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Jose Cedillo

University of San Diego, jcedillo@sandiego.edu

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UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Science

DOCTOR OF NURSING PRACTICE

Implementation of the American Diabetes Association Pharmacological Approach for Adults with

Type 2 Diabetes Mellitus with Cardiovascular Disease

by

Jose Cedillo, BSN, RN

A Doctor of Nursing Practice Portfolio presented to the

FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE

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DOCTOR OF NURSING PRACTICE

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Dr. Pedro Colio, Faculty Advisor

Dr. Cesar Pena, Clinical Mentor

Abstract

Introduction: The purpose of this evidence-based practice project is to improve the utilization of the 2022 ADA pharmacological approach for individuals with Type 2 Diabetic Mellitus (T2DM). The project implementation site was an outpatient clinic in Southern California with a large T2DM Hispanic population. The new ADA guidelines recommend selecting a glucagon-like peptide 1 (GLP-1RA) and/or sodium-glucose cotransporter two inhibitors (SGLT-2) when clinically appropriate to reduce the risk of major cardiovascular events in T2DM patients.

Background: According to the American Diabetes Association, ASCVD is the leading cause of morbidity and mortality for adult individuals with T2DM. The use of GLP-1RA and SGLT-2 is supported by both the American Heart Association (AHA) and the 2022 American Diabetes Association (ADA) Standards of Care for managing patients with cardiovascular disease and T2DM.

Methods: This evidence-based project is meant to promote quality improvement utilizing the Iowa Model to translate research findings into clinical practice.

Results: The project's intervention results demonstrated an increase of 5.1% in the utilization of new ADA treatment guidelines by providers.

Evaluation: Managing treatable risk factors that contribute to the development and progression of atherosclerotic disease is essential for reducing the risk of cardiovascular complications.

Implementing the ADA recommendations will increase the utilization of new evidence-based cardioprotective therapies.

Keywords: Diabetic Mellitus 2, coronary arterial disease, heart disease, atherosclerotic, hyperlipidemia, hypertension, cerebrovascular accident, myocardial infarct, obese, heart failure, left ventricular hypertrophy, Glucagon-like peptide 1, sodium-glucose cotransporter 2

Background and Significance

Atherosclerotic cardiovascular disease (ASCVD) is coronary heart disease (CHD), cerebrovascular disease, or peripheral arterial disease. ASCVD remains the leading cause of disability and mortality for individuals with diabetes. Diabetes mellitus accelerates the development of atherosclerosis due to increased levels of hyperglycemia, oxidative stress, and inflammation. On average, the onset of ASCVD with T2DM is 14.6 years earlier than without a diagnosis of T2DM (Low Wang et al., 2016). It is estimated that two-thirds of deaths in people with diabetes mellitus are attributable to cardiovascular disease (CVD). Types of CVD; 40% from ischemic heart disease, 15% from other forms of heart disease such as congestive heart failure, and 10% from cerebrovascular events (Low Wang et al., 2016). Hispanics are the largest minority in the United States and have an 80% higher rate of diabetes in adults than non-Hispanic whites (Aguayo-Mazzucato et al., 2019). A combination of unique sociocultural, genetic, and cultural factors can help explain the increased prevalence of diabetes in the Latino population (Aguayo-Mazzucato et al., 2019). With DM accelerating ASCVD and certain minorities predisposed to higher onset rates and risk factors, it is essential to consider these factors in pharmacological therapy selection. An estimated \$37.3 billion are spent yearly involving diabetes and cardiovascular disease (ADA, 2017). The new 2022 ADA guidelines consider pre-existing risk factors for ASCVD and advise selecting new proven therapies earlier in the treatment cycle. These new recommendations are based on results from clinical trials using GLP-1 and SGLT-2 for T2DM treatment that demonstrated improved hemoglobin A1c and reduced major adverse cardiovascular events (ADA, 2022). The current standard of care for T2DM includes risk reduction strategies with statins, antihypertensive therapies, and antihyperglycemic treatment therapies. The rates of cardiovascular complications are declining

yet remain higher for patients with diabetes mellitus than those without (Low Wang et al., 2016). This manuscript considers the mechanisms, history, and new pharmacological agents for treating patients with diabetes mellitus and cardiovascular disease.

