Glucose Gel to Keep Babies and Moms Together

At the end of this presentation learners will be able to:

- Discuss the literature related to implementation of glucose gel in newborn nursery.
- Describe the process of implementation of glucose gel in newborn nursery.

ProHealth Waukesha Memorial Regional Tertiary Care Hospital
21 bed Level III NICU
34 bed LDRP unit
301 inpatient beds
40,000 ED visits/yr

ProHealth Oconomowoc Memorial Community Hospital
12 bed LDRP
Level I Nursery
76 inpatient beds
17,000 ED visits/yr

~ 2,000+ births/year

Timeline
- Leg work (11/2015-6/2016) – Options, Literature, AWHONN National Conference, Reach out to other CNSs for ideas/help, THANK YOU ADVOCATE GENERAL!
- Recruit some early adopters/champions within organization (4-5/2016)
- Gather Stakeholders and write protocol (7/2016)
- Protocol presented to Division of Peds for approval (8/2016)
- SBAR to P&T Committee – glucose gel override in ADU (End of 8/2016 stocked)
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Options
- Dextrose 40% oral gel
- Formula
- Donor Milk
AAP – Postnatal Glucose Homeostasis

- "There has been no substantial evidence-based progress in defining what constitutes clinically important neonatal hypoglycemia, particularly how it relates to brain injury and that monitoring for, preventing and treating neonatal hypoglycemia remains largely empirical."
- "A reasonable (although arbitrary) cutoff for treating symptomatic infants is 40 mg/dl."
- Clinical Symptoms are not specific: jitteriness, cyanosis, seizures, apneic episodes, tachypnea, weak or high pitch cry, floppiness or lethargy, poor feeding, eye rolling, coma...
- "Any approach needs to account for the metabolic and physiologic status of infant and should not unnecessarily disrupt the mother-infant relationship and breastfeeding."

Pediatric Endocrine Society

- Screen High Risk Neonates:
  - High Risk: Sx of hypoglycemia, LGA/SGA, Pre/Postmature, IDM, Family hx of genetic hypoglycemia, physical assessment consistent with congenital syndrome associated with hypoglycemia, perinatal stress (CS for distress, maternal HTN/pre-eclampsia, IUGR, meconium aspiration, hypothermia, polycythemia, birth asphyxia...)
  - Goal: Plasma glucose > 50 mg/dl if less than 48 hr of life
  - > 60 mg/dl after 48 hr of life
  - Goal for Congenital hypoglycemia syndrome: Plasma glucose > 70 mg/dl
  - Exclude Persistent Hypoglycemia before DC home:
    - Any infant Sx of hypoglycemia, requiring IV dextrose, unable to maintain glucose >50 mg/dl prior ac, family hx of congenital hypoglycemia or physical assessment consistent with congenital syndrome associated with hypoglycemia

“Sugar Babies Study”

- Randomized, double blind, placebo controlled trial in New Zealand 2008-2010 (Harris, 2013)
- Resulted in decrease in hypoglycemia
  - 514 enrolled babies, 35-42 EGA, first 48 hr of life
  - Hypoglycemia - 118 dextrose, 119 placebo (n=237)
  - Primary Outcome: Treatment failure risk (≥46mg/dl after 2 treatment attempts)
    - RR 0.57 (95% CI 0.33-0.98; p=0.04)
  - Follow up at 24 months corrected gestational age (Harris, 2016):
    - 184 babies assessed (78% of original sample)
    - Mild neurosensory impairment, Processing difficulty & Developmental delay – similar between groups


- Two years of Gel in Nursery to prevent Level III NICU admission
  - Decrease NICU admissions for hypoglycemia by 73% (10.6% pre vs 2.9% post)
  - 88% of neonatal hypoglycemia was reversed during the first 24 hr of life
  - 49% avoided formula supplementation
  - No hyperglycemia (>90 mg/dl) or subsequent rebound hypoglycemia
  - 17/49 had initial Glucose of <25 mg/dl and required NICU admission (only 9 for hypoglycemia)
- Prior to Gel all 49 would have required NICU admission
- Infants requiring 2nd dose of gel – 82.5% has successful reversal

AAP Postnatal Glucose Homeostasis

- Glucose concentrations decrease to as low as 30 mg/dl in first hours after birth and generally stabilize above 45 mg/dl by 12 hours after birth
- Neonatal hypoglycemia occurs most commonly
  - SGA, infants of diabetic mothers and later preterm
  - Controversial: LGA (but recommendation is to include in screening)
- Asymptomatic: Late Preterm and SGA – screen for 24 hours
- Asymptomatic: LGA/IDM – screen for 12 hours
- At Risk Infants should be fed by 1 hour of life and POCT glucose checked 30 minutes later
- Target glucose concentration: >45 mg/dl BEFORE feedings
  - Sustain through multiple feed/fast cycles


