Pregestational Diabetes Mellitus Pilot Study with Diabetes Self Management Program (DSMP) and Wireless Enabled Meter

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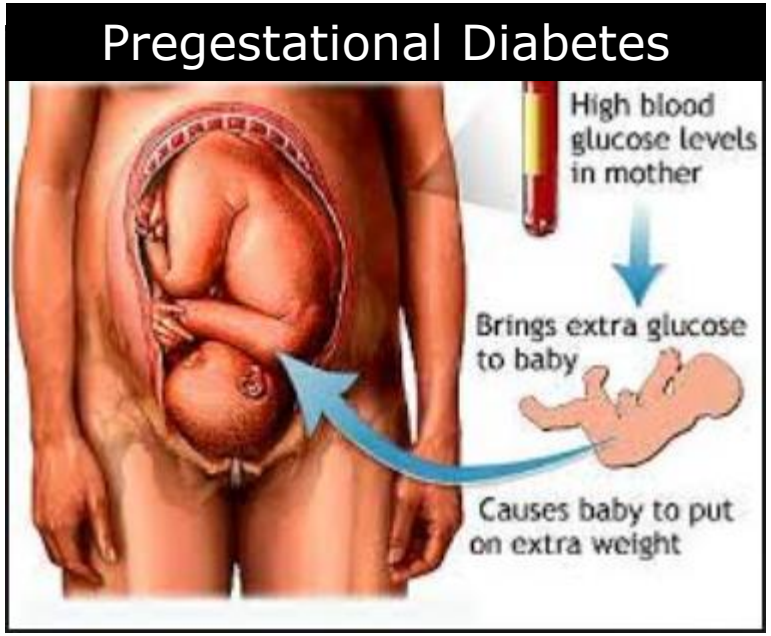
Disclosure

I have no meaningful conflicts of interest to declare.

Background

Background

- 14.9 million women have diabetes
- Type I or II complicates 1-2% of pregnancies
- Higher incidence in African Americans & Hispanics compared to Caucasians
- Obesity



Background

- Uncontrolled DM leads to:
  - SAB
  - Fetal anomalies
  - Preeclampsia
  - IUFD
  - Macrosomia
  - Neonatal hypoglycemia
  - Neonatal hyperbilirubinemia

Background

Insulin resistance increases with trimester	More frequent monitoring Medication adjustments
ACOG recommends targeted therapy for DM	Diet Exercise Nutrition counseling
OB/GYN Center: 2775 patients/year	16% have history of or overt diabetes
May 2016 Diabetes Self-Management program began	15-30 minute diabetes education sessions

Purpose

The purpose of this study is to provide improved management of diabetes during pregnancy using remote patient monitoring and improve patient understanding of diabetes and diabetes self-management.

Methods

Methods

- **Pilot study:** Prospective and retrospective
- ***Inclusion criteria*:**
  - Patients with pre-gestational Type I or II diabetes
  - 18 years or older
  - Care at OB/GYN Center
- ***Exclusion criteria*:**
  - Patients with gestational diabetes

Methods

Recruitment

- Patient presented for prenatal care
- Assessment
- Referred to DSMP via EMR
- CDE performed initial education visit

