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Commissioner

Certificate of Waiver
Advanced Life Support Services

Pursuant to the provision of the New Jersey Administrative Code, specifically N.J.A.C. 8:41-1.4, a waiver is issued to:

All New Jersey Mobile Intensive Care Programs

Granting specific relief waiving the Dextrose concentration requirements from the following provision(s) of Chapter 41 of the New Jersey Administrative Code, specifically permitting Mobile Intensive Care programs to substitute 10% Dextrose for any other concentration in the formulary:

SUBCHAPTER 6, ADMINISTRATION AND STORAGE OF MEDICATIONS
8:41-6.1, Medications and therapeutic agents (a)(6) Dextrose, 50 percent;
8:41-6.1, Medications and therapeutic agents (a)(7) Dextrose (5 percent in water, 10 percent in water and 25 percent in water);
8:41-7.18 Standing orders for unconscious person/altered mental status, (a)(5)(i) Administer 25 gm of 50 percent Dextrose in water intravenously;
8:41-8.9 Standing orders for pediatric seizures, (a)(4)(ii)(1)(B) For patients greater than or equal to one month of age, administer 0.5 g/kg of a 25 percent dextrose solution via IV/IO;
8:41-8.11 Standing orders for pediatric altered mental status, (a)(6)(ii) For patients greater than or one month of age, administer 0.5 g/kg of a 25 percent dextrose solution via IV/IO.

Justification: The American Society of Healthcare Pharmacists has noted shortages of both Dextrose 50% in June 2017 and Dextrose 25% in May 2017.

Equivalency: Dextrose 10% is already an approved concentration within the existing protocols. Peer-reviewed research has established that Dextrose 10% is feasible, safe, and effective as a therapeutic modality and avoids the theoretical risks including extravasation injury, direct toxic effects of hypertonic dextrose, and potential neurotoxic effects of hyperglycemia.

For: Cathleen D. Bennett, Commissioner

By: Scot Phelps, JD, MPH, Paramedic
Director, Office of Emergency Medical Services

Date issued: *June 27th, 2017*
Waiver Control Number: *17-8:41-6.1, 7.18, 8.9, 8.11-027*
Expiration date: *Indefinite*

D10 in the Treatment of Prehospital Hypoglycemia: A 24 Month Observational Cohort Study
H. Gene Hern , MD, Matthew Kiefer , MD, Derex Louie , PharmD, Joseph Barger , MD & Harrison J. Alter , MD, MS Published online: 05 Dec 2016

Introduction: Prehospital first responders historically have used an IV bolus of 50 mL of 50% dextrose solution (D50) for the treatment of hypoglycemia in the field. A local Emergency Medical Services (EMS) system recently approved a hypoglycemia treatment protocol of IV 10% dextrose solution (D10) due to occasional shortages and higher cost of D50. We use the experience of this EMS system to report the feasibility, safety, and efficacy of this approach.
Methods: Over the course of 104 weeks, paramedics treated 1,323 hypoglycemic patients with D10 and recorded patient demographics and clinical outcomes. Of these, 1,157 (87.5%) patients were treated with 100 mL of D10 initially upon EMS arrival, and full data on response to treatment was available on 871 (75%) of these 1,157. We captured the 871 patients' capillary glucose response to initial infusion of 100 mL of D10 and fit a linear regression line between elapsed time and difference between initial and repeat glucose values. We also explored the need for repeat glucose infusions as well as feasibility, and safety.
Results: The study cohort included 469 men and 402 women with a median age of 66. The median initial field blood glucose was 37 mg/dL, while the subsequent blood glucose had a median of 91 mg/dL. The median time to second glucose testing was eight minutes after beginning the 100mL D10 infusion. Of 871 patients, 200 (23.0%) required an additional dose of IV D10 solution due to persistent or recurrent hypoglycemia and seven (0.8%) patients required a third dose. There were no reported deaths or other adverse events related to D10 administration for hypoglycemia. Linear regression analysis of elapsed time and difference between initial and repeat glucose values showed near-zero correlation.
Conclusions: The results of one local EMS system over a 104-week period demonstrate the feasibility, safety, and efficacy of using 100 mL of D10 as an alternative to D50. D50 may also have theoretical risks including extravasation injury, direct toxic effects of hypertonic dextrose, and potential neurotoxic effects of hyperglycemia. Additionally, our data suggest that there may be little or no short-term decrease in blood glucose results after D10 administration.