Purpose

The ADA pharmacological T2DM treatment guidelines aim to streamline new evidence-based therapies into the standard of medical care for the T2DM patient with established ASCVD or High-Risk Factors. Multiple large randomized controlled trials now report statistically significant reductions in cardiovascular events in patients with type 2 diabetes treated with an SGLT2 inhibitor or GLP-1 RA (ADA, 2022). The therapeutic regimen should be tailored to comorbidities, patient-centered treatment factors, and management needs. It allows the clinician to decide whether to intensify risk reduction actions through these proposed newer drugs. A comprehensive cardiovascular disease risk reduction is essential, consisting of diet, exercise, and lifestyle recommendations as described in the ADA standards of care. The clinic site chosen for this project primarily serves the Hispanic community of Southern California. This minority community is more likely to be affected by certain risk factors for CVD and diabetes, such as metabolic syndrome, sedentary lifestyle, and obesity. Furthermore, once identified, CVD, diabetes, and their associated risk factors tend to be undertreated in this population (Diaz et al., 2012).

Providers cannot address the non-modifiable components predisposing the Hispanic population to develop T2D. However, there are certain risk factors subject to medical interventions that can prevent morbidity and mortality. This project's purpose is to focus on physician and patient education to use a patient-centered approach and increase utilization of these recommended therapies to help meet patient treatment goals.

Evidence for Problem

A literature review was conducted using the following databases through the Copley Library, including PubMed, CINAHL, Cochrane Library, and EBSCO host. Individuals with T2DM have an elevated risk of developing ASCVD, regardless of glucose-lowering strategies. ASCVD remains the leading cause of disability and mortality for individuals with diabetes. The current standard of care models comprehensively manages cardiovascular risk factors in the T2DM population. However, <20% of adults with T2DM without known CVD meet A1C, blood pressure, and lipid treatment goals. That percentage drops to <10% when including target BMI <30 kg/m². Among those with known ASCVD, the realities are worse, with only 6.8% meeting treatment goals and 2.7% meeting goals with a BMI <30 kg/m² target (Joseph et al., 2022).

National health organizations have updated treatment guidelines based on large randomized cardiovascular outcome trials utilizing GLP-1 RA and SGLT-2. The American Diabetes Association 2022 Professional Practice Committee updated its treatment algorithm to incorporate these new therapies. Traditionally the first-line therapy for treating hyperglycemia has been metformin and comprehensive lifestyle (ADA, 2022). For T2DM patients with established ASCVD or indicators of high ASCVD, an SGLT2 inhibitor or GLP-1 RA with demonstrated CVD benefit is recommended independently of A1C (ADA, 2022). Recognizing the multiple treatment goals and comorbidities for individuals with T2DM, alternative initial treatment approaches to metformin are acceptable. The new treatment algorithm aims to streamline these new therapies with evidence supporting cardiovascular risk reduction and glycemic management, prioritizing GLP-1 RAs and SGLT2 inhibitors for this high-risk patient population (ADA, 2022).

The American Heart Association (AHA) highlighted that cardiovascular disease in diabetes is multifactorial, and control of cardiovascular risk factors substantially reduces cardiovascular-associated complications. The AHA 2015 statement “Update on Prevention of Cardiovascular Disease in Adults with Type 2 Diabetes Mellitus in Light of Recent Evidence” recommends addressing modifiable risk factors responsible for cardiovascular disease in diabetes (Joseph et al., 2022). The AHA completed a meta-analysis of various cardiovascular outcome trials (CVOT) using GLP-1. The CVOT compared the traditional standard of care for T2DM to include oral antidiabetic, insulin, antihypertensives, diuretics, statins, and antithrombotic therapies vs. GLP-1 adjunct therapy. The CVOT's results showed a risk reduction of a 3-point major adverse cardiovascular event (10%–12%), cardiovascular mortality (12%–13%), all-cause mortality (12%), Myocardial infarct (MI) (6%–9%), and stroke (13%–14%) with GLP-1 adjunct therapy versus standard of care treatment alone (Joseph et al., 2022). Furthermore, the trial results varied depending on the specific GLP-1 used in treatment. Liraglutide GLP-1s reduced cardiovascular deaths, those treated with albiglutide had fewer MIs, and others who received injectable semaglutide and dulaglutide had fewer strokes (Joseph et al., 2022). Additionally, the EMPA-REG outcome trial looked at cardiovascular benefits using the SGLT-2 empagliflozin. Trial results showed that the group treated with empagliflozin had a significantly lower death rate from cardiovascular causes, 3.7%, vs. 5.9% in the placebo group (Zinman et al., 2015).