- Oral v sublingual v IV groups were compared for children 1-15 years of age
  - No treatment failures in sublingual and IV groups

Stewart, Sage & Reynolds (2015)

- 52 babies monitored for hypoglycemia using a UK protocol where 2 rounds of gel would be given prior to starting formula supplementation to treat hypoglycemia
  - 88% increase in breastfeeding rates at 3 months post discharge
- Decrease in admissions to Neonatal service

• Barennes, et al (2005) study in children suffering from hypoglycemia due to severe malaria living in Sub Sahara Africa
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  - 52 babies monitored for hypoglycemia using a UK protocol where 2 rounds of gel would be given prior to starting formula supplementation to treat hypoglycemia
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AWHONN National Conference 2016

- Several hospitals presented/discussed glucose gel PDSA/QI projects at AWHONN all with similar protocols and results
  - Use cut offs for treatment similar to AAP +/-
  - Limit # of gel treatments
  - Feed and encourage SSC immediately after gel
  - Reduction in NICU admissions


ADDITIONAL LITERATURE


- Comparison of 250 asymptomatic infants receiving glucose gel vs. 248 asymptomatic infants prior to implementation of gel protocol
  - >= 35 weeks EGA, asymptomatic with glucose 25-45 mg/dl
  - Max of 3 doses in 48 hour
  - Decrease in NICU admission/IV Dextrose for asymptomatic hypoglycemia
  - Pre-implementation 42% asymptomatic babies transferred vs. Post implementation only 20%, (p=0.01)
  - Absolute Risk Reduction for IV dextrose 15.54% (95%CI 7.32-23.76)
  - Most likely to admit to NICU:
    - LGA, delivered by CS, lower initial glucose level (39.7=/-6 vs 33.6 =/-9)
  - 1st Dose (n=250): 28% responded; 61% repeat;
  - 2nd Dose (n=152): 33% responded; 57% repeat;
  - 3rd Dose (n=87): 74% responded


- RCT dose finding trial (multiple arms)
- Gel given prophylactically
  - n=416
  - Risk of hypoglycemia was lowest with single dose of 200 mg/kg dextrose gel (RR 0.68; 95%CI 0.47-0.99, p=0.04)
  - Babies who received ANY gel were less likely to develop hypoglycemia than those who received placebo (RR 0.79, 95%CI 0.64-0.98, p=0.03)
  - NICU admission similar but NICU admission for hypoglycemia was lower in gel group (RR 0.46, 95%CI 0.21-1.01, p=0.05)


- Prospective, convenient sample in Australia
  - n= 100 prior to gel (feeding only) ; n=100 post implementation of gel
  - NICU admission for hypoglycemia reduced post gel (29% v14%, p=0.01)
  - Hypoglycemia recurrence was higher post-implementation (31% vs 49%, p=0.02)
  - Most neonates only needed 1 dose of gel (75%)


- Analysis of “Sugar Babies” subset (n=227)
  - 71% of hypoglycemic episodes occurred in first 12 hours
  - Median 4.5 hours of age
  - 24% had >=1 episodes
  - Blood glucose increase greatest after
    - Formula feeding v other feeding (p=.01)
    - Dextrose gel v placebo (p=.01) regardless of feeding type
  - Breastfeeding reduced need for repeat gel treatment (OR=0.52, CI 0.28-0.94I p=0.03)

Newman, K & Bunch, M (2017)

“No standardized guidelines that include the use of dextrose gel for prevention or treatment...although many hospitals have begun to adopt use of the gel. Clinical guidelines should be revised to include use of dextrose gel while long term studies clarifying thresholds for treatment are completed.”


• Brief Review of Literature
• Case study of a Pre and Post glucose gel experience from patient perspective
• Sample Protocol and staff teaching tips
  – Examples on how to draw up gel
  – Wiping out mouth with gauze
  – Splitting the dose and administering buccal with massage

Timeline

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1st Work Team – Develop Protocol

• Providers: Neonatology, Family Practice, Pediatric Dept. Chair, NNP, Community Pediatrician
• Nursing: LD RN, CNS, Asst LDRP Manager, NICU Manager
• Pharmacy

• Goal: Can we keep babies with their Moms and out of the NICU while still trying to protect breastmilk feeding?
  — Must have the gel stocked on the unit and on Override and given per Protocol.
  — Need EHR to calculate dosing quickly and ability to distinguish Neonatal gel dosing from Adult

