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Original Research

# Implementation and Evaluation of a Diabetic Ketoacidosis Order Set in Pediatric Type 1 Diabetes at a Tertiary Care Hospital: A Quality-Improvement Initiative

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## Key Messages

- Management of pediatric diabetic ketoacidosis is evidence-informed and has numerous clinical care guidelines, yet successful implementation and adherence are lacking.
- This quality-improvement initiative resulted in success in the implementation of the diabetic ketoacidosis order set, improved patient outcomes and provided a framework for further dissemination.

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## ABSTRACT

**Objectives:** Despite published clinical practice guidelines in pediatrics for the use of a standardized diabetic ketoacidosis (DKA) protocol, our centre lacked an accepted, evidence-informed protocol for pediatric DKA management. Our primary aim was to attain broad clinical uptake of a DKA order set. Secondary aims included improved standard-of-care DKA management principles regarding fluid, potassium and dextrose administration.

**Methods:** A pediatric multidisciplinary collaborative was created to examine evidence for the development and implementation of a DKA order set. A modified plan-do-study-act cycle guided by end-user feedback and early clinical outcomes allowed progressive order-set modifications and hospitalwide implementation. **Results:** We achieved 83% uptake of the order set for patients presenting to our tertiary centre and 67% uptake for patients transferred from peripheral centres. Following the implementation of the DKA order set, we observed improvements in DKA management, which included more appropriate intravenous (IV) replacement fluid rates (30% vs. 55.1%;  $p=0.03$ ); earlier administration of potassium to IV fluids (66% vs. 93.1%;  $p=0.006$ ); more appropriate potassium chloride dosing to IV fluid (40% vs. 79.3%;  $p=0.0007$ ) and earlier addition of IV dextrose (67.4% vs. 93.1%;  $p=0.009$ ).

**Conclusions:** Implementation of a DKA order set in a tertiary hospital required identification of key stakeholders, formation of a multidisciplinary team and the development of an evaluation process. There was an observed increase in physician order-set uptake and DKA management practice improvements. Future goals involve expanding the implementation and evaluation process to provincial regional and remote centres and analyzing the impact on resource utilization.

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amélioration de la qualité

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## R É S U M É

**Objectifs :** En dépit de la publication des lignes directrices de pratique clinique en pédiatrie sur l'utilisation d'un protocole normalisé relatif à l'acidocétose diabétique (ACD), notre centre n'avait pas de protocole reconnu de prise en charge fondée sur les données probantes de l'ACD chez les enfants. Notre principal objectif était d'atteindre dans la pratique clinique une utilisation générale des ordonnances pré-rédigées

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relatives à l'ACD. Les objectifs secondaires étaient les suivants: l'amélioration des principes de prise en charge de l'ACD selon les normes de soins dans l'administration des fluides, du potassium et du dextrose. *Méthodes* : Une équipe collaborative multidisciplinaire en pédiatrie a été créée pour examiner les données probantes sur l'élaboration et la mise en place d'ordonnances pré-rédigées relatives à l'ACD. Un cycle PDCA (pour penser, démarrer, contrôler, agir) modifié qui était orienté par les commentaires des utilisateurs finaux et les résultats cliniques préliminaires a permis de modifier progressivement les ordonnances pré-rédigées et de les mettre en place dans l'ensemble de l'hôpital.

*Résultats* : Nous avons atteint une utilisation de 83 % des ordonnances pré-rédigées chez les patients qui se présentaient à notre centre de soins tertiaires et une utilisation de 67 % chez les patients transférés des centres en périphérie. Après la mise en place des ordonnances pré-rédigées relatives à l'ACD, nous avons observé des améliorations dans la prise en charge de l'ACD, y compris des taux plus adéquats de fluides de remplacement par voie intraveineuse (IV; 30 % vs. 55,1 %;  $p = 0,03$ ), l'administration plus hâtive de potassium aux fluides IV (66 % vs. 93,1 %;  $p = 0,006$ ), le dosage plus adéquat de chlorure de potassium au fluide IV (40 % vs. 79,3 %;  $p = 0,0007$ ) et l'ajout plus précoce de dextrose IV (67,4 % vs. 93,1 %;  $p = 0,009$ ).

