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Matthew Turnquist
Maine Medical Center

Amy Haskins
Maine Medical Center

Christina Holt
Maine Medical Center

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Validity of neonatal POC glucose testing

Matthew Turnquist, MD[1], Amy Haskins, PhD[1], Christina Holt, MD, MSc[1]

[1]Maine Medical Center, Department of Family Medicine, Portland, ME

Background

Glucose monitoring a common invasive intervention in newborn period
- most commonly obtained laboratory value

Appropriate identification of hypoglycemia is critical:
- Severe hypoglycemia can lead to neurologic insult
- Cerebral palsy, developmental delay, seizures, death

Critical Issues

POC glucometers are subject to error in situations very common in neonates:
- Hypoxemia
- Poor perfusion
- Hyperbilirubinemia
- Abnormal hematocrit
- Acetaminophen administration
- Alcohol on the overlying skin
- Peripheral vasoconstriction

Current Recommendations vary:

ISO 2003 - 95% of values should fall:
- within +/- 15 mg/dl for glucose concentrations < 75 mg/dl

ISO 2013 - 95% of values should fall:
- within +/- 15 mg/dl for glucose concentrations < 100 mg/dl

FDA 2014 - 99% of all values should fall:
- within +/- 7 mg/dl for values < 70 mg/dl

Analysis of 17 different POC devices in 2017:
- 7 met ISO 2003 Criteria.
- 2 met ISO 2013 criteria (Ekhlaspour et al, 2017).

MMC uses FreeStyle Precision Pro meters, manufactured by Abbott
- No independent validation trial
- manufacturer website states that they are ISO 2013 compliant
- Not studied in neonates

GOOD NEWS! YOUR TEST INDICATES THAT YOU'RE IN THE NORMAL RANGE!

LOW   NORMAL   HIGH
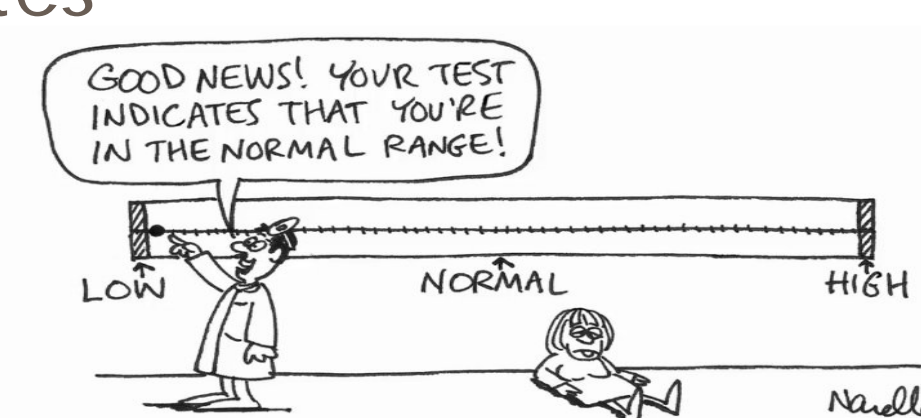
Question

What is the accuracy of neonatal glucose measures at MMC?

Methods

- Retrospective data analysis

INCLUDED:
- all infants on the FM and Newborn services from July 1st, 2017 to June 30th, 2018.
- < 30 days old
- had both a POC and a serum measurement performed within 30 minutes of one another, and no documented feeding or administration of glucose in the intervening time

EXCLUDED:
- Infants w/glucose of nutrition within 30 min of the first measurement with rising glucose value

Characteristics of Patients

Table 1: Properties of blood glucose samples by delivery type, age, and ICD10 codes (N=141)

		Number of infants	%
Delivery Type			
	Vaginal	74	52.48%
	C-section	65	46.10%
	Transfer from outside hospital	2	1.42%
Age in days			
	0	66	46.81%
	1	52	36.88%
	2-3	19	13.48%
	4+	4	2.84%
SGA		19	13.48%
LGA		18	12.77%
At risk for hypoglycemia		42	29.79%
DM in Mother		10	7.09%
Neonatal sepsis		0	0%
Hypoglycemia		19	13.48%
Neonatal seizure		0	0%
Neonatal abstinence		4	2.84%
Infants with multiple diagnosis codes		19	13.48%