The literature shows that evidence obtained from cardiovascular outcome trials has led to a paradigm shift by both diabetes and cardiology associations on their proposed T2DM treatment guidelines. Based on the results obtained from CVOT, they now include strong recommendations to use SGLT-2 and GLP-1 with proven cardiovascular benefits to reduce cardiovascular risk in this high-risk population (Marx, 2022).

Theoretical Framework

The Iowa Model was selected for its straightforward logical design and popularity. Frontline workers developed it, and revisions have improved the model over the years from their input. This model can help healthcare professionals apply evidence-based research into practice and achieve better patient outcomes. The Iowa model identifies knowledge or problem-focused triggers and utilizes a systematic framework with closed-loop feedback to implement change. The increased prevalence of diabetes in the Hispanic community subsequently increases the chance of CVD and associated complications. This model will be ideal for highlighting an opportunity to improve diabetes management with patients with cardiovascular disease. The Iowa model encourages healthcare professionals to question current practices and explore opportunities for improvement. The model will help use evidence-based practice to address problem-focused triggers. These triggers can be obtained from clinical problems, risk management data, and new practice guidelines (Melnyk & Fineout-Overholt, 2019). Where the proposed change falls within an organization's priorities is equally important to consider alongside cost and organizational buy-in. A proposed reason for the popularity and strength of the Iowa Model is from frontline workers whom themselves identify areas of improvement.

Project Plan Process

The facility chosen for this project was a Pulmonary and Internal medicine clinic, a private outpatient clinic in Southern California. This clinic mainly serves adult patients, ages 18 and above, with most of the patient population being Hispanic. In review, it was discovered that the providers did not routinely utilize the new treatment guidelines proposed by diabetes and cardiology associations for T2DM with established ASCVD or high-risk factors. A survey questionnaire was given to the clinic's providers, examining if specific practice guidelines were

followed in managing T2DM and specific antidiabetic medications used for patients with known CVD. The providers' answers varied depending on the patient's medical history and treatment goals. The providers did not routinely adhere to one sole guideline nor had a specific go-to medication for treating T2DM and CVD.

The project's target population was patients with T2DM with established ASCVD, high-risk factors such as hypertension, hyperlipidemia BMI >30%, Left ventricular hypertrophy, age >55, and Hispanic. Utilizing the clinic EMR system, a pre-intervention patient chart review was conducted to determine the percentage of patients prescribed a GLP-1 or SGLT-2 during the 2-month pre-intervention phase. The post-intervention period was over four months and consisted of providing the clinic's providers a review of new ADA treatment guidelines and clinically assessing patients who were appropriate for new ADA treatment recommendations.

Assessment of Findings

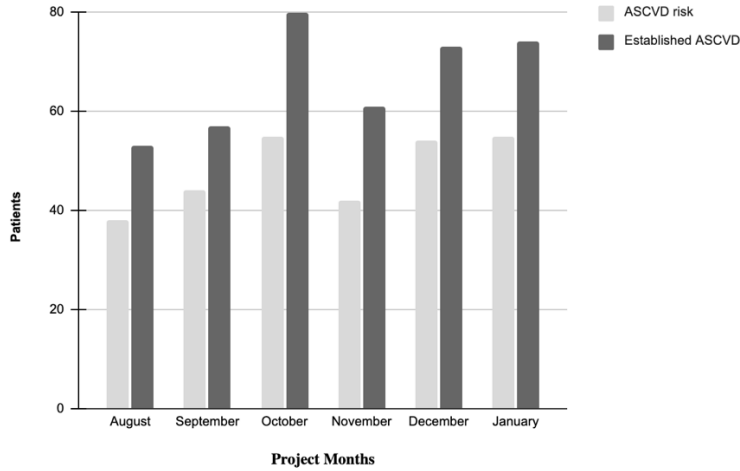
Two phases were assigned in data collection: the pre-intervention phase, August 2022 thru September 2022. The second phase, post-intervention, is from October 2022 thru January 2023. Utilizing the clinic's EMR system, 660 patient charts were reviewed in August. Only 53 patients were seen in August with an established history of ASCVD, and 38 patients with risk factors for ASCVD were on a GLP-1 or SGLT-2. In September's second month of pre-intervention, 688 patient charts were screened. Fifty-seven patients with established ASCVD and only 44 patients with risk factors were on a GLP-1 or SGLT-2. The total results for adherence to ADA guidelines in the pre-intervention phase were 14.24%. It comprised 8.16% of patients with established ASCVD and 6.08% with risk factors on a GLP-1 or SGLT-2.