*Conclusions* : La mise en place des ordonnances pré-rédigées relatives à l'ACD dans un hôpital de soins tertiaires a exigé de déterminer les principaux intervenants, la création d'une équipe multidisciplinaire et l'élaboration d'un processus d'évaluation. Nous avons observé une augmentation de l'utilisation des ordonnances pré-rédigées chez les médecins et des améliorations dans les pratiques de prise en charge de l'ACD. Les objectifs futurs consistent à étendre la mise en place et l'évaluation du processus aux centres régionaux provinciaux et aux centres en régions éloignées, et à analyser les répercussions sur l'utilisation des ressources.

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## Introduction

Diabetic ketoacidosis (DKA) is a common, potentially life-threatening complication in patients with newly diagnosed and with established type 1 diabetes. DKA is defined as a triad of hyperglycemia, ketonemia and metabolic acidosis (venous pH <7.3 and/or serum bicarbonate <15 mmol/L) resulting from an absolute or relative insulin deficiency (1). In the pediatric population, the presentation of DKA may occur in as many as 15% to 67% of newly diagnosed patients and in 1% to 10% of established patients per year (2). Meanwhile, the estimated incidence of type 1 diabetes in Canada is 25.9 per 100,000 children younger than 15 years of age, which is 1 of the highest rates globally (2). Given that 20% of Saskatchewan's 1.1 million residents are younger than 18 years of age (2016 Canadian census data), pediatric and emergency medicine providers across our province will routinely encounter pediatric DKA and should be adept in its management.

Because of the high incidence of pediatric DKA and its potential for morbidity, the underpinnings of optimal management of pediatric DKA have been well established and have led to numerous, published, evidence-informed clinical care pathways (1,3). Clinical care pathways are interventions with structured multidisciplinary plans of care that provide translation of guidelines and clinical evidence into patient care at the provider level (4). Standardized clinical pathways have been demonstrated to decrease hospital costs and lengths of stay without increased readmission rates (5). For the majority of health-care practitioners, problem-solving skills are well developed, but in a challenging work environment, many may struggle to attend carefully to competing demands and to recall detailed information quickly, and they may possess suboptimal computation (6). Key processes in improving safety in health-care outcomes include avoidance of rote memory, process simplification and process standardization based on the best available evidence (6).

Except for Saskatoon, all other pediatric tertiary care centres across Canada endorsed a hospital-established or province-specific care pathway for the management of DKA at the time of this undertaking (2). As a result, our centre's practitioners were utilizing a wide variety of other Canadian guidelines, resulting in significant variability in clinical care. Clinical variation was seen in all areas of management: initial fluid bolus and replacement fluid administration, potassium supplementation, glucose administration and

laboratory-investigation frequency. This variation in care raised concerns for patient safety and optimal care, resource utilization and practitioner inefficiencies.

Through implementation of an evidence-guided DKA order set, our interdisciplinary team's intent was to optimize patient care and reduce potential safety events by reducing unnecessary variability, optimizing resource utilization, enhancing understanding of clinical DKA management and improving care efficiency. Our primary aim was to attain broad clinical uptake of the DKA order set at our tertiary care centre over a 12-month implementation period. Secondary aims included improvements in DKA management: appropriate fluid bolus volumes and replacement rates; initial potassium management; and timely dextrose supplementation.

## Methods

### Clinical setting

Royal University Hospital is the provincial pediatric tertiary care centre, situated in Saskatoon, Saskatchewan, and it is affiliated with the University of Saskatchewan. This centre has 42 general pediatric inpatient beds and 10 pediatric intensive care unit (PICU) beds. There are approximately 30 admissions for pediatric DKA per year. Clinical care is provided by the pediatric diabetes and endocrinology service with support from the PICU, pediatric emergency department, pediatric transport and general pediatric services, each of which includes pediatric residents and other trainees.