Challenges and Replies

• Feeding can bring up blood sugar by itself do we really want to intervene? AAP supports feed and recheck....
• What about preservatives?
• What about the flavoring?
• Rebound hypoglycemia?
• Preservative in the gel was similar to the competitor brand of 24% sucrose neonatal liquid used for pain relief
• Fewer preservatives and “less” flavor that infant acetaminophen
• Studies reviewed did not show this as a major concern nor did those who presented at AWHONN report rebound hypoglycemia. Keep encouraging PO feeds q2 hr and skin to skin to reduce the risk. Additionally our protocols call for continued monitoring of POCT glucose at subsequent feeds

Syringes......

$$_$$$_
Glucose Gel and E.H.R

Auto Calculates based on weight entered into the flowsheets

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- Go live Protocol (10/2016)
  - Extra selling

Glucose Gel Protocol – Version 1

- Protocol
  - ≥ 35 weeks
  - < 48 hr of age, LDRP/Nursery
  - MAX 2 doses for 1 episode
  - Limit 4 doses in 24 hours
  - Feed & skin to skin after all gel treatment
  - Repeat POCT glucose 1 hr after gel
- RN to treat with gel and call with any symptomatic neonate
- Treatment is based on POST-feeding POCT glucose for asymptomatic infants (If the orders state to “Refeed”) initially ...
- NICU may give with provider order only

Sample Orders for SGA/ Preterm Monitoring 2016

- D/T and Value POCT Glucose Prior to Gel1 (feed)
- D/T and Quality of Feeding
- D/T of Glucose Gel1 – Fed post gel? Quality/type? Skin to Skin?
- D/T and Value POCT Glucose Post Gel1
- If needed – D/T of Glucose Gel2
- D/T and Value of POCT Glucose Post Gel2
- Transfer to NICU? IV Glucose? Additional Treatment? Comments?

Audit Report

- MRN, DOB/Time, EGA, Weight, Feeding Intent, Reason for Monitoring
- D/T and Value POCT Glucose Prior to Gel1 (feed)
  - D/T and Quality of Feeding
- D/T of Glucose Gel1 – Fed post gel? Quality/type? Skin to Skin?
- D/T and Value POCT Glucose Post Gel1
- If needed – D/T of Glucose Gel2
- D/T and Value of POCT Glucose Post Gel2
- Transfer to NICU? IV Glucose? Additional Treatment? Comments?
Early Opportunities Identified

- Gel doesn’t replace a feeding
- Don’t supplement AND give gel — Goal is to keep mom/baby together and promote breastfeeding not supplementing
- Provider orders to NOT give gel
- Goal is over 45 mg/dl not 35 mg/dl
- Not intended to treat persistent hypoglycemia
- General confusion as to when exactly to gel because it wasn’t clear in the order set as the order set was written before gel was ever talked about.

4 MONTHS GOES BY.....

Order Set Revision....Some Improvement....

Timeline

- Go live Protocol (10/2016) — Extra selling
- 4 month — Evaluation Presented to Division of Peds (4/2017)
- Normal Newborn Policy & Protocol due for Review (4/2017) — Workgroup requested to revisit Hypoglycemia and Glucose Gel
- Order set revision again – (6/2017 recommendations approved Division)
- Re-education of staff by Staff Champions and Charge Nurses (8/2017)
- Glucose Gel Policy/Newborn Order Set revision live (8/29/2017)

Staff Concerns Since Implementation

- “It’s really hard to convince a late preterm to eat the first time, let alone eat twice and then add in low blood sugar....”
- “Is it really okay to allow the blood sugar to be low for 2 or 3 hours? It seems like we are needing to do a lot of 2nd gel doses and it’s because babies are just wiped out and don’t want to eat again and again.”
- “Seems like all these gel doses are forcing a lot more heel pokes than before we had gel!”
- “Shouldn’t there be a cut off of too low – POC Glucose <25 really should at least be called to provider or go to NICU, even if they are asymptomatic....”

2nd Work Team – Revisions

- Providers: FP Senior Resident
- Nursing: Mom-Baby RN, New Grad RN/Orientee, L&D RN, CNS, CNS student
- Goals of 2nd Work Group- Clarification, Simplification, Safety Net
Recommendations

- Add Glucose gel to Newborn order set default selected as PRN hypoglycemia with limit of 4 doses
- Add verbiage “Feed within 1 hour of life”, time first POCT glucose to RN worklist
- Changed verbiage in order set to add clarification for both normal and abnormal blood sugars

Timeline

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Highlight of changes

Prior to Changes

- Gel is done based on low post feeding POCT values unless the infant had a prior hypoglycemic event

After the Changes

- Glucose gel will be given with low POCT values prefeed and if remains low post feed.
- No more consideration for if infant had prior hypoglycemic event in determining when to gel
- So we will gel sooner and hopefully need less 2nd doses

NEW Order Sets Modifications

- Clarification of Glucose Homeostasis
  - Notify physician if infant does not achieve glucose homeostasis (2 consecutive PRE feed blood sugars greater than or equal to 45mg/dl) is not achieved by indicated time.
- Clarification re: actions if symptomatic
  - If infant symptomatic and POCT less than 40, RN to order STAT serum glucose, administer glucose gel, feed infant and notify physician. Do not hold gel/feed awaiting lab draw.

