ED), Extended Care</p> <p>Framework: Not discussed</p> <p>Measures: (1) Patient outcomes (2) Professional practice (3) Length of stay (LOS) (4) Hospital costs</p> <p>Analysis Plan: Assess the methodological quality of all included studies using the Effective Practice and Organization of Care (EPOC) risk of bias tool.</p> <p>Procedure: Categorize studies comparing CPW's with usual care and those comparing CPW's as part of a multifaceted intervention with usual care.</p>	<p>Conclusion Validity: No limitations discussed.</p> <p>Internal Validity: Variation in study design and settings prevented statistical pooling of results for LOS and hospital costs. Poor reporting prevented the identification of characteristics common to successful CPW's.</p> <p>External Validity: Results cannot be generalized due to the specificity of CPW and where it was implemented.</p> <p>Construct Validity: Results may be interpreted differently.</p> <p>Reliability: Low. CPW variability limits generalizability within this study.</p> <p>Precision: Statistically significant results with 95% confidence interval (CI)</p>	<p>27 studies met inclusion criteria for the definition of CPW and methodological quality.</p> <p>20 studies compared stand-alone CPW's with usual care.</p> <p>These studies indicated reduction in in-hospital complications (odds ratio (OR) 0.58; 95% CI, 0.36-0.94) and improved documentation (OR 11.95; 95% CI 4.72-30.30). No evidence of differences in readmission to hospital or in-hospital mortality. LOS reported significant reductions. A decrease in hospital costs and charges was observed.</p>	<p>CPW's are associated with reduced in-hospital complications.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
			<p>Seven studies compared CPW's as part of multifaceted intervention with usual care. No evidence of differences was found between intervention and control groups. Objectively measured patient outcomes included mortality, hospital readmissions, complications, and adverse events. Professional practice outcomes measured were documentation in medical records, patient satisfaction, and quality measures as appropriate to the specific aim of the CPW.</p> <p>A major finding was the significant reduction in in-hospital complications</p>	

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
			associated with the introduction of CPWs.	

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 3: Yang, Y., Hu, X., Zhang, Q., Cao, H., Li, J., Wang, J., Shao, Y., & Xin, S. (2016). Effect of clinical nursing pathway for endoscopic thyroidectomy in Chinese patients: a meta-analysis</p> <p>Evidence Level I – Meta-analysis</p> <p>Quality A High – Sufficient sample size for the study design. Adequate control with definitive conclusions</p>	<p>Design: Meta-analysis</p> <p>Sample: Research trials, particularly randomized controlled trials (RCT’s) comparing the use of a clinical nursing pathway to usual care for patients undergoing endoscopic thyroidectomy. Six controlled trials were identified including 550 thyroidectomy patients. 282 received care guided by CPW, and 268 received usual care.</p> <p>Setting: Inpatient treatment during endoscopy</p> <p>Framework: Not discussed</p> <p>Measures: (1) Hospital LOS (2) Patient satisfaction (3) Hospital charges</p> <p>Analysis Plan: Mean difference and 95% CI for LOS, hospital charges, and risk ratio for patient satisfaction. Heterogeneity of effect size was assessed using Cochrane Q-statistic and R-statistic. If $P > 0.10$ a fixed-effect model was used. If $P \leq 0.10$ a random-effect model was used. Publication bias was assessed by Begg’s rank correlation test and Egger’s linear regression test with $p < 0.10$ indicating statistical significance.</p> <p>Procedure: LOS was obtained by review of medical records. Hospital charges were obtained from medical records.</p>	<p>Conclusion Validity: Limitations listed. Reasonable sample size.</p> <p>Internal Validity: All trials described as RCTs did not meet RCT standards.</p> <p>External Validity: Studies were written in Chinese, which could indicate publication bias.</p> <p>Construct Validity: Most of the included trials did not use validated treatment satisfaction questionnaires for patient satisfaction.</p> <p>Reliability: All included trials were classified as having a moderate or high risk of bias by methodological quality assessment.</p> <p>Precision: $P < 0.10$ indicates statistical significance.</p>	<p>CPW’s reduced hospital stays by 1.56 days (95% CI - 2.08 to -1.04 days) compared with usual care. Neither Begg’s rank correlation test ($P=0.260$) and Egger’s linear regression test ($P=0.304$) showed evidence of publication bias.</p> <p>Use of CPW’s reduced hospital charges by 1200 yuan (95% CI - 2000 to -500 yuan) compared with usual care in a random-effect model.</p> <p>CPW’s increased patient satisfaction compared with usual care in a random-effect model (RR 1.29; 95% CI 1.04-1.60).</p>	<p>The use of a clinical nursing pathway reduced hospital LOS and hospital charges while improving patient satisfaction for patients undergoing endoscopic thyroidectomy. Evidence for use of CPW’s for patients undergoing endoscopic thyroidectomy is encouraging; however, methodological flaws of included trials preclude recommendations.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
	Total patient satisfaction was defined as the proportion of patients who responded “very satisfied” or “satisfied” when surveyed.			