### Stakeholder engagement

A multidisciplinary team, including pediatric endocrinology, PICU, pediatric emergency department, general pediatrics, pediatric residents, pediatric nurses and nurse educators, pediatric clinical pharmacy and laboratory medicine, was assembled to create the order set. The team reviewed literature focused on pediatric DKA management, including appraisal of published national and international protocols, and the team synthesized findings to create a clinical order set based on the best available evidence while ensuring practicality within our clinical context. A hospital-appointed forms committee ensured that the order set met safety and standardization requirements.

### Intervention development

A modified plan-do-study-act approach was employed to develop, test and assess the order set systematically (Fig. 1). Initial editions were appraised by potential end-users, resulting in a series of revisions to tailor end-users' needs and address clinical concerns. Subsequently, the order set was mock-tested using previous pediatric DKA data; this resulted in further alterations, including automatic dextrose-addition cues (if blood glucose dropped below certain thresholds) and potassium addition or withholding recommendations (i.e. withholding potassium if there is initial hyperkalemia with anuria). Upon clinical implementation, end-user feedback and order-set review occurred following the first 5 patients to identify any areas of critical concern, of which none were identified. Subsequent interim review at 6 months post-implementation led to a revised edition that included interunit transfer orders, modifications of fluid administration and pharmacy instructions for IV fluid preparation.