Methods

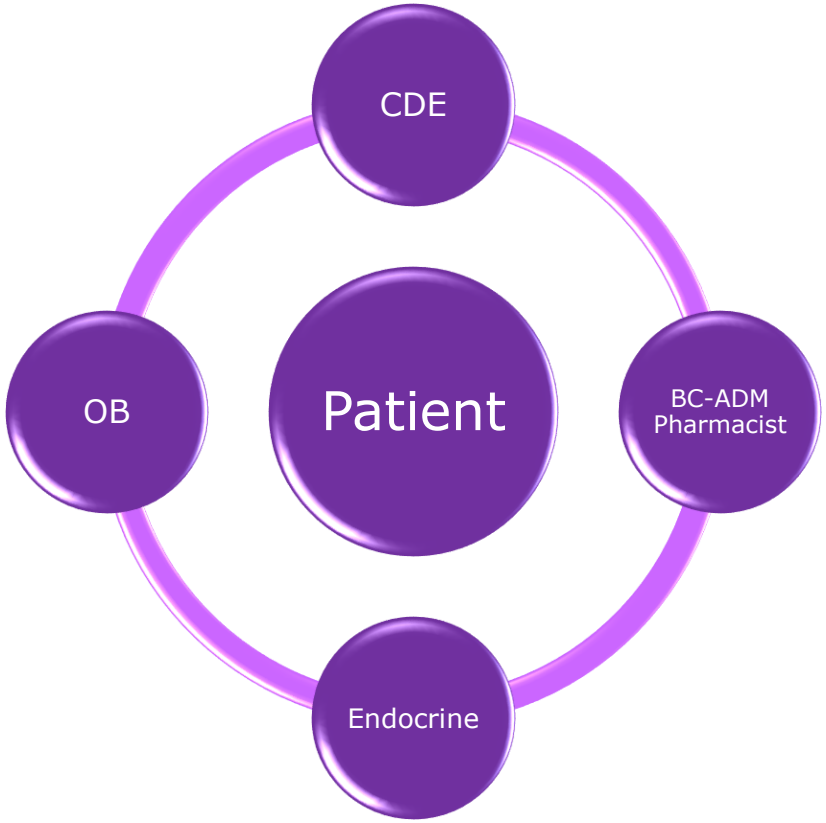
Retrospective group

- June 2016 - January 2017
- 25 patients
- Standard of care
  - *CGM

Intervention group

- February 2017 - January 2018
- 25 patients
- Standard of care with enhanced model
  - Wireless meter
  - *CGM

Methods



Patient Care Team

- Co-management for treatment decisions
  - 15-30 minute CDE session
  - Face-to-face contact with OB
  - Referral as needed

Methods

Data Collection

- Between visits: Remote review, contacted patient via text/phone/email/meter message
- EMR documentation
- Chart review
- RedCap database
- PHQ-8 at study start and end
- Diabetes Assessment Pre/post-questionnaire

Methods

Outcomes

Primary:

- Increased adherence rate of DM monitoring
- Increased medication utilization

Secondary:

- Improved patient understanding
- Improved self-management
- Decreased hyper/hypoglycemic events
- Time to achieve euglycemia
- Less pre-delivery admissions
- Less maternal-fetal complications

Statistical Analysis

R STATISTICAL SOFTWARE

STUDENT'S *T*-TEST OR WILCOXON RANK-SUM

CHI-SQUARED OR FISHER'S EXACT TEST

P-VALUES < 0.05 WERE STATISTICALLY SIGNIFICANT

Results

Results

Demographics

- Only one baseline difference noted

Intervention group started study at **10.8** weeks

Standard group started study at **15.4** weeks

(p = 0.02)

Results

Table 1: Demographics			
	Type of Participant		
	Intervention	Standard Diabetes Care	P-value
N	25	25	
Age, Mean ± SD	29.2 ± 6.16	31.6 ± 6.39	0.174
Pregestational Diabetic Type, N(%)			0.529
Type 1	8 (32)	6 (24)	
Type 2	17 (68)	19 (76)	
Gestational Age at Enrollment, Mean ± SD	16.2 ± 7.18	NA	
Gestational Age at Start of Study, Mean ± SD	10.8 ± 4.82	15.4 ± 7.93	0.028
On Medication at Study Start, N(%)			0.758
Yes	17 (68)	18 (72)	
No	8 (32)	7 (28)	
Number of Medications at Study Start, N(%)			0.295
1	8 (32)	4 (16)	
2	8 (32)	12 (48)	
3	1 (4)	2 (8)	
4	0 (0)	0 (0)	
5	0 (0)	0 (0)	
>5	0(0)	0(0)	
NA	8 (32)	7 (28)	
Type of Medication, N(%)			
Metformin	6 (24)	3 (12)	0.269
Glyburide	1 (4)	0 (0)	0.312
DPP-4	0 (0)	0 (0)	
SGLT2	0 (0)	0 (0)	
Insulin	12 (48)	17 (68)	
Patient Provided Glucose Log at Study Start, N(%)			
Yes	23 (92)	NA	
No	2 (8)	NA	

Results

Tracking Visits

- No differences noted in type and number of visits
  - Prenatal care visits
  - Hospital admissions
  - Emergency Department
  - OB Triage
  - LOS

