



# Empagliflozin and/or Metformin: a Combination Approach for Uncontrolled Type 2 Diabetes

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## Introduction

Increased emphasis has been placed on glycemic management in response to the rising prevalence of type 2 diabetes mellitus (T2DM) in the United States. Type 2 Diabetes is a chronic progressive disease associated with severe complications that include cardiovascular disease, stroke, amputation, end-stage kidney disease, blindness, and premature death. The United States Centers for Disease Control and Prevention (CDC) estimates that over 34.2 million people are living with diabetes in the United States alone; 90–95% of these individuals have been diagnosed with T2DM (Rowley et al., 2017). With more than 4000 new cases of diabetes are diagnosed each day, the CDC predicts that the number of people living with diabetes may reach ~55 million. The resources needed to provide adequate care for all patients with T2DM place a considerable economic burden on healthcare systems that may already be overwhelmed.

Effective clinical management of type 2 diabetes mellitus (T2DM) requires an optimized treatment plan to ensure adequate glycemic control and reduce the incidence of diabetic complications. Because of the progressive nature of T2DM, standard first-line treatment with metformin is frequently insufficient to achieve glycemic control. In these cases, additional agents are required.

## Abstract

**Background:** Current guidelines recommend metformin as the first-line agent for the management of Type 2 Diabetes (T2D) when diet and exercise are insufficient. When monotherapy with metformin is intolerant or contraindicated, or not sufficiently effective to reach the glycated hemoglobin (HbA1c) target, a second anti-glycemic agent (AHA) as an alternative or add-therapy to metformin is recommended by all guidelines. The quality improvement project was initiated in the Fall semester with a 10-day reflective practice log to assess my current practice. A review of the clinical practice log allowed me to evaluate my current practice and to identify three opportunities to improve my practice. I developed three potential PICOT questions and selected one for the QI project with the guidance of my Doctor of Nursing Practice (DNP) chairperson. I performed a literature review in search of the best evidence-based intervention to improve my practice. My current practice is metformin 500-1000mg twice daily. The new evidence-based intervention was to initiate empagliflozin 10-25mg once daily as a monotherapy or as a combination therapy with metformin. After the QI proposal was submitted, an approval letter was obtained from the IRB at UTEP and my work site manager prior to the start of the quality improvement project. The QI project was implemented for six weeks in the Spring term.

## Methods

**Purpose:** This Quality Improvement (QI) project aims to use a sodium-glucose cotransporter 2 (SGLT2) inhibitor alone or in combination with other agents to improve glycemic control in patients 18 to 78 years of age with uncontrolled T2DM (HbA1c >7%) within 4 weeks.

### Context:

This evidence-based QI project was carried out at the Ben Archer Health Center, an FQHC located in rural Las Cruces, New Mexico. There are approximately 12 clinics included within this organization that are distributed throughout the southwest region of the state. The QI project started on September 5, 2021, with CITI training for IRB human research, HIPAA, research populations, ethical considerations, and regulations.

### Intervention:

On September 7, 2021, I conducted a needs assessment using a 10-day reflective practice log (RPL) to identify opportunities to improve my current practice at Ben Archer Health Center. The data that was collected in the RPL included demographics such as age, gender, the reason for the visit, diagnosis, assessment tools used, intervention, and the need for follow up visits. Diagnosis codes (ICD-10) and Current procedural codes (CPT) were also included in the RPL.

### Review of Patients

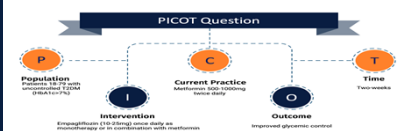
One-hundred-thirteen patients were recorded in the RPL. Thirty-four different diagnoses were identified. Eleven percent were diagnosed with T2DM. Each diagnosis was color coordinated and the top three diagnosis were in specific colors.

### Insights gained

After reviewing my ten-day RPL, I identified three potential opportunities to improve the care that I presently provide for my patients. Three potential PICOT questions were developed. I met with my Doctor of Nursing Practice (DNP) chairperson and selected one PICOT question for the QI project. Once the chairperson approved my project, I performed a literature review.

### PICOT Question

This DNP QI Project aims to use an evidence-based research validated intervention to improve glycemic control in patients with uncontrolled T2DM at Ben Archer Health Center in Las Cruces, NM.



**DNP QI Proposal The Plan-Do-Study-Act (PDSA) model** guided the DNP QI project. This tool involves a circular motion and multiple interactions in an improvement cycle. Plan involves planning the change. Study includes analyzing results. Do is carrying out the change. Study involves analyzing results to determine what went wrong or was learned.



