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Expanding Use of Sodium-Glucose Cotransporter-2 Inhibitor (SGLT2i) In Managing Patients with Diabetes and Chronic Kidney Disease in Primary Care

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DOI: https://doi.org/10.46409/sr.NEZS2815



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Wu, S. (2023). Expanding Use of Sodium-Glucose Cotransporter-2 Inhibitor (SGLT2i) In Managing Patients with Diabetes and Chronic Kidney Disease in Primary Care. [Doctoral project, University of St Augustine for Health Sciences]. SOAR @ USA: Student Scholarly Projects Collection. https://doi.org/10.46409/sr.NEZS2815

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Expanding Use of Sodium-Glucose Cotransporter-2 Inhibitor (SGLT2i) In Managing Patients with Diabetes and Chronic Kidney Disease in Primary Care

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This Manuscript Partially Fulfills the Requirements for the

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October 23, 2023

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Abstract

Practice Problem: In 2022, the addendum of standards of medical care in diabetes management was annotated to recommend the broader use of sodium-glucose cotransporter 2 inhibitors (SGLT2i) to treat patients with Type 2 diabetes mellitus (DM) and diabetic nephropathy. Despite the Department of Veterans Affairs' (VA) efforts to include SLGT2i as a formulary, non-restrictive prescription in the primary care ordering menu, the overall utilization rates of SGLT2i remained relatively low in primary care.

PICOT: The PICOT question that guided this project was: In patients with DM and chronic kidney disease (CKD) (P), how does an evidence-based guideline algorithm bundle (I) compared to standard care (C) affect providers' adherence and prescribing practices of including SGLT2 inhibitors (O) within 10 weeks (T)?

Evidence: An extensive evidence literature review supported that the algorithm approach with current guidelines has allowed clinicians to identify patients eligible for SGLT2i was based on comprehensive risk assessment with various comorbidities and risk factors. The guideline-based algorithm was a quick reference guide to provide clarity and indication for patients with the most significant potential benefits from SGLT2i therapy.

Intervention: The algorithm bundle, designed to reflect the current guidelines, was intended to enhance primary care clinicians' prescribing confidence in SGLT2i and guide better decisionmaking. The algorithm bundle comprised the physical laminated algorithm card, embedded reminder in the e-prescribing menu, and a focused education session for the primary care providers.

Outcome: The project outcomes reflected that the algorithm bundle has clinical significance in improving prescribers' knowledge of SGLT2i agents and practice compliance, as evidenced by a

rise in SGLT2i prescriptions.

Conclusion: The algorithm bundle intervention in this project resonates with the American Diabetic Association's (2022) latest recommendation to widen indications for using SGLT2 to optimize the management of DM and CKD patients. The evidence supports using a guideline-based algorithm to guide clinicians with a comprehensive assessment of high-risk patients and a better decision-making tool. Continued efforts to educate and audit primary care providers are essential to identify potential knowledge gaps and to sustain practice compliance of using SGLT2 i as part of the standard of care.

Expanding Use of Sodium-Glucose Cotransporter-2 Inhibitor (SGLT2i) In Managing Patients with Diabetes and Chronic Kidney Disease In Primary Care

In 2020, the American Diabetes Association (ADA) revised its guidelines to recommend the use of sodium-glucose cotransporter-2 inhibitor (SGLT2i) as the standard of care in treating patients with type 2 diabetes mellitus and comorbidities such as heart failure and chronic kidney disease (CKD; Seaborg, 2020). The 2022 ADA guidelines called for expanding the role of SGLT2i as an initial treatment. The primary aims for recommending the use of SGLT2i are to prevent and slow the progression of chronic kidney disease, or CKD (ADA, 2023). However, primary care providers have a lower rate of initiating SGLT2i agents than nephrologists or endocrinologists (National Kidney Foundation, n. d.). Possible reasons may have been the underappreciated benefits of SGLT2i among primary care providers due to a lack of clear understanding regarding the implementation of SGLT2i in clinical practice or being unaware of the updated ADA guidelines (Evans et al., 2022).

The purpose of this scholarly project was to formulate an algorithm bundle intervention to improve clinicians' confidence and accelerate the uptake of SGLT2i therapy. The goal was to ensure providers' adherence to guideline-directed monitoring and treatment and facilitate clinicians' practice by including SLGT2i therapy in all patients with diabetes and CKD in the primary care setting.