October 2022 thru January 2023 was the post-intervention phase. Six hundred fifty-five patient charts were screened in October. Eighty patients with established ASCVD and 55 with

risk factors were prescribed a GLP-1 or SGLT-2. In November, 678 charts were reviewed, showing 61 patients with established ASCVD and 42 patients with risk factors on a GLP-1 or SGLT-2. In December, 598 charts were reviewed. Seventy-three patients with established ASCVD and 54 patients with risk factors were prescribed a GLP-1 or SGLT-2. In the final month of January 2023, 622 patient charts were screened, showing 74 patients with established ASCVD and 55 patients with risk factors prescribed a GLP-1 or SGLT-2. The total results for adherence to ADA guidelines in the post-intervention phase were 19.34%. It comprised 11.28% of patients with established ASCVD and 8.06% of patients with risk factors on a GLP-1 or SGLT-2. An overall difference of 5.1% increase in adherence to the ADA treatment guidelines.

Figure 1

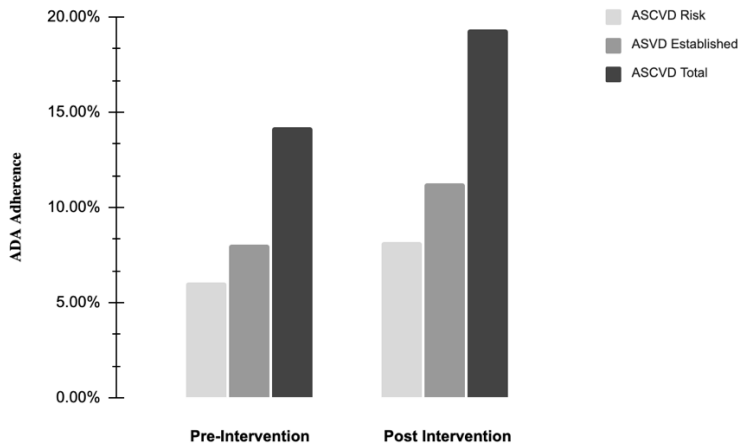
Patients with ASCVD Risk and Established ASCVD are Prescribed a GLP-1 or SGLT-2



Note: This figure demonstrates the number of patients prescribed a GLP-1 or SGLT-2 over six months.

Figure 2

ADA Guideline Adherence Pre and Post Intervention



Note: This figure demonstrates adherence to ADA treatment guidelines between pre and post-intervention periods. Project results showed a total increase of 5.1% in the utilization of new ADA guidelines with intervention.

Cost/Benefit Analysis for Sustainability of Project

The increased prevalence of T2DM and the associated cost of cardiovascular complications to the individual and the healthcare system must be addressed. An estimated \$37.3 billion are spent yearly involving diabetes and cardiovascular disease (ADA, 2017). On average, one hospitalization for a stroke costs \$22,657, and a myocardial infarction costs \$41,505. If one single event is prevented by utilizing these new medications, it offsets the medication cost.

By implementing this project, the prescribing provider may prevent a major cardiovascular event, thus reducing morbidity and overall mortality to their patient population. The patient will be the one who will bear the cost of the medication, which varies depending on insurance.