RESULTS

POC values as a Function of serum values
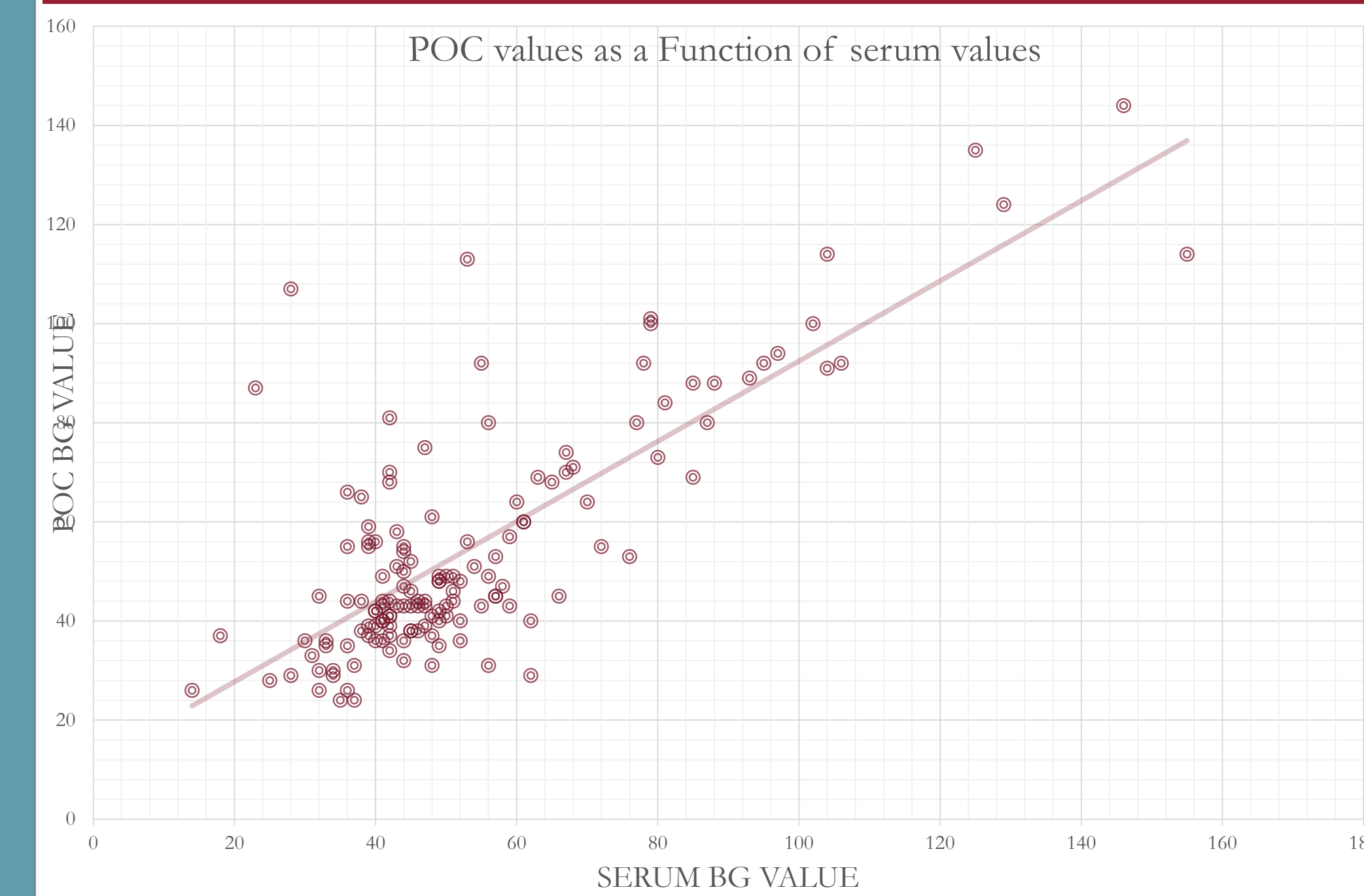
Mean Serum - POC reflects degree of bias. All categories have significant error in measurement, but only in neonates with low serum measurements is that error biased toward overestimation.

	N	Mean absolute difference (mg/dl)	Standard deviation of absolute difference (mg/dl)	Mean POC	Mean Serum	Mean Serum-POC
Overall	141	10.23	12.14	54.93	53.74	-1.19
Serum <40	31	13.13	17.59	42.32	33.07	-9.25
Serum >40	110	9.42	10.06	58.48	59.43	0.95
Age in Days						
0	66	9.82	9.69	53.38	54.11	0.73
1	52	11.4	15.86	55.90	53.00	2.90
2-3	19	8.74	9.19	56.53	52.11	-4.42
4+	4	9.00	4.69	60.25	61.25	1.00
Weight						
AGA	104	9.99	11.52	57.36	55.83	-1.53
SGA	19	8.42	6.59	49.32	49.42	0.10
LGA	18	13.56	18.67	46.83	45.38	-1.45
Infant of DM Mother	10	9.20	9.89	55.50	54.90	-0.60

POC Glucometer performance relative to ISO Guidelines

	Number of samples	Number of POC > 15 mg/dl different than Serum
Overall	141	30 (21.28%)
Serum <40	31	9 (29.03%)
Age in Days		
0	66	14 (21.21%)
1	52	12 (23.08%
2-3	19	3 (15.79%)
4+	4	1 (25.00%)
Weight		
AGA	104	22 (21.15%)
SGA	19	3 (15.79%)
LGA	18	6 (33.33%)

RESULTS

POC Sensitivity for BG <40: 64.5% (± 16.4%)

POC Specificity for BG <40: 52.6% (± 15.9%)

	Serum <40	Serum ≥40
POC <40	20	18
POC ≥40	11	92

CONCLUSIONS:

- Our POC meter appears to have poor sensitivity for hypoglycemia

- Our meter appears to have clinically significant error, with a bias toward overestimation of glucose in hypoglycemic infants

- Our meter does not appear to be meeting FDA or ISO guidelines in this population

Strengths and Limitations

Retrospective data analysis resulted variable timing of POC and serum testing (mean of 16 minutes between samples, SD of 8 min). This study would benefit from an interventional design with simultaneous measurements.

All intervention times were based on Epic records, which may not be entirely accurate or complete.

Acknowledgements

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