## Theoretical Framework

**Plan:** Identify patients between the ages of 18–79 years with new-onset T2DM or previously-diagnosed T2DM that remained uncontrolled on metformin (i.e., HbA1c >7%). Initiate empagliflozin as monotherapy or as a combination treatment for patients already taking metformin.

**Do:** I documented baseline HbA1c levels before initiating treatment. Patients were scheduled for a two-week post-treatment follow-up to assess drug tolerance and HbA1c levels.

**Study:** I compared HbA1c levels before and after two weeks of treatment.

**Act:** Based on the analysis of the results of HbA1c testing, I determined the efficacy of these drug regimens at improving blood glucose levels in patients 18-79 using an evidence-based intervention.

### IRB application and work site letter approval

The QI project used evidence-based literature and methodologies and complied fully with the federal regulations and requirements regarding the rights and welfare of the human participants. These requirements included: A work letter from work site manager approval letter to implement a QI project, submit QI project proposal and application to UTEP IRB.

On November 9, 2021, UTEP IRB letter of approval was obtained for this QI project entitled “Empagliflozin and/or metformin: A combination approach for uncontrolled Type II diabetes. The IRB determined this project did not meet the definition of human subject research under the purview of the IRB according to federal regulations. On November 01, 2021, I was granted permission by the worksite manager at Ben Archer to conduct the QI project.

### Study of interventions

The QI project was performed during a six-week time frame that started on January 20, 2022. During the first four weeks, the patients were evaluated, and interventions were initiated. The final two weeks were for follow-up. Patients who met inclusion criteria for the QI project were between 18–78 years of age with new-onset or a known diagnosis of T2DM with an HbA1c level >7%. I recorded the HbA1c levels at the initial visit and determined whether or not the patient was taking metformin. I encouraged the patients to measure their fasting blood glucose levels every morning and to bring their glucose logs to their two-week follow-up visit. The patient was then capable of making an informed decision to accept or decline the intervention. The patients who took part in the QI project returned to the clinic two weeks after the initiation of the intervention. I recorded a post-intervention HbA1c level during the follow-up visit to evaluate the efficacy of the treatment protocol. I also recorded weight and blood pressure at each visit. The QI project intervention incorporated the PDSA cycle consistent with its goal.

### Kurt Lewin's Model of Change

The theoretical framework that guided this QI project included a three-step process (i.e., unfreezing, changing, and refreezing). The theory explains the three-step interventions the innovator must accomplish to establish and to make the new evidence base treatment permanent.



## Outcomes

The results of my completed DNP project will have a direct impact on my patients as they will have improved glycemic control on an evidence-based treatment with empagliflozin. Overall, improved fasting glucose levels may also be used to monitor the improved management of T2DM. Additional visits will provide us with the opportunity to address this and other concerns.

## Conclusion

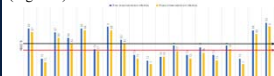
The QI project aimed to improve glycemic control in patients with uncontrolled T2DM using empagliflozin as a monotherapy or in combination with metformin. This QI project showed that the use of an SGLT2 inhibitor to treat T2DM is a safe, tolerable, and effective evidence-based option that will reduce HbA1c and fasting blood glucose levels.

### Ethical Considerations

Inclusion criteria for the QI project required adults 18-78 years of age with uncontrolled T2DM. Patients who qualified for the QI project were consulted regarding the decision to initiate the new treatment. I reviewed the intervention and its intended results with each patient and also discussed the most common side effects of each medication that are currently listed in Epocrates and the literature. The patient was then capable of making an informed decision to accept or decline the intervention.

## Results

Nineteen patients met the inclusion criteria of this QI project. Eighteen were female between the ages of 23–78 years; sixteen of these patients were Hispanic, and two were Caucasian. The one male patient who elected to undergo treatment with empagliflozin was a Hispanic between 40 to 50 years of age. All 19 patients who elected to undergo treatment with empagliflozin completed the recommended follow-up visit scheduled for two weeks following the initiation of treatment. The outcomes of this QI project are shown in Figure 4. The average pre-intervention HbA1c level was 8.08%. The average post-intervention HbA1c level was 7.87%, representing an overall improvement of 0.21% (Figure 4).



In addition to reductions in HbA1c, I observed several other secondary outcomes, including weight loss (Figure 5), increased mental clarity, stronger motivation to manage their T2DM, and improved satisfaction with their treatment regimens.