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 4: Al Nemri, A., Amer, Y.S., Gasim, H., Osman, M.E., Aleyadhy, A., Al Otaibi, H., Iqbal, S.M., Aljurayyan, N.A., Assiri, A.M., Babiker, A., & Mohamed, S. (2016). Substantial reduction in hospital LOS of children and adolescents with diabetic ketoacidosis after implementation of clinical practice guidelines in a university hospital in Saudi Arabia</p> <p>Evidence Level III - Case-control retrospective study/ Organization Experience/ Quality Improvement</p> <p>Quality A High - Sufficient sample size for the study design. Adequate control with definitive conclusions</p>	<p>Design: Organization Experience/Quality Improvement</p> <p>Sample: Pediatric patients (<16 years old) presenting to King Khalid University Hospital in DKA. The pre-implementation group included patients who fulfilled DKA inclusion criteria and were admitted between January 2008 and December 2010. The post-implementation group consisted of patients meeting the same criteria admitted from January 2011 to 2014.</p> <p>Setting: King Khalid University Hospital in Riyadh, Saudi Arabia</p> <p>Framework: Not discussed</p> <p>Measures: (1) Patient demographics including age and sex (2) Number of DKA episodes (3) Laboratory measures including hemoglobin A1C and blood gas results (4) LOS in ED and hospital</p> <p>Analysis Plan: Statistical analysis was performed using SPSS. Measurable variable data were expressed as mean and standard deviations. Dichotomous and nominal variables were expressed as percentages and compared using the X test. T-tests for independent groups were used to compare pre and post-intervention groups in respect to</p>	<p>Conclusion Validity: Good. Limitations listed. Results are statistically meaningful.</p> <p>Internal Validity: King Khalid University Hospital has limited resources and bed availability. PICU bed availability was not accounted for as a possible influential variable on ED LOS.</p> <p>External Validity: This was a non-randomized historical control study, which could limit generalizability.</p> <p>Construct Validity: Fair. assumptions cannot be made that resources allocated at this tertiary care center are available elsewhere.</p> <p>Reliability: Good. Limitations listed.</p> <p>Precision: Statistical significance was set at $p<.05$</p>	<p>63 episodes of DKA in 41 different patients were treated using CPG compared with 40 episodes in 33 patients with DKA treated before CPG implementation. Patient demographics between the two groups were similar. The mean hospital LOS was 68.6 hours (+/- 53.1) in the post-CPG implementation group compared to 107.4 hours (+/- 65.6) in the pre-CPG implementation group ($p<.001$). The reduction in hospital LOS equates to 1700 bed days saved per year per 1000 patients. ED LOS increased.</p>	<p>Implementation of CPG for DKA decreased hospital LOS at King Khalid University Hospital. Positive outcomes were noted for patients including a decreased LOS, particularly in the PICU.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
	measurable variables including age and LOS. Procedure: Sample participants managed for DKA using clinical practice guidelines (CPG) were compared with those treated before CPG implementation.			

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 5: Askari, M., Tam, J.L.Y.Y., & Klundert, J. (2021). The effectiveness of clinical pathway software in inpatient settings: a systematic review</p> <p>Evidence Level III – Systematic Review</p> <p>Quality C Lower A clear plan for data analysis was not discussed. Results are not backed by statistically significant data.</p>	<p>Design: Systematic Review</p> <p>Sample: 12 articles were included after study criteria were applied out of 2904 article results. Criteria included peer-reviewed international journal articles identified by the data source MEDLINE published between January 2000-January 2018.</p> <p>Setting: Not specified</p> <p>Framework: Structure-Process-Outcome (SPO) model of Donabedian</p> <p>Measures: (1) Process of care in terms of adherence to guidelines (2) Costs (3) Patient outcomes (mortality) (3) Staff outcomes (satisfaction)</p> <p>Analysis Plan: Not discussed</p> <p>Procedure: Systematically synthesize the perceived effectiveness of CPW software in inpatient settings. Articles were identified through a systematic search of MEDLINE including Scopus and Pubmed.</p>	<p>Conclusion Validity: The study does not produce generalizable results based on the data provided.</p> <p>Internal Validity: The research studies evaluated lacked common themes, which may have led to issues quantifying data.</p> <p>External Validity: Results are not generalizable</p> <p>Construct Validity: The study was poorly constructed in terms of measurable outcomes.</p> <p>Reliability: Poor. Study findings are not backed by sufficient evidence.</p> <p>Precision: Not discussed</p>	<p>50% of studies were conducted in the United States, 25% in Europe, 17% in Asia, and 8% in Canada. CPW design concentrated on the following medical conditions: stroke, pneumonia, heart failure, and oncological conditions. Ten studies present quantitative results on process indicators including LOS. Five studies reported patient outcomes including mortality. One study presented quantitative results on patient satisfaction. Three studies presented quantitative results on user satisfaction. None of the 12 studies present direct evidence on mechanisms explaining how CPW software</p>	<p>CPWs may lead to improvements in LOS, timeliness of care, and diagnostic effectiveness. Effects on costs call for further research.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
			implementations produce contextual results.	