Significance of the Practice Problem

The evidence has been well established that the negative effect of diabetes mellitus and the cardiovascular risks associated with hypertension directly impact the progression of CKD (Kovesdy, 2022). Globally, diabetic kidney disease (DKD) or diabetic nephropathy is recognized as a common cause of end-stage kidney disease or ESKD (Perkovic et al., 2022). Predominately, patients with DM and CKD are identified and managed in primary care. The associated health challenges of this high-risk population highlight the importance of the primary care providers' roles in managing DM and the early detection of DKD. In 2022, the addendum of standards of medical care in diabetes management was annotated to recommend the wide use of SGLT2i to treat patients with type 2 diabetes and DKD (American Diabetes Association Professional Practice Committee, 2022). Despite the Department of Veterans Affairs' (VA) efforts to include SLGT2i as a formulary, non-restrictive prescription in the primary care ordering menu, the overall utilization rates of SGLT2i remained relatively low in primary care (Milder et al., 2021). Today, less than 20% of patients with both DM and CKD under the VA primary care were prescribed SGLT2i.

DKD is a serious microvascular complication of uncontrolled type 1 diabetes and type 2 diabetes (Varghese & Jialal, 2022). According to the National Kidney Foundation (2016), there were more than 51,000 new cases of kidney failure in 2013, and over 247,000 people suffered from kidney failure resulting from diabetes. Approximately 40% of the patients with diabetes eventually developed DKD (Alicic et al., 2017). The global prevalence of diabetes is projected to rise, which may accelerate growth in patients requiring renal replacement therapy or dialysis (Zimbudzi et al., 2020). Hence, diabetic patients with diabetic nephropathy or ESKD will have more health challenges and poor quality of life due to multiple co-existing micro and macrovascular complications (Zimbudzi et al., 2020).

Moreover, managing CKD, diabetic nephropathy, and vascular complications are the main drivers of the financial and health burden. In 2017, Medicare spending for CKD management, renal replacement therapy (RRT), and significant CKD complications exceeded \$120 billion (Betts et al., 2021). On average, the annual Medicare spending was \$87.2 billion in

2019 for patients with CKD, or \$24,453 per patient (Centers for Disease Control and Prevention, 2022). Specifically, patients with CKD Stages 3A, 3B, and 4 had incurred incremental increases in healthcare expenditures of \$1,732, \$2,632, and \$6,949, respectively, compared with Stage 1 CKD patients (McQueen et al., 2017).

Expanding the utilization of SGLT2i was one of the priorities to improve renal and cardiovascular outcomes, minimize vascular and kidney complications, and ultimately reduce the overall healthcare costs related to CKD and enhance patients' quality of life and expectancies. In the cardiovascular outcome trial study in diabetic patients, SGLT2i showed a 38% relative risk reduction in cardiovascular death, a 35% risk reduction in hospitalization from heart failure, and a 32% risk reduction in death from other causes (Alicic et al., 2017). Most primary care practitioners understand their patients' comorbidities well and are familiar with their overall cardiovascular risks. Therefore, primary care clinicians' awareness of the cardio and reno-protective benefits of SGLT2i was critical in optimizing the management of the identified high-risk patient population with DM and CKD.

PICOT Question

The PICOT question for this project was as follows: In patients with DM and CKD (P), how does an evidence-based guideline algorithm bundle (I) compared to standard care (C) affect providers' adherence and prescribing practices of including SGLT2 inhibitors (O) within ten weeks (T)?

The project setting was the primary care clinics at the VA. The participants for this EBP project were 12 randomly selected primary care providers: physicians and nurse practitioners. To enhance primary care clinicians' knowledge of the current guidelines, an algorithm bundle was designed and provided to the primary care providers as a reference for clinical decisions. The

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algorithm bundle consisted of the simplified clinical pathway that reflects the 2022 ADA practice guidelines which recommended that providers consider initiating SGTL2i therapy in those diagnosed with type 2 DM and CKD. The algorithm was designed in two forms: a pocket card and clinical decision support within the e-prescribing menu under the diabetes category. Enriched prescribing clinicians' knowledge about the indications and precautions for using SGLT2i was the essence of the algorithm bundle intervention.

Clinicians' practice compliance was measured in terms of the SGLT2i prescriptions rate. Comparing numbers of SGLT2i prescriptions pre and post-intervention helped to determine if the algorithm bundle would enhance providers' clinical decisions. The desired outcome for the project was to have at least a ten percent increase in SGLT2i prescriptions post-intervention. This evidence-based practice project occurred over eight to ten weeks.

Evidence-Based Practice Framework & Change Theory

To better address each phase of the project, an evidence-based framework and change theory were the underpinnings to guide successful project development. Johns Hopkins Evidence-Based Practice Model (JHEBP) and Lewin's Change Theory offered a systemic approach to help navigate each project stage (Dang et al., 2022).