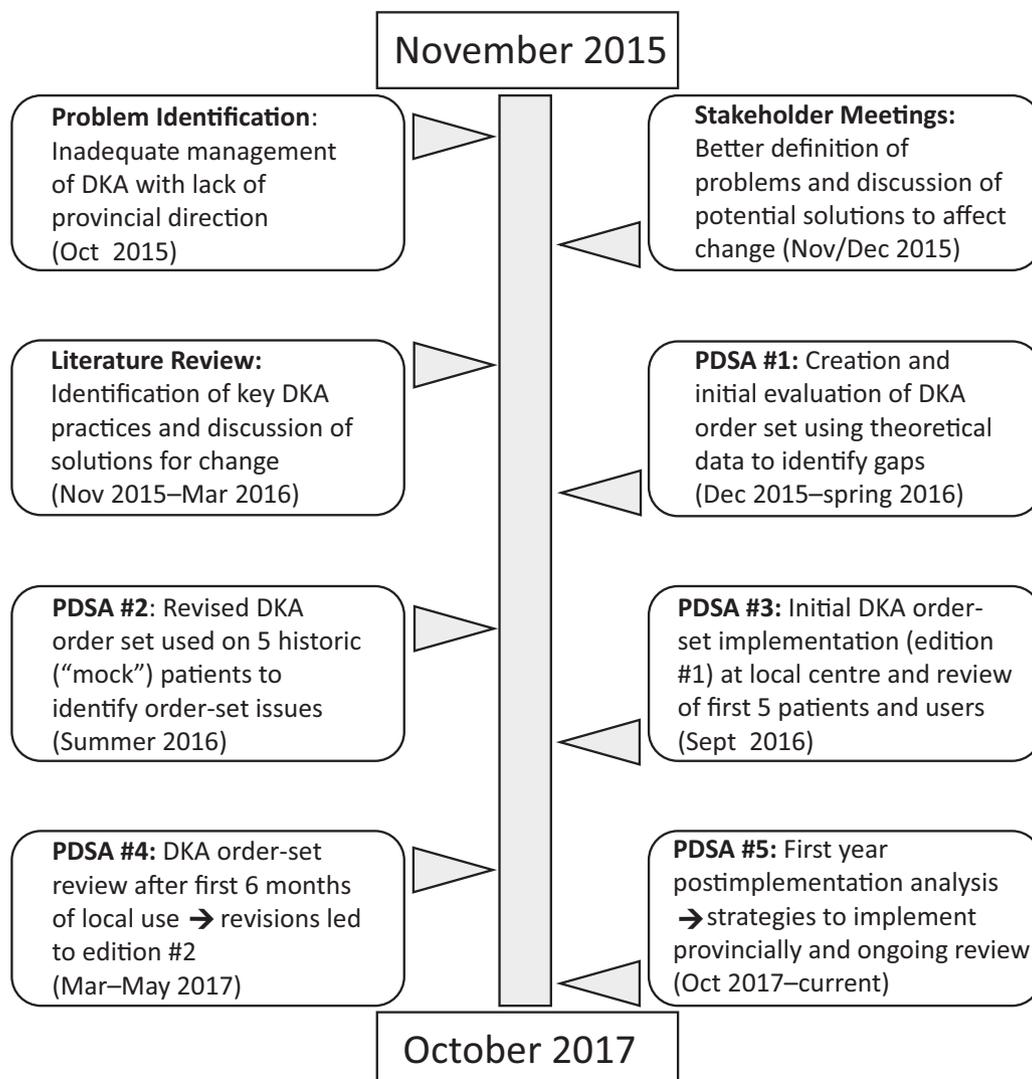
### Education

Prior to and during the rollout of the DKA order set, education was provided to targeted users in a variety of settings, including

provincial pediatric grand rounds, pediatric resident academic half days, nursing education days and pediatric departmental meetings. The order set was made available in paper copies and digitally on the hospital's Infonet–Physician Orders for increased accessibility. Physician and nursing leads in the emergency department, PICU and inpatient wards were notified of the rollout of the DKA order set.

### DKA order-set design

The Pediatric Diabetic Ketoacidosis–Therapy Initiation Order Set was approved for use in September 2016, later supplanted by a second edition in May 2017. The order set's basic components include patient-identifying information and DKA criteria, PICU consultation criteria, standard nursing tasks, baseline and ongoing laboratory investigations, IV fluid recommendations, including potassium and glucose requirements, and IV insulin administration. Reverse-side information components included discussion points concerning commonly encountered challenges in DKA management and instructions for fluid preparation. Key features included automatically triggered decision-making points for the addition of dextrose, cues for adequate fluid bolus volumes and replacement volumes and interunit transfer sign-off to minimize order re-entry.



**Figure 1.** DKA order set development and implementation process. DKA, diabetic ketoacidosis; PDSA, plan-do-study-act.

## Evaluation process

A preimplementation retrospective chart review was completed for pediatric patients presenting to our centre with DKA between April 2014 and September 2016, identifying 50 cases of DKA (39 unique patients). A multipronged electronic medical-record search was completed to capture all pediatric DKA admissions. Pediatric physicians' billings