Research Proposal: Impact of Student Pharmacist-Led Educational Intervention on the Management of Gestational Diabetes (SPEID)

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Background

- National data shows an increasing prevalence of gestational diabetes mellitus (GDM), complicating 1 out of every 12 pregnancies[1,2].
- GDM has been associated with an increased risk of maternal and fetal complications, including new-onset type 2 diabetes (T2DM), preeclampsia, and macrosomia[1,3].
- Clinical pharmacy services and interventions have demonstrated benefit for patient outcomes across many disease states[4,5].
- Expanding care to include a targeted, student pharmacist-led educational intervention in GDM management has potential merits for both students to gain clinical expertise and patients to improve glycemic control.

Aims & Hypothesis

Hypothesis: In comparison to hospital standards of care, the inclusion of APPE student-led educational interventions as part of multidisciplinary care will improve blood sugar management, patient quality of life, and diabetes knowledge in women with gestational diabetes.

Aims: Assess the effect of APPE student-led educational intervention on…

I. Blood sugar management in patients with GDM.
II. Maternal and fetal outcomes in patients with GDM.
III. Quality of life (QOL) in patients with GDM.
IV. Diabetes knowledge and self-management in patients with GDM.

Methodology

Study Design

We propose a **single-center, prospective, open-label randomized controlled study** over a 1.5-year enrollment period. Patients will be randomly assigned in a 1:1 ratio to the control or intervention group.

- Setting: Large community teaching hospital with a daily census of 650 patients with an associated outpatient Women's Health Clinic
- Average of 10 APPE students per month

Study Population

- Women at gestational age (GA) 24-28 weeks meeting ADA criteria for diagnosis of GDM[1].

Sample Size & Power Calculation

We estimate that a total of 142 patients are required to give us 80% power to detect a difference at a two-sided significance level of $\alpha = 0.05$[5,6].

Endpoints

- Primary: Proportion of patients with FPG ≤ 95 mg/dL at 9 months GA.
- Secondary: Percent change in A1C from baseline to 9 months GA, OGTT results, hypoglycemic episodes, maternal & fetal outcomes, diabetes knowledge, self-management, and QOL.

Timeline

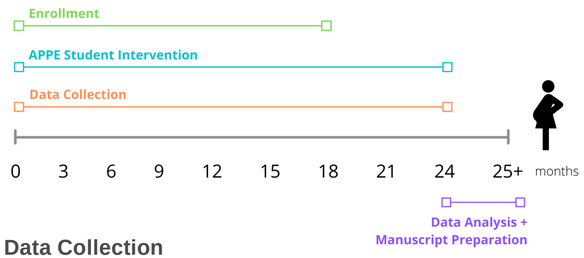
Intervention

APPE students will receive a mandatory 2-hour training module, consisting of pre- and post-assessment questions regarding GDM knowledge and confidence in counseling with a mock counseling session with a preceptor.

- 1st visit (baseline): Student will review standardized educational materials, self-monitoring of blood glucose, and relevant pharmacologic therapy counseling information with patient.
- 2nd visit (1 mo. post-enrollment), 3rd visit (9 months GA), 4th visit (6-8 weeks postpartum): Students will reinforce lifestyle modifications, assess glycemic control, and answer patient-specific questions.

Control

The control group will receive the hospital's standard of care with visits to an endocrinologist, obstetrician-gynecologist (OB-GYN), and dietician.



Data Collection

- At each (1st, 2nd, 3rd, and 4th) visit, patients will have their fasting plasma glucose (FPG) measured and fill out 3 questionnaires – SF-36, DKT2, and DSMQ.
- Patients' A1C levels will be taken at baseline (1st visit) and 9 months GA (3rd visit).
- A 75-g OGTT (oral glucose tolerance test) will be administered 6-8 weeks postpartum (4th visit).

Statistical Analysis

All outcomes will be analyzed based on the intent-to-treat population.

Budget Allocation

Total Cost: $49,280.20

- The clinical pharmacist (PI)'s and OB-GYN's pays account for a total of $22,380.20[7,8].
- Patients will be compensated $22.50 per visit (totaling $90 across all 4 visits) for their time – total $16,200.
- Costs of laboratory tests[9] (FPG, A1C, OGTT) and external statistical analysis are a total of $10,700.

Feasibility & Limitations

- Delivery of patient education may be inconsistent among APPE students.
- Treatment bias may occur due to the unblinded nature of the study.
- Relying on patient-reported hypoglycemic episodes may introduce recall bias into the data collection and affect internal validity.

Impact & Future Directions

- Current lack of data on similar interventions in the management of GDM demonstrates a gap in treatment understanding for this population of pregnant women.
- Similar types of APPE student-based interventions can be developed for patients with other disease states, thereby allowing students to strengthen their clinical skills and benefit a larger patient population.
- Future studies can lengthen the time frame in order to examine maternal onset of T2DM.

References

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