Johns Hopkins Evidence-Based Practice Model

The Johns Hopkins Evidence-Based Practice (JHEBP) Model was the tool intended to guide the problem-solving approach of the practice (Dang et al., 2022). The JHEBP Model consists of a three-step process called PET: practice question, evidence, and translation (Dang et al., 2022). In this project, the practice question was a focused foreground question that applied the PICO approach to explore reasons for clinicians' suboptimal adherence to the guidelines of using SGLT2i. The next step of the PET process was to compile evidence to bridge the gap for

the limited uptake of SGLT2i prescribing practice. This step involved a rigorous database search, a systematic literature review, and synthesizing all relevant studies (Johns Hopkins Medicine, n.d.). The translation stage required synthesizing findings to develop recommendations (Johns Hopkins Medicine, n. d.).

Lewin's Change Theory

Kurt Lewin's Change Theory was the theoretical foundation that was used to guide the planned change of this project. Lewin's theory includes a three-step process: unfreezing, changing, and refreezing (Nursing Theory, n. d.). Lewin's theory also featured three major concepts: driving force, restraining force, and equilibrium (Nursing Theory, n. d). Unfreezing means recognizing and releasing the old behavior (Nursing Theory, n. d). The driving force, or changing, pushes toward the desired direction, where the change facilitates and causes a shift in equilibrium. Restraining force is the counterforce that hinders change. Equilibrium will be achieved or freezing when the driving force equals the restraining force and no change occurs (Nursing Theory, n. d).

Lewin's conceptual framework aligned with this project, guiding the behavioral transformation into a new norm. It helped to understand the determinants of the transition process, identified the strengths, reduced resistance force, and sustained changes (Errida & Lotfi, 2021). During this process, the unfreezing stage required clinicians to understand and uncover the need for change and the knowledge deficit. The in-service education and review of current guidelines enhanced practitioners' understanding and awareness. The next stage was the driving force application. Managing and facilitating behavioral change can be challenging (Errida & Lotfi, 2021). Therefore, possible barriers were carefully examined at this stage. Incorporated the algorithm bundle as the supportive tool had reduced possible resistance forces and facilitated a

smooth change transition. The algorithm bundle helped to support clinicians' decision-making when evaluating treatment plans for the identified high-risk patient populations. During the final refreezing stage, the clinicians adopted the efforts by critically evaluating high-risk patients, reviewing criteria per algorithm guidelines, and making the best decision when prescribing SGLT2i.

Evidence Search Strategy

The literature search was conducted to identify barriers to prescribing SGLT2i in primary care and evidence supporting the decision algorithm intervention. The first part of the literature search used the key phrase: "low use SGLT2i in primary care." The inclusion criteria consisted of adults aged 18 years and older, type 2 DM, CKD, SGLT2i, and primary care settings. Databases include MEDLINE, CINAHL, ScienceDirect, and PubMed. Articles in English, peer-reviewed, full-text, and articles with publication dates between 2020 and 2022 were selected to narrow the search. Exclusion criteria were applied to limiting news articles, e-books, books, and magazines for final selection for abstract review.

The second part of the search used the key phrase: "decision algorithm for prescribing SGLT2i". The search was conducted through the same database and Google Scholar. The search was limited to full-text academic journals and articles with publication dates between 2020 and 2022. Further limitations were applied by using the keyword "algorithm." A quick abstract preview was performed on all eligible articles prior to accessing the full-text articles. However, considering the clinical-decision support algorithms are being utilized strategically globally, any international articles correlating to the guideline algorithm are determined to fit the inclusion criteria.

Evidence Search Results

The first part of the search with key phrases yielded 386 articles. After applying the automatic exclusion criteria, 52 articles resulted in a preliminary abstract review. Articles related to pediatric CKD, drug information about SGLT2i and non-primary care were removed. Four with duplicating articles and articles sought to describe the liver disease, roles of SGLT2i, and adverse effects associated with SGLT2i were excluded. Finally, eight articles were identified that meet the desired criteria for addressing prescribing practice barriers of SGLT2i in primary care. Only the title with the keyword "algorithm" was selected in the second part of the literature search. Twenty-eight articles underwent abstract preview, which yielded six qualified articles for the final full-body review. Two articles focused on IT algorithms were removed due to their inconsistency with the PICOT question. Four articles were found relevant to the decision support algorithm pertaining to the context of prescribing SGLT2i.

Collectively, 12 articles were determined for the final literature synthesis. Four studies were conducted and published in Canada, three in the United States, one in the United Kingdom, one in Australia, and one in Hong Kong. A summary of the literature review process with eligible publications that were selected for the project is reflected in the PRISMA diagram (see Figure 1).