Results

Educator Visits

Contact via Text

- Intervention: N of 13
- Standard: N of 4

***p* = 0.007**

Contact via Phone

- Intervention: mean 9.65
- Standard: mean 5.27

***p* = 0.011**

Contact via Office

- Intervention: mean 12.8
- Standard: mean 8.72

***p* = 0.017**

Results

- Intervention group spent more time in education vs. standard care group
  - 4.44 hours vs. 2.89 hours
  - $p = 0.03$

Results

Pregnancy Outcomes

- No differences in:
  - Medication adjustments
  - Timing/amount of hyper/hypoglycemic events
  - Mode of delivery
  - Infant anomalies
  - Infant delivery weight
  - Delivery gestational age
  - APGARs
  - Delivery complications

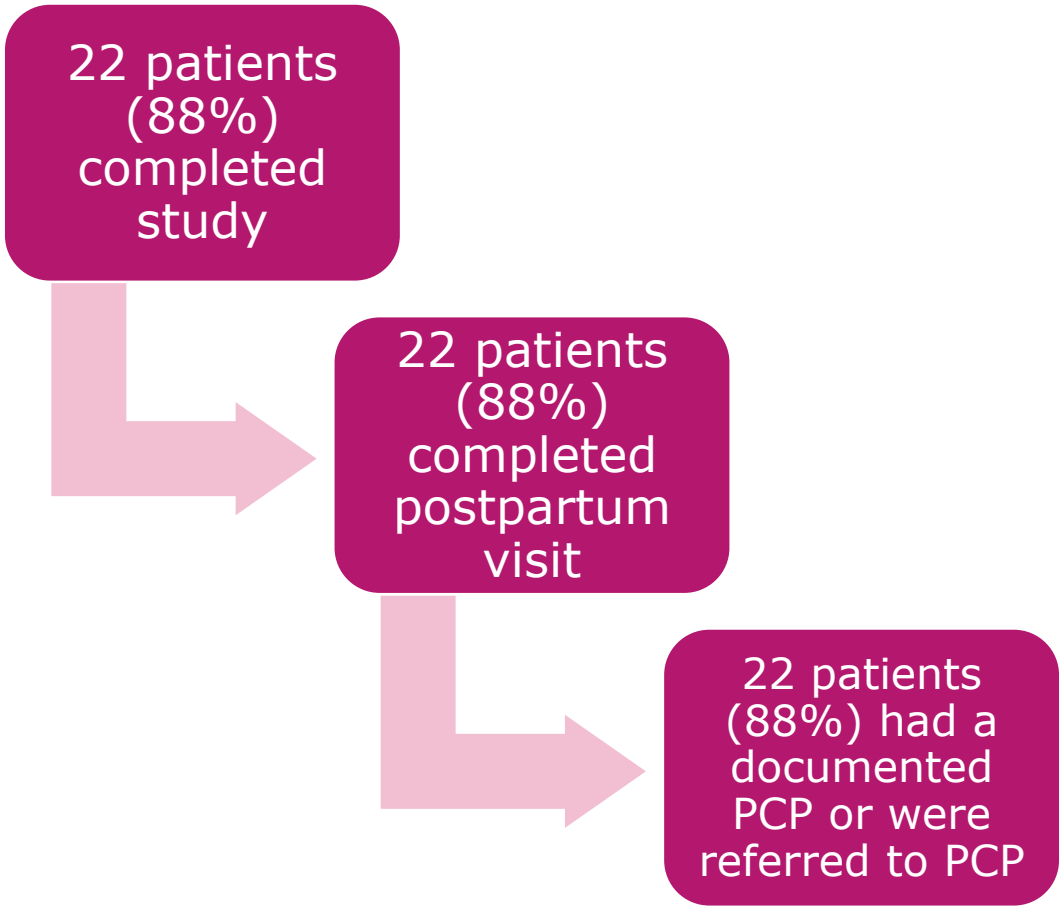
Results

Pregnancy Outcomes

	Intervention (n = 25)	Control (n = 25)	*p*-value
Hypoglycemic events	12.7 ± 22.7	5.6 ± 9.02	0.180
Hyperglycemic events	20.5 ± 29.1	9.32 ± 19.7	0.141
Use of continuous glucose monitor, n (%)	15 (60)	6 (24)	0.010
Gestational age at delivery, weeks	34.8 ± 4	36 ± 2.45	0.213
Neonatal hypoglycemia, n (%)	3 (12)	9 (26)	0.047