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 6: Baumer-Mouradian, S.H., Gray, M.P., Wolfgram, P.M., Kopetsky, M., Chang, F., Brousseau, D.C., Frenkel, M.M., & Ferguson, C.C. (2019) Improving emergency department management of diabetic ketoacidosis in children</p> <p>Evidence Level III - Organization Experience/ Quality Improvement</p> <p>Quality A High – Participant-driven inquiry. Insightful interpretation and inquiry</p>	<p>Design: Quality Improvement (QI)</p> <p>Sample: ED patients aged 1-20 years old with a chief complaint of DM, DKA, hyperglycemia, or blood sugar problems. 783 patients with diabetes mellitus evaluated for DKA in a pediatric ED between January 2015 and July 2018 were included in the study sample.</p> <p>Setting: Tertiary-care, pediatric academic medical center located in Milwaukee, Wisconsin.</p> <p>Framework: Not discussed</p> <p>Measures: (1) Time to determine DKA (2) Percentage of patients receiving IV placement (3) ED LOS</p> <p>Analysis Plan: Descriptive statistics and statistical process control charts were used to measure the intervention impact. Mann-Whitney U and unpaired t-tests were conducted to measure differences in percentage, time, and average values pre and post-intervention.</p> <p>Procedure: Four key interventions including (1) point of care (POC) tests, (2) order panels, (3) provider guidelines, and (4) nursing guidelines</p>	<p>Conclusion Validity: Good. Limitations listed. Adequate sample size. Generalizable results.</p> <p>Internal Validity: A multidisciplinary team tasked with standardizing DKA management was implemented at the study setting in the summer of 2017.</p> <p>External Validity: Results are based on assumptions about the availability of POC testing capabilities.</p> <p>Construct Validity: Institutional classification of DKA may vary, which could alter the generalizability of results.</p> <p>Reliability: Fair. Situational awareness may factor into results with QI initiatives.</p> <p>Precision: Control limits were set at +/- 3 standard deviations.</p>	<p>In non-DKA patients, IV placement decreased from 85% to 36% ($p<.001$). ED LOS decreased from 206 minutes to 186 minutes ($p=.009$). POC testing and order panel use increased from 0% to 98% and 90%. DKA determination time improved mean values of 86 minutes to 26 minutes. 72-hour ED return rates decreased from 13% to 7% in any patient presenting with concern for DKA.</p>	<p>Quality improvement methodology can achieve a meaningful reduction in DKA determination time, percentage of IV placement, and ED LOS.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 7: Broberg, M.C.G., Rose, J.A. & Slain, K.N. (2020). The relationship between estimated median household income and critical care length of stay in children with diabetic ketoacidosis</p> <p>Evidence Level III - Retrospective study</p> <p>Quality C Lower - Lack of statistically significant results</p>	<p>Design: Retrospective study</p> <p>Sample: Children (<19 years old) admitted with DKA to a PICU over 27 months (October 1, 2013-December 31, 2015). 171 patients met sample criteria. 46.8% (n=80) were classified as living in a low-income neighborhood.</p> <p>Setting: Medical/Surgical PICU in a tertiary academic medical center</p> <p>Framework: Not discussed</p> <p>Measures: (1) Demographics including age, race, and gender (2) PICU LOS (3) DKA severity at admission (4) PICU readmission for DKA within the study period</p> <p>Analysis Plan: SigmaPlot 12.5 was used to conduct statistical analysis. Descriptive statistics were used to interpret demographic data. Categorical data were expressed as percentages. A Chi-square test was used to compare DKA severity and readmission risk between children classified as low-income versus those who were not. Mann-Whitney U test was used to compare LOS.</p> <p>Procedure: Patients were identified using Virtual PICU Systems. Patients were classified as low-income based on</p>	<p>Conclusion Validity: Good. The study is retrospective in nature.</p> <p>Internal Validity: The location of the study could influence results.</p> <p>External Validity: Geographical factors may influence results in other locations</p> <p>Construct Validity: The study was conducted at a single site.</p> <p>Reliability: Good. Limitations listed</p> <p>Precision: Two-sided p-value of <0.5 was considered statistically significant.</p>	<p>Median PICU LOS was 0.9 days (0.7-1.1). Median hospital LOS was 2.6 days (1.8-3.17). DKA resolution was similar between control and intervention groups. Insulin infusion duration and PICU LOS were similar between groups. Readmission rates, glycemic control, and hemoglobin A1C did not statistically differ between groups. Median hemoglobin A1C of 11.7% indicates poor glycemic control among both groups.</p>	<p>Living in a low-income zip code was not associated with increased DKA severity, PICU LOS, or hospital readmission for DKA. Identification of social determinants of health is not a statistically or clinically significant intervention to decrease LOS in pediatric patients admitted for DKA.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
	zip code where median household income is estimated less than 200% of the federal poverty threshold or \$48,016 per family of 4.			