claimed from April 2014 to September 2016, using the diagnostic terms *diabetes*, *diabetic ketoacidosis* and *DKA*, were reviewed. Further, all medical records for patients 0 to 17 years of age with discharge diagnoses according to the International Statistical Classification of Diseases and Related Health Problems (10th revision) for DKA were reviewed. Remaining data were collected through review of outpatient electronic medical records and provincial electronic laboratory repositories.

The variables collected included basic patient demographic data, location and acuity details of presentation, PICU consultation requests, presenting biochemistry, initial and replacement fluid management, insulin management and electrolyte management. Complications of management were collected; they included hypoglycemia (blood glucose <4 mmol/L); hypokalemia (mild <3.5 mmol/L, moderate 2.5 to 2.9 mmol/L or severe <2.5 mmol/L) and management strategies for clinically suspected cerebral edema, such as bed positioning maneuvers or therapies (mannitol or hypertonic saline use). Additional postimplementation variables collected included clinical uptake cues (defined as order set use prior to or immediately following initial fluid bolus or at presentation to Royal University Hospital) and clinical over-rides (defined as edited and/or added orders).

The University of Saskatchewan and the Saskatoon Health Region research ethics boards approved the review and collection of data from patients' medical records for the purposes of this quality-improvement initiative.

## Statistical analysis

Descriptive measures (means) were used for baseline characteristic comparisons. T tests were used for continuous variables, and chi-square analysis was used for categorical variables, or the Fisher exact test was used when cell sizes were <5. Analysis was undertaken using SAS, v. 9.4 (SAS Institute, Cary, North Carolina, United States).