We still will check POCT glucose at the same times, for the same reasons and, for the same length of time... BUT when we gel is changing
NEW Order Set Modifications - Asymptomatic

- Initial glucose instructions to include “feed within 1 hour of life and check POCT glucose 30 minutes after first feeding”

NEW Order Sets - Asymptomatic

Birth to 4 hours
Routine, continuous for 4 hours. If initial POCT glucose is greater than or equal to 25, continue POCT prior to each feeding: encourage feeding every 2-3 hours.

1. If initial POCT glucose is less than 25:
   - Administer gel, infused intravenously and notify physician. Recheck POCT 1 hour after gel
   - If repeat POCT glucose:
     - Less than 25: administer gel, infuse and notify physician. Recheck POCT 1 hr after gel
     - 25-40: administer gel, infuse and notify POCT
     - Greater than 40, continue POCT prior to each feeding: encourage feeding every 2-3 hrs.

2. Notify physician if infant does not achieve POCT greater than 40 after 2 doses of gel.

4 hr to 24 hr (or 12 hr if LGA, IDM)
Routine, continuous for 24 hours. If prefeed POCT glucose is greater than or equal to 35, continue POCT prior to each feeding: encourage feeding every 2-3 hours.

1. If prefeed POCT glucose is less than 35:
   - Administer gel, feed and recheck POCT glucose 1 hour after gel
   - If repeat POCT glucose:
     - Less than 35: administer gel, refeed, and notify physician. Recheck POCT 1 hour after gel
     - 35-45: administer gel, refeed and recheck POCT 1 hour after gel
     - Greater than 45, continue POCT prior to each feeding: encourage feeding every 2-3 hrs.

2. Notify physician if infant does not achieve POCT greater than 45 after 2 doses of gel or if infant needs more than 4 doses of gel within a 24 hour period.

ASYMPTOMATIC

- Reminders
  - Symptomatic infants with POCT <40 need to be called to provider immediately after gel as they are more likely to need NICU admission
  - If glucose is <25 for 2 hours, call provider for NICU admission order (per NICU Admission policy).
  - Need to get OVER 45 mg/dl if you are treating hypoglycemia.
Reminders

- Glucose gel is ordered “per protocol, co sign required”.
- Gel is stable once opened for 1 hour. After that you will need to obtain a new one
- SKIN TO SKIN is key as it allows for better stabilization/homeostasis of neonate

Timeline

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  — Extra selling
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- Glucose Gel Policy/Newborn Order Set revision live (8/29/2017)
- Continued Staff support and education

The Data

PDSA Cycle 1 (8/2016-8/2017)
- 71 hypoglycemic episodes
- 60 babies
- 70.4% Intended to Breastfeed
  — 1.4% Intend to Formula feed
- Mean EGA=38 1/7
- Mean POCT Glucose PreGel1 =31
- Mean Increase in POCT after 1st dose of Gel =18.39
- 25.4% episodes require 2 doses of gel
- 23.3% of babies needing gel were ultimately admitted to NICU admission or needed IV glucose

PDSA Cycle 2 (9/2017-3/8/2018)
- 61 episodes
- 50 babies
- 96.7% Intended to Breastfeed
  — 3.3% Intend to Formula feed
- Mean EGA=38 2/7
- Mean POCT Glucose PreGel1 =29
- Mean Increase in POCT after 1st dose of gel =18.03
- 31.1% episodes require 2 doses of gel
- 8% of babies needing gel were ultimately admitted to NICU admission or needed IV glucose
  — (p=0.05)
Combining Both Cycles (132 Episodes)

**NICU Admissions/IV Glucose**
- 18 Babies
- Mean POCT Glucose prior to Gel1 = 27.79 mg/dl
- Mean Increase in POCT Glucose after Gel1 = 12 mg/dl
  - Range of increase: -23 to 57
- Mean EGA = 37 6/7

**Infants Remaining on LDRP**
- 92 Babies
- Mean POCT Glucose prior to Gel1 = 30 mg/dl
- Mean Increase in POCT Glucose after Gel1 = 19 mg/dl
  - Range of increase: -8 to 78
- Mean EGA = 38 1/7

Combined PDSA Cycles

Combine PDSA – IDM (42 episodes)
Breastfeeding Rate PC-05

Glucose gel wasn't the only thing we did in this time span but it helped promote the message and remove barriers to promoting and protecting exclusive breastfeeding.

Thanks to the Team

and many more staff nurses who helped with audits as well as coaching/educating their peers.

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