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 8: Edholm, K., Lappé, K., Kukhareva, P., Hopkins, C., Hatton, N.D., Gebhart, B., Nyman, H., Signor, E., Davis, M., Kawamoto, K., & Johnson, S.A. (2020). Reducing diabetic ketoacidosis intensive care unit admissions through an electronic health record-driven, standardized care pathway</p> <p>Evidence Level III - Retrospective, observational preintervention to postintervention study</p> <p>Quality A High - Data and literature are linked to relevant literature. The report evaluates efforts to evaluate and enhance data quality.</p>	<p>Design: Retrospective, observational preintervention to postintervention study; Quality Improvement</p> <p>Sample: Patients 18 years and older presenting to Emergency Department (ED), qualifying for hospital admission based on laboratory criteria or ICD-10-CM diagnosis code for DKA between January 1, 2016, to January 31, 2018. Patients presenting between January 1, 2016, and February 28, 2018, were classified as preintervention. Patients presenting February 1, 2017, to January 31, 2018, were classified as postintervention. A gap in time was used for intervention education and training. 106 admissions included in the pre-implementation group. 108 admissions included in the post-implementation group.</p> <p>Setting: Large academic medical center.</p> <p>Framework: Not discussed.</p> <p>Measures: Primary outcomes: (1) ICU admission. Secondary outcomes: (2) Treatment with insulin drip (3) ED and hospital LOS (4) Time to first insulin dose (5) Time to the resolution of hyperglycemia (6) Time to anion gap closure (7) Time to initiation of basal insulin (8) Hemoglobin A1C ordered (9) Treatment-induced hypokalemia (10)</p>	<p>Conclusion Validity: Good. Limitations identified. Adequate sample size.</p> <p>Internal Validity: Laboratory criteria is non-specific for DKA. ICD-10 codes may be incorrect. Serum ketones are a part of ADA diagnostic criteria for DKA; however, the lab takes 1-3 days to result at this institution. Ketones were unable to be incorporated into the CPW.</p> <p>External Validity: Hospital costs did not account for inflation because Consumer Price Index was 0% between 2016-2018. Results could be due to secular trends.</p> <p>Construct Validity: Study conducted at a single site, which could limit generalizability.</p> <p>Reliability: Good. It was admitted intervention was multifaceted, so aspects most responsible for observed effects cannot be discerned.</p>	<p>ICU admissions decreased from 67% to 41.7% ($p<.001$). Diabetes nurse educator consults increased from 45.3% to 63.9% ($p=.006$). Time to initiation of basal insulin increased from 18.19+/-1.25 hours to 22.47+/-1.76 hours ($p=.05$). Reopening of the anion gap increased from 4.7% to 13.9% ($p=.02$), but was not associated with hospital LOS ($p=.87$). Thirty-day ED return visit decreased from 12.3% to 2.8% ($p=.008$). No differences were observed in other metrics.</p>	<p>Implementation of a standardized DKA care pathway using subcutaneous insulin as a treatment for mild to moderate DKA significantly decreases ICU admissions for DKA continuous insulin infusions and improved patient education. Significant increases in completion of nurse educator consultations and reduction in return ED visits within 30 days were noted. Potential benefits of CPWs for pediatric DKA management were noted without significant increases in</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
	<p>Hypoglycemia (11) Reopening of anion gap occurring after correction (12) Diabetes nursing educator consultation (13) 30-day hospital readmission (14) Inpatient mortality (15) Total direct hospital cost</p> <p>Analysis Plan: Categorical variables compared using chi-squared tests. Continuous variables were compared using t-tests.</p> <p>Procedure: P-values <0.05 were considered significant.</p>	<p>Precision: Observation of statistically significant results with $p < 0.05$ were considered significant.</p>		<p>clinically meaningful adverse events including hypoglycemia, treatment-induced hypokalemia, hospital readmission, or mortality.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 9: Everett, E.M., Copeland, T.P., Moin, T., & Wisk, L.E. (2021). National trends in pediatric admissions for diabetic ketoacidosis</p> <p>Evidence Level III - Retrospective review</p> <p>Quality A High - Transparency exhibited in data analysis. Insightful interpretation of results</p>	<p>Design: Retrospective review</p> <p>Sample: 149,535 DKA admissions identified using the Healthcare Cost and Utilization Project KID database for 2006, 2009, 2012, and 2016</p> <p>Setting: 42,000 hospitals across 46 states caring for pediatric patients admitted in DKA</p> <p>Framework: Not discussed</p> <p>Measures: (1) Hospital-level variables including region, ownership, and size (2) Patient-level variables including age, sex, race/ethnicity, admission payer, income, and urbanicity (3) LOS; (4) Total charges</p> <p>Analysis Plan: Stata version 15.1 was used to analyze descriptive statistics describing the weighted frequency of DKA admissions including hospital-level variables and patient-level variables. LOS and charges were compared across years. Multivariable logistic regression was used to evaluate adjusted odds of DKA admission by the hospital and patient-level variables.</p> <p>Procedure: Using the Healthcare Cost and Utilization Project KID database, DKA admissions were identified in patients \leq 21 years old from 42,000 hospitals across 46 states.</p>	<p>Conclusion Validity: Limitations listed, large sample size</p> <p>Internal Validity: Miscoding of patients could influence results.</p> <p>External Validity: Good. Generalizable results</p> <p>Construct Validity: Excellent. Very large sample set.</p> <p>Reliability: Good. Generalizable results due to large sample size.</p> <p>Precision: Results were reported with 95% confidence intervals.</p>	<p>149,535 DKA admission were noted between 2006 and 2016. DKA admission rates increased from 120.5 (95% CI) in 2006 to 217.7 (95% CI) in 2016. Mean charges per admission increased from \$14,548 to \$20,997 from 2006 to 2016. Mean LOS decreased from 2.51 days to 2.28 days. Higher DKA rates were noted among 18-20-year-old females, black youths, without private insurance, with lower incomes, and from nonurban areas. The greatest increase in DKA rates was noted among young adult men, without private insurance, and from nonurban areas.</p>	<p>Pediatric DKA admission rates have increased by 40% in the United States between 2006 and 2016. Vulnerable subgroups remain at the highest risk. Pediatric DKA admissions are a costly burden in American healthcare.</p>