## Results

The DKA order set was implemented on September 12, 2016. Following implementation, data were collected for all pediatric patients admitted with DKA over a 12-month period as the first-year implementation phase. We analyzed 30 DKA episodes in the treatment (postintervention) group, of which there were 29 unique patients (complete treatment data were available for 29 of the 30 episodes).

There were no differences in patients' characteristics, including age, sex, location of presentation, severity of DKA or history of new or previously diagnosed diabetes, between the control (pre-intervention) and treatment (postintervention) groups (Table 1). In the first year of implementation, we achieved 73% clinical uptake of the order set in all patients, 30% of order set activations occurring prior to any DKA-related therapy. Of those presenting to our tertiary centre, order-set uptake was 83%; patients transferred from peripheral sites to our centre had an order-set uptake, at any point during their DKA care, of 67% (Table 2).

Patients received an initial IV bolus prior to insulin treatment 92% of the time in the control group and 96.7% of the time in the treatment group ( $p=0.78$ ). Fluid bolus volumes of  $\leq 20$  mL/kg were comparable in the control (83%) and treatment (76%) groups

**Table 1**

DKA order set control and treatment group patient characteristics

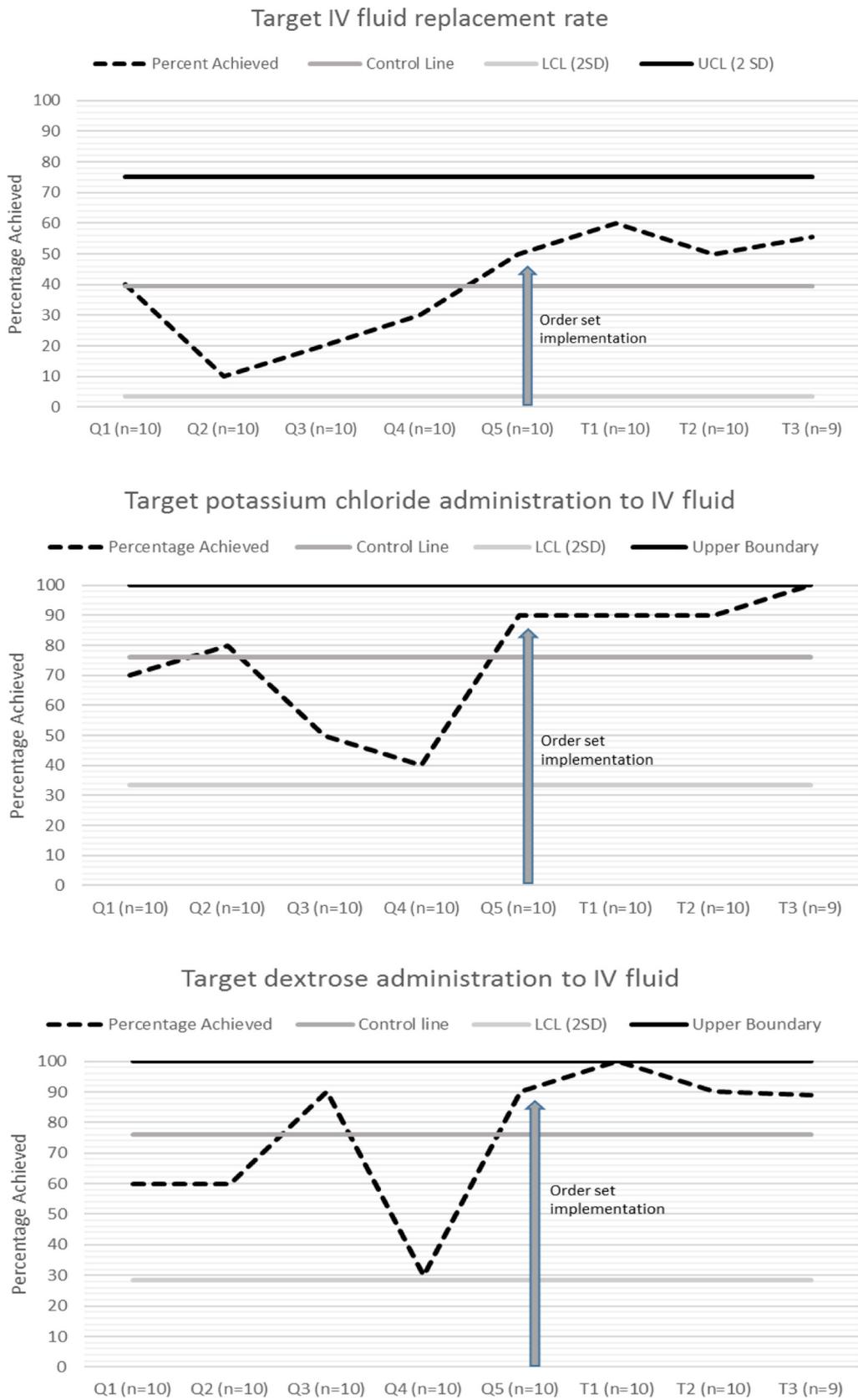
	Control group	Treatment group	p value
Number of patients	50	30	
Age (years)	12.1 (3.7)	11.1 (5.4)	0.93
Sex (female, %)	28 (56.0%)	19 (63.3%)	0.51
New diagnosis (%)	19 (38%)	15 (50%)	0.29
Location at presentation			
Tertiary (Saskatoon)	27 (55.1%)	12 (40.0%)	0.31
Urban (>50,000)	2 (4.1%)	3 (10.0)	
Urban/rural (<50,000)	20 (40.8%)	15 (50.0%)	
Initial site of admission			
Pediatric ICU	18 (36.0%)	16 (53.3%)	0.061
Pediatric ward	32 (64.0%)	13 (43.3%)	
Emergency room (only)	0	1 (3.3%)	
Biochemical profile (presentation)			
pH	7.1 (0.1)	7.1 (0.1)	0.17
Bicarbonate	9.5 (6.2)	7.6 (4.8)	0.10
Glucose	31.4 (11.7)	29.6 (11.1)	0.52
Sodium	136.5 (5.6)	134.9 (5.7)	0.23
Potassium	4.9 (0.7)	4.7 (0.9)	0.24
Chloride	101.7 (8.8)	99.4 (9.2)	0.26