Dextrose 10% in the treatment of out-of-hospital hypoglycemia.
Kiefer MV, Gene Hern H, Alter HJ, Barger JB.

INTRODUCTION:
Prehospital first responders historically have treated hypoglycemia in the field with an IV bolus of 50 mL of 50% dextrose solution (D50). The California Contra Costa County Emergency Medical Services (EMS) system recently adopted a protocol of IV 10% dextrose solution (D10), due to frequent shortages and relatively high cost of D50. The feasibility, safety, and efficacy of this approach are reported using the experience of this EMS system.
METHODS:
Over the course of 18 weeks, paramedics treated 239 hypoglycemic patients with D10 and recorded patient demographics and clinical outcomes. Of these, 203 patients were treated with 100 mL of D10 initially upon EMS arrival, and full data on response to treatment was available on 164 of the 203 patients. The 164 patients' capillary glucose response to initial infusion of 100 mL of D10 was calculated and a linear regression line fit between elapsed time and difference between initial and repeat glucose values. Feasibility, safety, and the need for repeat glucose infusions were examined.
RESULTS:
The study cohort included 102 men and 62 women with a median age of 68 years. The median initial field blood glucose was 38 mg/dL, with a subsequent blood glucose median of 98 mg/dL. The median time to second glucose testing was eight minutes after beginning the 100 mL D10 infusion. Of 164 patients, 29 (18%) required an additional dose of IV D10 solution due to persistent or recurrent hypoglycemia, and one patient required a third dose. There were no reported adverse events or deaths related to D10 administration. Linear regression analysis of elapsed time and difference between initial and repeat glucose values showed near-zero correlation.

CONCLUSIONS:
In addition to practical reasons of cost and availability, theoretical risks of using 50 mL of D50 in the out-of-hospital setting include extravasation injury, direct toxic effects of hypertonic dextrose, and potential neurotoxic effects of hyperglycemia. The results of one local EMS system over an 18-week period demonstrate the feasibility, safety, and efficacy of using 100 mL of D10 as an alternative. Additionally, the linear regression line of repeat glucose measurements suggests that there may be little or no short-term decay in blood glucose values after D10 administration.

Dextrose 10% or 50% in the treatment of hypoglycaemia out of hospital? A randomised controlled trial
C Moore, M Wollard. Accepted for publication 29 December 2004

Objective: To investigate whether 10% dextrose given in 5 g (50 ml) aliquots is more effective than 50% dextrose given in 5 g (10 ml) aliquots in the treatment of out of hospital hypoglycaemia.
Design: Randomised controlled trial.
Setting: Out of hospital patients attended by paramedics from a large UK ambulance service.
Participants: 51 unresponsive adult patients with blood glucose levels (4 mmol/l.
Intervention: 5 g (50 ml) intravenous aliquots of 10% dextrose or 5 g (10 ml) intravenous aliquots of 50% dextrose to a maximum dose of 25 g.
Main outcome measures: To compare for each dextrose concentration the time to achieve a Glasgow Coma Scale (GCS) score of 15, and the dose required to obtain a blood glucose level of >4.5 mmol/l.
Results: There were no statistically significant differences between the groups with regard to age or sex, median pretreatment GCS, pretreatment blood glucose level, or proportion of patients with insulin dependent diabetes. Following treatment, there were no statistically significant differences in median time to recovery (8 minutes), median post-treatment GCS, or number of subjects experiencing a further hypoglycaemic episode within 24 hours (four per group). The median total dose of dextrose administered was significantly less with the 10% concentration (10% = 10 g, 50% = 25 g, p,0.001) and median posttreatment blood sugar levels were also significantly lower (10% = 6.2 mmol/l and 50% = 9.4 mmol/l, p = 0.003). There were no reports of extravasation injuries in either group. **Conclusions**: Dextrose 10% delivered in 5 g (50 ml) aliquots is administered in smaller doses than dextrose 50% delivered in 5 g/10 ml aliquots, resulting in lower post-treatment blood glucose levels. We therefore recommend it as the intravenous treatment of choice for adult hypoglycaemia.