Brief Reference, Type of study, Quality rating	Methods	Threats to Validity/ Reliability	Study Findings	Conclusions
<p>Article 10: Flood, K., Nour, M., Holt, T., Cattell, V., Krochak, C., & Inman, M. (2019). Implementation and evaluation of a diabetic ketoacidosis order set in pediatric type 1 diabetes at a tertiary care hospital: a quality-improvement initiative</p> <p>Evidence Level III - Retrospective chart review/ Organization Experience/ Quality Improvement</p> <p>Quality A High - Insightful interpretation of data, transparency to the theme, and category formation</p>	<p>Design: Organization Experience/Quality Improvement</p> <p>Sample: Pediatric patients (ages 0-17 years) presenting to Royal University Hospital diagnosed with DKA between April 2014 and September 2017. 50 cases noted between April 2014 and September 11, 2016, were classified as the pre-intervention group. 30 cases noted between September 12, 2017, and September 2018 were classified as the post-intervention group.</p> <p>Setting: Royal University Hospital in Saskatoon, Saskatchewan (A pediatric tertiary care center)</p> <p>Framework: Not discussed</p> <p>Measures: (1) Patient demographics (2) Location and acuity details or presentation (3) Presence of a PICU consult (4) Biochemistries (5) Initial and replacement fluid management (6) Insulin management (7) Electrolyte management; Complications of management including (8) Hypoglycemia (classified as blood glucose <4mmol/L) (9) Hypokalemia (potassium < 3.5 mmol/L) (10) Management strategies for suspected cerebral edema Post-implementation variables collected also included (11) order set use before or</p>	<p>Conclusion Validity: Good. Limits identified. Results generalizable.</p> <p>Internal Validity: In the first year of order set implementation, 73% of all qualifying patients were treated using the DKA order set.</p> <p>However, only 30% had order-set activation immediately. IVF administration may have occurred before DKA diagnosis.</p> <p>External Validity: Debate exists on protocol specifics.</p> <p>Construct Validity: Successful DKA order-set implementation may be influenced by confounding factors including (1) physician buy-in, (2) access to POC testing, and (3) general knowledge of order set awareness.</p> <p>Reliability: Good. Study limitations were acknowledged.</p>	<p>Following order set rollout, 73% clinical uptake of the order set was achieved for the first year. 30% of order set activation occurred before any DKA-related treatments. Initial IV bolus administration before insulin treatment occurred 92% of the time in the control group and 96.7% of the time in the treatment group (p=0.78). Fluid bolus volumes \leq 20mls/hr were comparable in both groups (83% in control group and 76% in treatment group, p=0.51). IV fluid replacement rates achieving the goal of 4-6mls/kg/hour per weight were 30% in the control group and 55.1% in the treatment group</p>	<p>The International Society for Pediatric and Adolescent Diabetes guidelines suggest all medical centers have written guidelines for the management of pediatric DKA. However, the presence of guidelines (order sets/protocols) does not always result in provider uptake. Post DKA order set implementation improvements in DKA management included (1) more appropriate IVF replacement rates (30% to 55.1%, p=0.03), (2) earlier administration of potassium to IV fluids</p>

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	<p>after initial fluid bolus administration and (12) clinical overrides.</p> <p>Analysis Plan: Descriptive statistic means were used to compare baseline characteristics. T-tests were used for continuous variables. Chi-square analysis was used for categorical variables. Fisher exact test was used for cell sizes <5. Analysis was conducted using SAS.</p> <p>Procedure: A DKA order set was implemented on September 12, 2016. Before rollout, provider education was given on order set details.</p>	<p>Precision: Statistically meaningful results</p>	<p>(p=0.03). 72% of the control group patients received less than target fluid replacement volume. Patients receiving the recommended 40mEq/L of potassium chloride to initial IV fluids from 40% to 79.3%, p=0.0007). Dextrose administration prior to serum glucose <17mmol/L increased significantly from 67.4% to 93.1%, p=0.009). No statistically significant differences in hypoglycemia were noted.</p>	<p>(66% to 93.1%, p=0.006), (3) improved potassium chloride dosing to IV fluids (40% to 79.3%, p=0.0007), and (4) earlier addition of IV dextrose (67.4% to 93.1%, p=0.009).</p>