( $p=0.51$ ); of note, there was no capacity for adjusted fluid analysis for suspected decompensated shock. IV fluid replacement rates achieving the target of 4 to 6 mL/kg/h (based on weight) were 30% in the control group and 55.1% in the treatment group ( $p=0.03$ ). For those outside of target IV fluid range, 72% of control patients received less than target fluid replacement rates. We observed an increase in patients' receiving the recommended 40 mEq/L of potassium chloride to initial IV fluids (40% vs. 79.3%;  $p=0.0007$ ). There was no difference in the number of episodes of moderate or severe hypokalemia (10% vs. 6.7%;  $p=0.70$ ). Administration of dextrose to IV fluids at or prior to serum glucose <17 mmol/L increased significantly (67.4% vs. 93.1%;  $p=0.009$ ); however, no statistically significant difference in episodes of hypoglycemia occurred. Control charts depicting the percentage of target outcomes achieved for IV fluid maintenance rates (mL/kg), addition of potassium chloride to IV fluid, and early administration (glucose <17 mmol/L)

**Table 2**

DKA order set outcomes: comparison of control group vs. treatment group

Target	Treatment group (n=30)	%	
DKA order set use (postimplementation)	At any time during therapy (%)	73	
	From onset of therapy (%)	30	
	Presenting at tertiary hospital, anytime (%)	83	
	Presenting at transferring hospital, anytime (%)	67	
	Control group (n=50)	Treatment group (n=29)	p value
Initial therapy:	46 (92.0%)	29 (96.6%)	0.78
IV fluid bolus given			
1st h IV fluid bolus: $\leq 20$ mL/kg (%)	41/50 (82%)	22/29 (75.9%)	0.51
IV fluid replacement rate: 4-6 mL/kg/h	15/50 (30%)	16/29 (55.1%)	0.03
Potassium administration: with replacement IV fluid (%)	33/50 (66.0%)	27/29 (93.1%)	0.006
Potassium administration: 40 meq/L at initiation (%)	20/50 (40.0%)	23/29 (79.3%)	0.0007
Moderate to severe hypokalemia: potassium <3.0 mmol/L (%)	5/50 (10.0%)	2/29 (6.7%)	0.70
Dextrose administration: at/prior to glucose <17 mmol/L (%)	33/50 (67.4%)	27/29 (93.1%)	0.009
Hypoglycemia: glucose <4 mmol/L (%)	3/50 (6.1%)	1/29 (3.4%)	0.99
Intervention(s) for: suspected cerebral edema	2/50 (4.0%)	2/29 (6.7%)	0.62



**Figure 2.** Control charts for IV fluid replacement, potassium chloride administration and dextrose administration. LCL, lower control limit; Q, control group quintiles; T, treatment group tertiles; UCL, upper control limit.

of dextrose to IV fluid are seen in [Figure 2](#) (control group, quintile clusters; treatment group, tertile clusters). Control vs. treatment group data showed no differences in bicarbonate use ( $n=2$  vs.  $n=0$ ), decreases of insulin infusion rates  $<0.5$  units/kg/h or sliding-scale use prior to DKA resolution ( $n=6$  vs.  $n=3$ ), and mannitol/hypertonic saline use ( $n=1$  vs.  $n=1$ ).

## Discussion

To our knowledge, this is the first Canadian pediatric quality-improvement initiative to examine the development and systematic implementation of a DKA order set. This study illustrates the processes and evaluative procedures for implementation of a pediatric DKA order set and provides evidence of early gains at our centre in the improvement of pediatric DKA management.

In pediatric DKA, there is sufficient evidence to suggest that optimizing DKA management—with emphasis on appropriate fluid and electrolyte management—leads to a reduction in adverse outcomes. White et al demonstrated, through precise fluid selection, rate and electrolyte/glucose composition, that clinically detectable cerebral edema can be significantly lessened in relation to purported rates (7). In the face of such evidence, the International Society for Pediatric and Adolescent Diabetes guidelines suggest that all centres should have written guidelines for the management of pediatric DKA (1).

However, the presence of clinical practice guidelines does not result simply in practitioner uptake and change in behavior. Implementation of DKA guidelines, protocols and order sets requires rigorous design, evaluation, clinical awareness and ongoing education and promotion to ensure success; and even rigorous implementation procedures may not result in the desired clinical improvements (8). Data from adults in the study by Dhatariya et al in the United Kingdom show significant management and care-process gaps despite the widespread availability of DKA guidelines (9). Suboptimal adherence to pediatric DKA management has also been demonstrated, including recent data from Canada (10). However, given the large number of clinical and biochemical parameters that may be assessed for guidelines adherence, it can be debated how well or how poorly adherence to DKA guidelines truly occurs. The demonstration of shifts in care processes, early clinical outcome improvements and changes in clinical attitudes and understanding may be sufficient to confirm successful early implementation.

Thus, there remains great impetus for care improvement because safe and effective patient care is paramount for all health-care providers. Koves et al demonstrated improvement in several critical areas of DKA management, including potassium- and insulin-infusion management, with a robust design and implementation strategy following evidence-based quality improvement principles (11). In our first-year implementation phase, 73% of all patients (83% presenting at our centre) were placed on the DKA order set, though only 30% had order-set activation from the very onset. The lack of immediate activation may reflect challenges in access (lack of electronic order entry), clinician awareness or barriers to behavior changes by physicians. Further, it is plausible that IV fluid administration commenced prior to biochemical DKA confirmation. Clinically, we observed an increase in target IV potassium and glucose administration timing and more robust rates of replacement IV fluid. Equally important, there was no increase in clinical adverse outcomes, including hypokalemia, hypoglycemia and cerebral edema. Beyond measureable outcomes, the planning and implementation of the order set promoted staffwide education and awareness surrounding pediatric DKA management.