Results

Postpartum Outcomes



Results

Questionnaires

- PHQ-8:
  - Pre-test – 22 patients, mean score 13.8
  - Post-test – 5 patients, mean score 5
  - Score ≥ 10 indicates major depression
- Diabetes Assessment:
  - No differences noted pre-test to post-test

Discussion

Discussion

Increased phone contacts, office visits and text messaging noted for intervention group

Overall increased time in education

More use of CGM along with wireless meter

Accurate, real-time data

Log comparison

Better informed treatment decisions

Earlier delivery

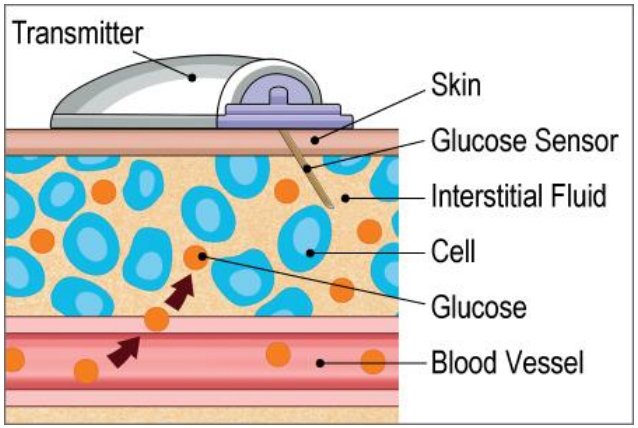
Decreased neonatal hypoglycemia

Discussion

- 88% of intervention group:
  - Completed the study
  - Postpartum visit
  - Long-term follow up with PCP
- Postpartum
  - Lost to follow up
  - Insurance coverage ends with pregnancy
  - End of access to care
- Technology improves biofeedback and ownership of disease process

Discussion

- Telehealth impact on obstetrics
  - 2010 Patient Protection and Affordable Care Act
- Mixed data on outcomes
  - 2017 Cochrane review
  - CONCEPPT trial
- Continuous glucose monitor (CGM)