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<p>Article 11: Ilkowitz, J. T., Choi, S., Rinke, M. L., Vandervoot, K., & Heptulla, R. A. (2016). Pediatric type 1 diabetes: reducing admission rates for diabetes ketoacidosis</p> <p>Evidence Level III - Observational preintervention to postintervention study</p> <p>Quality B Good - Transparency provided in data interpretation; Awareness of researcher bias</p>	<p>Design: Observational pre-intervention to post-intervention study</p> <p>Sample: Patients admitted to a hospital setting between 2007 and July 2014. Patients admitted between 2007-2010 were classified as the pre-intervention group. Patients admitted 2012-July 2014 were classified as the post-intervention group.</p> <p>Setting: Urban tertiary care center which is part of a larger health system with approximately 130 diabetes-related admissions per year.</p> <p>Framework: Not discussed</p> <p>Measures: (1) DKA hospital admissions (2) 30-day readmissions (3) LOS for DKA admissions</p> <p>Analysis Plan: Descriptive statistics used to present demographics and outcomes of interest pre-intervention (2007-2010) and post-intervention (2012-July 2014). Non-normal distribution of outcomes of interest (admissions, admissions with DKA, and LOS) compared with Wilcoxon rank-sum test. Fischer exact test was used to examine differences between pre-and post-intervention periods.</p>	<p>Conclusion Validity: Good sample size. Limitations listed.</p> <p>Internal Validity: The hospital experienced an increase in the type 1 diabetes mellitus (T1DM) patient population throughout the study. Faculty and staff turnover within the facility could have impacted results.</p> <p>External Validity: Positive effects might have been a source of association rather than interventional effects.</p> <p>Construct Validity: Study location is limited to a single site belonging to an Accountable Care Organization. The influence and support of a strong culture with an emphasis on quality of care and efforts to reduce cost and waste may influence results elsewhere.</p> <p>Reliability: Unmeasured secular factors may contribute to change in outcomes such as individual variation, family support,</p>	<p>Statistically significant reductions in all three outcomes of interest were noted. Postintervention, DKA admissions decreased by 44% ($p=.006$). Thirty-day readmission rates decreased from 20% to 5% ($p=.001$). Median LOS significantly decreased ($p<.0001$). Median hemoglobin A1C decreased from 10.3% to 8.9% ($p<.02$).</p>	<p>Clinical and multipronged program interventions can lead to significant reductions in DKA hospitalizations, 30-day readmissions, and LOS for pediatric T1DM patients.</p>

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	<p>Procedure: Data analyzed using nonparametric Kruskal-Wallis test.</p>	<p>and socioeconomic factors. Data that may violate the independent assumption of statistical tests could reduce the significance of results.</p> <p>Precision: Fischer exact test used to examine differences pre-and post-intervention.</p>		

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<p>Article 12: Pruitt, L. G., Jones, G., Musso, M., Volz, E., & Zitek, T. (2019). Intravenous fluid bolus rates and pediatric diabetic ketoacidosis resolution</p> <p>Evidence Level III - Retrospective chart review</p> <p>Quality A High - Purpose clearly stated, findings relevant to topic, good literature review</p>	<p>Design: A retrospective chart review</p> <p>Sample: All pediatric patients (<19 years old) admitted from the emergency department of a single regional tertiary medical center with a diagnosis of DKA</p> <p>Setting: Emergency department of a single regional tertiary medical center in Baton Rouge, Louisiana</p> <p>Framework: Not discussed</p> <p>Measures: Patients who received a bolus of 10 cc/kg or less in the ED were compared to patients who received >10 cc/kg of IV fluids. The primary outcome was the difference in hospital LOS between the two groups. Secondly, the two groups were compared with regards to the timeframe of <u>bicarbonate</u> normalization.</p> <p>Analysis Plan: T-tests were used to compare the two treatment groups for continuous variables and <u>chi-square tests</u> for categorical variables. Initially, groups were assessed with univariate analyses. Clinical characteristics with statistically significant differences between groups on <u>univariate analysis</u> as variables in a multivariable <u>regression analysis</u> to adjust for confounders were used.</p>	<p>Conclusion Validity: Reasonable. Limitations provided.</p> <p>Internal Validity: This was not a controlled study; therefore, other variables could have influencing factors.</p> <p>External Validity: The study was conducted at a single facility; therefore, results may not be generalizable to all geographical or regional locations.</p> <p>Construct Validity: The study was performed at a single facility. Local practices (such as the consistent use of 0.9% NaCl rather than lactated ringers) may not be the same at other facilities.</p> <p>Reliability: Fair. The primary aim was to evaluate the association of IV fluid bolus amounts in pediatric DKA patients. Magnesium was ordered in >99% of patient encounters despite</p>	<p>170 pediatric DKA ED visits were analyzed. Patients who received a 10 cc/kg bolus or less of fluids in the ED had a mean hospital LOS > that was 0.38 days longer (95% CI: 0.006 to 0.75 days) than those who received >10 cc/kg. On multivariable regression analysis, the difference between groups was diminished and no longer statistically significant. The time to bicarbonate normalization was 0.12 days longer (95% CI -0.029 to 0.27) in the 10 cc/kg or less group than the >10 cc/kg group.</p>	<p>Pediatric DKA patients who received an initial IV bolus of 10 cc/kg or less had similar hospital lengths of stay and rates of <u>bicarbonate</u> normalization compared to patients who received larger initial IV fluid boluses. There were zero cases of <u>hypomagnesemia</u> in this sample of pediatric DKA patients, and a magnesium level should not be routinely ordered in these patients.</p>