Pediatric DKA fluid management is a consistent source of debate; the data are evolving and emerging, and management is further challenged by clinician expertise and interpretation of fluid

deficits (12). It is this variability that, at least historically, led to less aggressive fluid recommendations in early DKA treatment due to the concern about cerebral edema, particularly in centres with less familiarity with pediatric DKA (13,14). In our study, clinician determination of fluid status could not be formally assessed, and we observed no difference in the initial bolus volumes between study phases. Most patients received  $\leq 20$  mL/kg of saline, in keeping with the most currently published pediatric DKA principles at the time of this study. However, we note that recent data from the Pediatric Emergency Care Applied Research Network Fluid Therapies Under Investigation in DKA study demonstrate that a more rapid fluid administration bolus (20 mL/kg, rather than 10 mL/kg, as in our order set) was noninferior with respect to neurologic outcomes and, in fact, may be superior in those with severe DKA. Fluid administration rates after the initial fluid bolus may vary based on clinical indicators, and the type of fluid (0.45% normal saline or 0.9% normal saline) can be left to practitioner discretion (15,16). Ongoing revisions to the DKA order set will occur in light of these emerging data and as new evidence arises so as to ensure adherence to best clinical practice.

The success of the DKA order set implementation can be attributed to identification of key stakeholders in DKA care and the formation of a multidisciplinary team that strived to improve DKA care in our pediatric population. Barriers to more successful implementation are related to 1) physician buy-in and subsequent changes in physician practice; 2) lack of point-of-care access to the order set; and 3) general awareness of the presence of the order set. Continued targeted education, promotion and strategies to improve accessibility, including translation to electronic order entry, should lead to increased and earlier use of the order set.

Despite a successful pilot implementation, our collaborative is aware of current and future limitations. This project reflects a single-site implementation with a motivated and receptive audience, the presence of pediatric endocrinologists and the ability to ensure utilization with direct face-to-face interaction. Further expansion to other provincial centres, especially where routine pediatric care is lacking, may be challenging. Last, this project focused only on development and implementation factors as well as early signals of clinical improvement; long-term gains, including reductions in resource utilization, DKA complications and length of stay, could not be assessed.

Future directions will include outreach to users in peripheral regional and community centres and, ultimately, universal implementation of a province-wide pediatric DKA order set. Although we did not directly engage stakeholders outside of our centre during this project, we took several key steps to ensure order-set usability at nontertiary centres. These included 1) province-wide accepted order set formatting; 2) end-user quick-hit instructions on use of the order set and trouble-shooting; and 3) recommendations from pharmacy concerning fluid/insulin mixing. We are optimistic that our current provincial climate—with a move to a single health authority, the opening of the province's first dedicated pediatric hospital, and transition to electronic order entry—will facilitate implementation of this order set beyond the bounds of our health centre. Furthermore, we intend to provide ongoing education, promotion and clinical assessment of order set revisions to achieve sustained practice change. To ensure the effectiveness of our ongoing intervention, we plan to collaborate with key stakeholders at our regional centres (and, if possible, the Ministry of Health) to assess indicators of DKA order set accessibility and implementation, including 1) the presence of immediate or point-of-care access to our order set in emergency departments across the province; 2) the use of the order set across regional centres peripherally; and 3) a reduction in interhospital transfers of pediatric DKA patients (which may suggest increased capacity of local care providers in DKA management). We expect the ongoing transition to a single

health authority for our province, the opening of a new pediatric hospital and the transition to complete electronic order entry to facilitate this ongoing evaluative process.

## Conclusions

Improvement in DKA management at our centre was achieved through the development and implementation of an evidence-guided pediatric DKA order set. Ongoing assessment, revision and expansion of the order set are predicted to improve the quality and safety of DKA care for pediatric patients throughout the province.

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## Author Disclosures

Conflicts of interest: None.

## Author Contributions

Proposal and ethics preparation, MI; improvement cycles/order-set design, KF, MN, TH, VC, CK and MI; data collection, MI, KF; data interpretation, MI, KF; manuscript preparation and review, MI, KF, MN, TH, VC and CK.

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