Patient Log

9/24
fasting - 120
2 hr brk - 127
2 hr lun - 131
2 hr din - 139

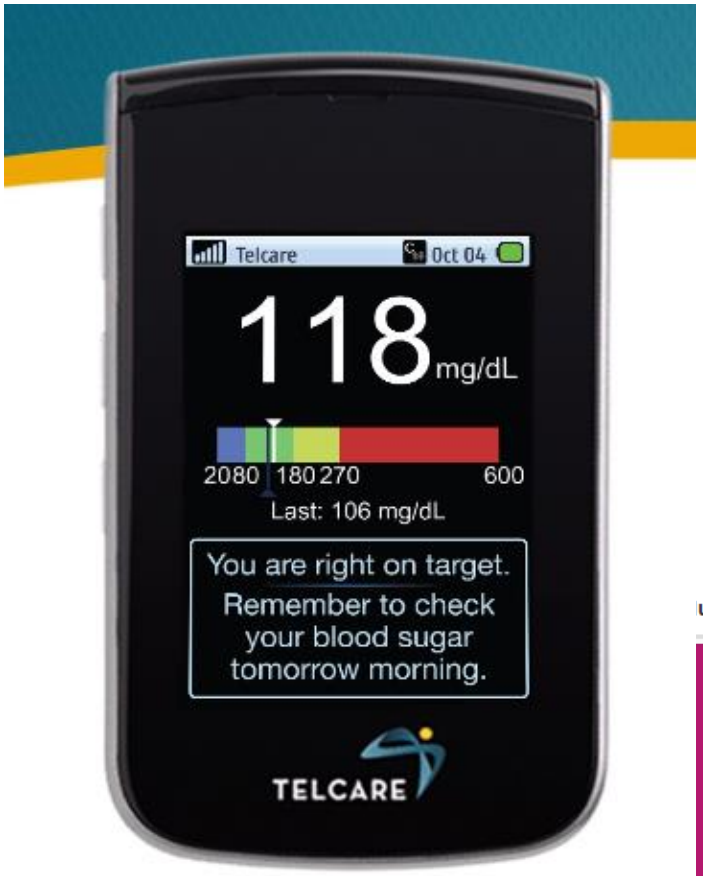
9/25
2 hr brk - 130
2 hr din - 146

9/26
fasting - 98
2 hrs brk - 136
2 hrs lun - 142
2 hrs din - 151

9/27
fasting - 107
2 hrs brk - 123
2 hrs lun - 133
2 hrs din - 147

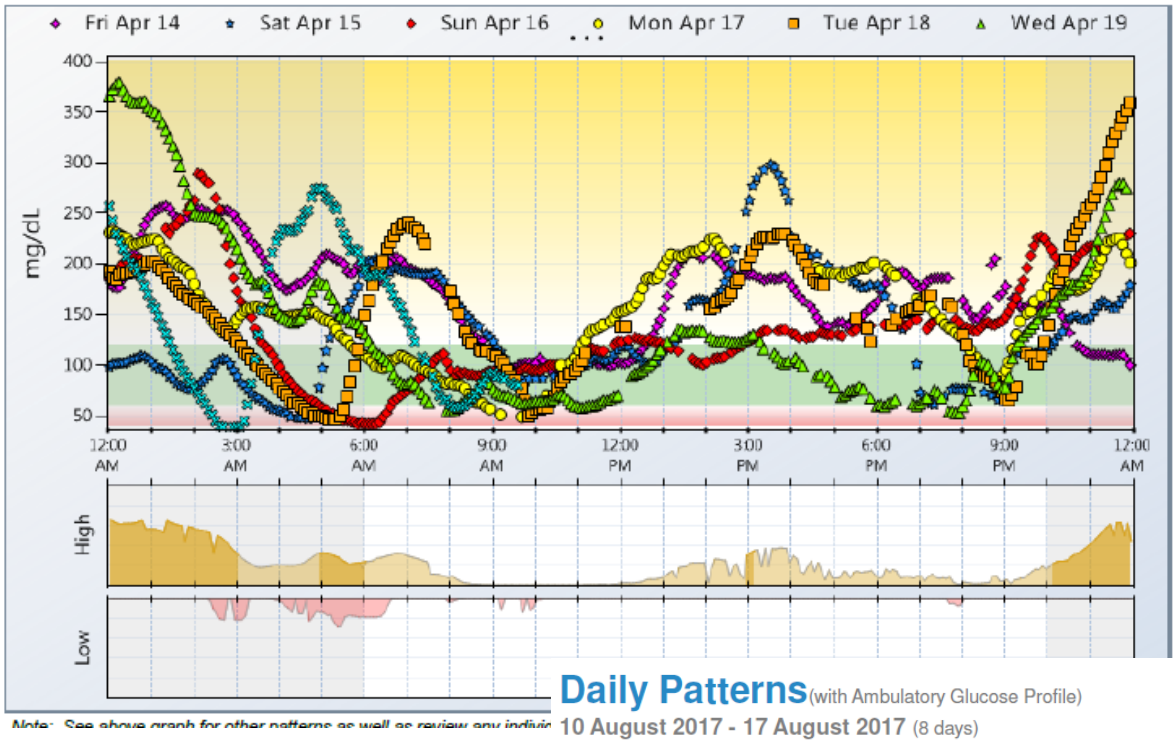
9/28
fasting - 116
2 hrs brk - 130
2 hrs lun - 138
2 hrs din - 148