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	<p>Procedure: Patient information was obtained from the <u>electronic medical records</u>. Data was collected from the initial ED presentation until the time of hospital discharge. Analyzed data included basic patient demographics, metabolic panel results, initial pH, disposition location and times, treatments administered, and adverse neurologic outcomes including cerebral edema.</p>	<p>lack of identified hypomagnesemia.</p> <p>Precision: Difference in mean hospital LOS between the group receiving 10ml/kg IV fluid bolus and the group receiving >10ml/kg IV fluid bolus was 0.38 days (95% CI: 0.0006 to 0.75 days) with p=0.043.</p>		

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<p>Article 13: Rooholamini, S.N., Clifton, H., Haaland, W., McGrath, C., Vora, S.B., Crowell, C.S., Romero, H., & Foti, J. (2017). Outcomes of a clinical pathway to standardize use of maintenance intravenous fluids</p> <p>Evidence Level III - Organization Experience/ Quality Improvement</p> <p>Quality B Good - Participation-driven inquiry with insightful interpretation.</p>	<p>Design: Quality Improvement</p> <p>Sample: Pathway eligible patients July 1, 2014-June 30, 2015, and July 1, 2015-June 30, 2016. To be pathway eligible, patients were euvolemic with required IV fluids based on clinical judgment. Patients were excluded from pathway eligibility if they were considered hypovolemia, hypervolemia, critically ill, on parenteral nutrition or a ketogenic diet, severely dysnatremic prior to IVF initiation, <40 weeks postmenstrual age, diabetic, or admitted to critical care.</p> <p>Setting: Tertiary, 370-bed, university-affiliated children’s hospital, and regional referral center</p> <p>Framework: Not discussed.</p> <p>Measures: IV fluid (IVF) use including (1) median duration, (2) proportions of isotonic and hypotonic IV fluid, (3) adherence to monitoring recommendations, (4) incidence of associated severe dysnatremia, (5) potassium-containing IV fluid use in the ED, and (6) costs.</p> <p>Analysis Plan: Population characteristics in both periods were compared using t-tests for mean continuous variables, x*2 tests for categorical variables, and Wilcoxon rank tests for a median of</p>	<p>Conclusion Validity: Good. Limitations listed. Adequate sample size.</p> <p>Internal Validity: Estimated 60% Power Plan usage despite efforts to embed order sets within medical and surgical plans. The study assumes the availability of an EMR.</p> <p>External Validity: Generalizability may be problematic due to study results occurring at a single site.</p> <p>Construct Validity: No national benchmarks served as a basis for the study to provide a comparison point.</p> <p>Reliability: Good. Limitations were clearly outlined and discussed.</p> <p>Precision: Statistical significance was not specified.</p>	<p>Median IVF infusion hours did not change. Isotonic maintenance IVF use increased significantly from 9.3% to 50.6%. Hypotonic fluid use decreased from 94.2% to 56.6%. Significant increases in daily weight measurement and recommended serum sodium testing were noted. Cases of dysnatremia increased from 2 to 4 among pathway-eligible patients. ED patients experienced significant increases in potassium-containing IVF use (52.9% to 75.3%). No significant changes were noted in total hospitalizations or lab test costs.</p>	<p>Design and implementation of a clinical standard work pathway to guide maintenance IVF use at a children’s hospital succeeded in changing and sustaining prescribing practices away from hypotonic IVF and toward monitored use of isotonic IVF when concerns for increased AHD secretion.</p>

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	<p>continuous variables. Linear regression was estimated for each time period. Wald tests were used to compare slope parameters across periods.</p> <p>Procedure: Use of an evidence-based CPW to guide providers on the indications for IV fluids, preferred composition, and appropriate clinical monitoring.</p>			