Implications for Practice

These two types of therapies, GLP-1 receptor agonists and SGLT-2 inhibitors have been recognized for their cardiovascular morbidity and mortality benefits. Studies have shown that there has been a steady increase in prescription rates of these medications, but overall usage remains relatively low (Gill et al., 2022). The patient, physician, and system-based factors have been identified as barriers to translating trial data to real-world clinical applications. One of the significant contributors to this challenge is knowledge diffusion delay. In a survey investigating barriers to prescribing SGLT-2 inhibitors and GLP-1 analogs, the top three barriers reported by providers were their lack of knowledge, discomfort, and concerns about introducing confusion into care (Gill et al., 2022).

Additionally, providers were concerned about the costs borne by the patient and the need for prior authorization. From the patients' perspectives, barriers are comprised of a lack of

knowledge regarding benefits, fear of side effects, personal preference, and cost (Gill et al., 2022).

Conclusions

This project's results showed an opportunity to implement new evidence-based treatment guidelines for T2DM and cardiovascular disease patients. Diabetes is a significant public health concern, especially in specific minority populations with higher prevalence rates. Although the overall management of diabetes mellitus has improved over the decades, there is still a need for improved cardiovascular prevention. This project can be replicated in similar office settings, and future research could focus on the sustainability of these proposed medications.

References

- American Diabetes Association (ADA) (2017). *Pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes-2018*. American Diabetes Association. <https://doi.org/10.2337/dc18-S008>
- American Diabetes Association (ADA) (2022). Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: *Standards of Medical Care in Diabetes—2022*. *Diabetes Care* 1 January 2022; 45 (Supplement_1): S125–S143. <https://doi.org/10.1002/dmrr.3097>
- Aguayo-Mazzucato, C., Diaque, P., Hernandez, S., Rosas, S., Kostic, A., & Caballero, A. E. (2019). Understanding the growing epidemic of type 2 diabetes in the Hispanic population living in the United States. *Diabetes/metabolism research and reviews*, 35(2), e3097. <https://doi.org/10.1002/dmrr.3097>
- Diaz, V. A., Mainous, A. G., 3rd, Williamson, D., Johnson, S. P., & Knoll, M. E. (2012). Cardiovascular and diabetes risk perception in a Hispanic community sample. *Ethnicity & disease*, 22(1), 5–11
- Duff, J., Cullen, L., Hanrahan, K., & Steelman, V. (2020). *Determinants of an evidence-based practice environment: An interpretive description – implementation science communications*. BioMed Central. <https://doi.org/10.1186/s43058-020-00070-0>
- Gill, G. S., Latif, A., Hilleman, D., Lavie, C. J., & Alla, V. M. (2022). Challenges in Implementing Evidence Based Cross-Disciplinary Therapies: Are Cardiovascular

Specialists Ready to Claim SGLT-2 Inhibitors and GLP-1 Analogs?. *Current problems in cardiology*, 47(7), 100878.

<https://doi.org/10.1016/j.cpcardiol.2021.100878>

Joseph, J. J., Deedwania, P., Acharya, T., Aguilar, D., Bhatt, D. L., Chyun, D. A., Di Palo, K. E., Golden, S. H., & Sperling, L. S. (2022). Comprehensive management of cardiovascular risk factors for adults with type 2 diabetes: A scientific statement from the American Heart Association. *Circulation*, 145(9). <https://doi.org/10.1161/cir.0000000000001040>

Marx, N., Husain, M., Lehrke, M., Verma, S., & Sattar, N. (2022). GLP-1 receptor agonists for the reduction of atherosclerotic cardiovascular risk in patients with type 2 diabetes. *Circulation*, 146(24), 1882–1894. <https://doi.org/10.1161/circulationaha.122.059595>

Low Wang, C. C., Hess, C. N., Hiatt, W. R., & Goldfine, A. B. (2016). Clinical update: Cardiovascular disease in diabetes mellitus. *Circulation*, 133(24), 2459–2502. <https://doi.org/10.1161/circulationaha.116.022194>

Zinman, B., Wanner, C., Lachin, J. M., Fitchett, D., Bluhmki, E., Hantel, S., Mattheus, M., Devins, T., Johansen, O. E., Woerle, H. J., Broedl, U. C., & Inzucchi, S. E. (2015). Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. *New England Journal of Medicine*, 373(22), 2117–2128. <https://doi.org/10.1056/nejmoa1504720>