9/29
fasting - 122
2 hrs brk - 131
2 hrs lun - 136
2 hrs din - 152

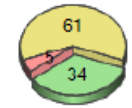


Telcare System

um	Active Date	Daily Tests	Prescribed	Adherence	Last Reading	Low Readings (24h)	High Readings (24h)
	2017-04-27	0.29	4	0.07	2019-05-04	0	0
	2017-04-27	0.00	7	0.00	2018-03-05	0	0
	2017-05-02	0.00	4	0.00	2017-09-26	0	0
	2017-05-04	0.00	7	0.00	2018-03-01	0	0
	2017-05-11	0.00	4	0.00	2017-08-15	0	0
	2017-05-16	0.00	4	0.00	2017-08-11	0	0
	2017-05-18	0.00	4	0.00	2017-09-17	0	0
	2017-05-18	0.00	4	0.00	2017-08-12	0	0
	2017-05-30	0.00	0	0	2017-09-20	0	0
	2017-05-30	0.00	7	0.00	2017-11-29	0	0
	2017-06-01	0.00	4	0.00	2018-02-28	0	0



Statistics	
Average Glucose	147 mg/dL
Sensor Usage	7 of 7 Days
Calibrations / day	3.7
Standard Deviation	± 63 mg/dL
	61 % High
	34 % Target
	5 % Low
Target Range	60 - 120 mg/dL
Nighttime	10:00 PM - 6:00 AM



Interpretation

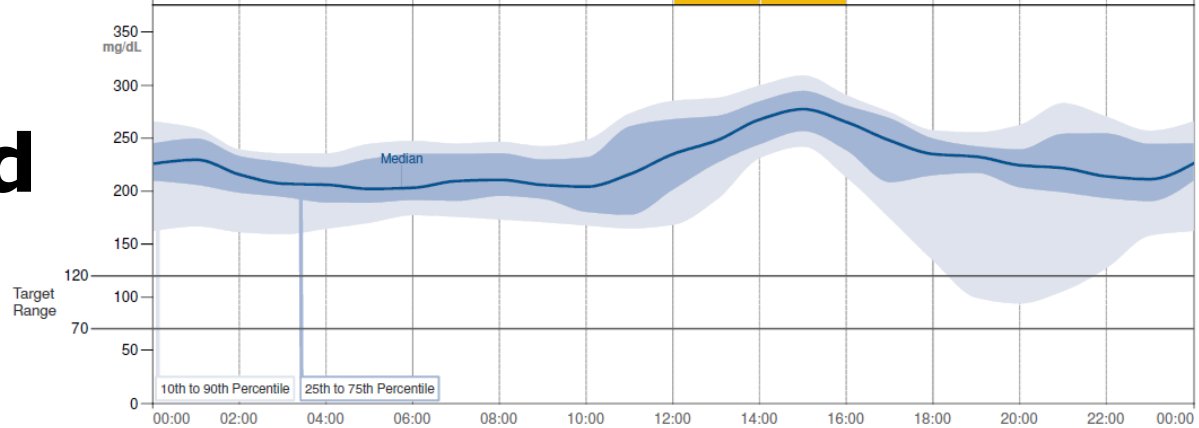
Daily Patterns (with Ambulatory Glucose Profile)

10 August 2017 - 17 August 2017 (8 days)

FreeStyle Libre Pro

Estimated A1c 9.4%, or 79 mmol/mol

	Daily Average	00:00	02:00	04:00	06:00	08:00	10:00	12:00	14:00	16:00	18:00	20:00	22:00	00:00
Glucose mg/dL	222	223	205	207	211	209	219	246 High	275 High	235	214	216	213	



CGM Download

Discussion

- Study limitations
  - Sample size
  - Patient buy-in
    - Glucose testing 1-2X/day
    - Recommended 4X/day
- Convenience of testing
- Social barriers to healthcare
  - Remote data review and treatment adjustments
- Improved communication
- Results clinically significant

Conclusion

- Remote glucose monitoring with wireless technology in diabetes for pregnant mothers is an enhanced care model
- More time is spent in education
- Treatment decisions are more obvious
- Leads to improved patient engagement

Future Implications

Studies to include a larger patient population and patients with gestational diabetes.

The standard of care

Acknowledgements

Faculty Mentor: Dr. Megan Schellinger, Dr. Jessica Odom

DM Educators: Kathy Fincher, Casey Fiocchi, Michelle Stancil, Dr. Jessica Odom, Hannah White

Statistics Team: Dr. Alex Ewing, Xiyan Tan

Allison Heustess, Sarah Thibaudeau

Grant Funding: Dept. of OB/GYN

Residents and Staff of OB/GYN Center

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