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<p>Article 14: Shaffer, A.D., & Dohar, J.E. (2020). Evidence-based telehealth clinical pathway for pediatric tympanostomy tube otorrhea</p> <p>Evidence Level III - Retrospective case series</p> <p>Quality B Good - The study demonstrates diligence and verification of data.</p>	<p>Design: Retrospective case series</p> <p>Sample: Patient calls to otolaryngology nurse’s line between 3/2018-11/2018 regarding otorrhea. Eighty-two patients were included in the study.</p> <p>Setting: Tertiary pediatric hospital</p> <p>Framework: Not discussed</p> <p>Measures: (1) Antibiotic prescription (2) Additional phone call for otorrhea within subsequent six weeks (3) Treatment failure classified as urgent care or clinic visit for otorrhea (4) Requirement of additional antibiotic for acute otitis media</p> <p>Analysis Plan: Descriptive statistics were used to summarize the data. Categorical data were summarized using n. Continuous data were tested for normality using Shapiro-Wilk tests. Associations between patient characteristics and treatment failure were assessed using logistic regression or Wilcoxon rank-sum tests.</p> <p>Procedure: Nurses completed a standardized form including patient/caregiver responses of purulence, tympanostomy tube history, fever, ear erythema, bacterial rhinosinusitis, sore throat, and immunodeficiency.</p>	<p>Conclusion Validity: Limitations were provided, and results are generalizable to other populations.</p> <p>Internal Validity: Cost analysis was not performed.</p> <p>External Validity: The study was conducted as a single site.</p> <p>Construct Validity: The primary study limitation included the retrospective chart review design.</p> <p>Reliability: Fair. Statistically meaningful data was provided.</p> <p>Precision: Data was not normally distributed and therefore summarized as median (range).</p>	<p>The median age of the 82-patient sample was 2.5 years (range 0.3-20.2 years). The median distance from the hospital location was 27.1 miles (range 0.8-139.0 miles). All patients have a history of tympanostomy ear tubes. Clinic visits were obviated in 83% of patients. Seventy-nine out of 82 patients received an antibiotic prescription. Sixteen patients had an additional phone call for otorrhea within the subsequent six weeks. Treatment failure classified as in-person visits to urgent care or clinic for otorrhea occurred in 14 patients. 24% of patients required additional antibiotics.</p>	<p>An evidence-based telehealth clinical pathway for tympanostomy tube otorrhea effectively diagnosed and treated 83% of patients with otorrhea without the need for an emergency room or office clinical assessment. A clinical pathway is an effective approach to serve a select group of patients with shared problems and a common diagnosis through efficient, cost-effective, and time consciousness care.</p>

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	<p>Completed forms were sent electronically to a provider for determination of uncomplicated acute otitis media. Prescription antibiotics for ototopical drops were ordered when deemed appropriate without an in-person evaluation.</p>			

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<p>Article 15: Zee-Cheng, J.E., Webber, E.C. & Abu-Sultaneh, S. (2017). Adherence to pediatric diabetic ketoacidosis guidelines by community emergency departments' providers</p> <p>Evidence Level III - Retrospective chart review</p> <p>Quality A High - Insightful data interpretation. The transparency provided in data interpretation</p>	<p>Design: A retrospective chart review</p> <p>Sample: Patients 18 years and under who were admitted to the pediatric intensive care unit (PICU) between April 2013 and April 2015 with a DKA diagnosis. Patients treated through Riley Hospital for Children at Indiana University Health emergency department were excluded. 100 patients met the study criteria and were included in the study sample.</p> <p>Setting: Riley Hospital for Children PICU at Indiana University Health; 36-bed unit within a 305-bed, academic, tertiary care children's hospital</p> <p>Framework: Not discussed</p> <p>Measures: (1) Demographic data including age, gender, a new diagnosis of T1DM, & presence of insulin pump; DKA guideline parameters initiated at referring facility were collected including (2) IV insulin bolus administration, (3) subcutaneous insulin bolus administration, (4) administration of fluids greater than 40mls/kg in less than two hours, (5) use of non-isotonic fluids, (6) sodium bicarbonate administration, and (7) hourly glucose checks. The geographic location of each referring facility concerning to the study setting was also noted.</p>	<p>Conclusion Validity: Threats were listed. Sample size moderate.</p> <p>Internal Validity: The study was retrospective in nature.</p> <p>External Validity: Confounding variables on study results could influence results including provider training and skillset.</p> <p>Construct Validity: The study was conducted at a single site, which could influence generalizability.</p> <p>Reliability: Good. Study limitations were acknowledged</p> <p>Precision: Statistically meaningful results</p>	<p>100 patients were referred from 56 different hospital sites with an average distance of 62 miles from Riley Hospital for Children PICU. 37% of the sample were treated per all six established guideline parameters. 30% received an IV insulin bolus. 61% received recommended hourly glucose checks. No significant association was noted between non-adherence and patient demographics or referring facility distance. Therapies contradictory to guidelines including IV insulin bolus administration and sodium bicarbonate administration in</p>	<p>Non-adherence to guidelines by community emergency department providers for the treatment and medical management of pediatric patients in DKA exists in the state of Indiana. The two guidelines most frequently defied are the administration of an IV insulin bolus and hourly glucose checks.</p>

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	<p>Analysis Plan: Statistical analysis was conducted. Mann-Whitney test evaluated the effect of demographic variables on adherence to DKA guideline parameters entirely and individually. Chi-square tests evaluated the demographic variable effect on individual DKA parameters. Logistic regression established odds ratio for each demographic variable for DKA guideline parameter adherence.</p> <p>Procedure: Patients included in the study sample were evaluated using the outlined analysis plan.</p>		<p>pediatric DKA patients still occur.</p>	