The level of evidence and the quality of these eligible articles were evaluated using the Johns Hopkins Evidence-Based Practice Model Appraisal Tool. Four cross-sectional and three qualitative studies were rated Level III and Grade A and B in quality. Two quantitative appraisals and one retrospective cohort study were rated Level II and Grade A quality (see Appendix A). Two articles with extensive systemic reviews of major randomized trials (RTC) were rated Level I for the strength of evidence and Grade A for high quality (see Appendix B).

Themes with Practice Recommendations

A literature review uncovered several themes regarding the barriers to the prescribing practice of SGLT2i therapy, along with practice recommendations for each barrier. The literature synthesis identified the following themes: limited knowledge, prescribing disparities, restricted access, and clinical decision support.

Limited Knowledge

The wealth of evidence from the literature review appreciates the outcome benefits and clinical value of SGLT2i. However, the prescribing rate of SGLT2i remains sub-optimized. Much effort in the studies focuses on understanding the underlying reasons for the underutilization of SGLT2i. The most significant barrier to under-prescribing SGLT2i was clinicians' limited knowledge and lack of confidence and mastery in utilizing SGLT2i therapy (Banjara et al., 2022; Colling et al., 2021; Gao et al., 2020; Ghazwa et al., 2022; Hao et al., 2022; Milder et al., 2021; Vasti et al., 2022). Clinicians were uncertain of the harms and benefits of SGLT2i in multimorbidity populations and unfamiliar with the adverse effects of SGLT2i (Hao et al., 2022).

Despite a high prevalence of primary care clinicians acknowledging the critical roles of SGLT2i and the cardiovascular and renal benefits of SGLT2i, clinicians commonly perceive SGLT2i primarily for its glycemic efficacy (Banjara et al., 2022; Colling et al., 2021; Gao et al., 2020; Ghazwa et al., 2022; Hao et al., 2022; Milder et al., 2021; Vasti et al., 2022). There needs to be more understanding that the benefit of SLGT2i is independent of glycemic control (Li et al., 2020; Ng et al., 2022; Yau et al., 2022). Education intervention helps to close the gap between knowledge and practice for clinicians in managing complex patients with T2DM and

CKD (Banjara et al., 2022; Colling et al., 2021; Gao et al., 2020; Ghazwa et al., 2022; Hao et al., 2022; Milder et al., 2021; Vasti et al., 2022).

Concise education intervention focuses on guidelines, risks, and benefits of SGLT2i and dose titration. Educating clinicians on skills to utilize risk prediction assessment may be critical to increasing the use of SGLT2i therapy (Goa et al., 2020). Essentially, education with system support is vital in underpinning primary care clinicians' confidence in clinical decision-making, enhancing knowledge, information about insurance coverage, and the process of prior authorization for SGLT2i (Colling et al., 2021). Additional training and ongoing education to emphasize the paradigm shift from glycemic management toward cardio-renal protection is the key to increasing the utility of SGLT2i (Ng et al., 2022).

Prescribing Disparities

Disparities in adopting SGLT2i prescribing practices were found among different specialties. Endocrinologists were the most frequent specialty prescribing SGLT2i, followed by internal medicine (IM) physicians, cardiologists, and nephrologists (Ghazwa et al., 2022; Milder et al., 2021; Vasti et al., 2022). Some studies found that primary care clinicians preferred endocrinologists to determine the initiation of SGLT2i therapy due to uncertainty of their clinical responsibilities, time constraints, lack of comfort discussing side effects, and a lack of resources to follow up with patients when starting patients on SGLT2i therapy (Colling et al., 2021; Hao et al., 2022; Ng et al., 2022; Milder et al., 2021).

In addition, there were concerns about the safety profile of SGLT2i use in high-risk, medically complex patient populations (Banjara et al., 2022; Colling et al., 2021; Gao et al., 2020). Four studies suggested that the SGT2i prescription rates are associated with patients' characteristics and comorbidities (cite each). Despite being eligible, elderly patients with a

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higher number of comorbidities such as heart failure, history of stroke or transient ischemic attack, DM-related, and renal impairment were less likely to receive SGLT-2i treatments (Banjara et al., 2022; Ghazwa et al., 2022; Ng et al., 2022; Vasti et al., 2022). In addition, the odds of under-prescribing were significantly lower among patients with T2DM who were receiving insulin, obese, and had suboptimal blood pressure (Ghazwa et al., 2022).

These findings highlighted the need for a multifaceted intervention to include pharmacists, endocrinologists, and nephrologists to support primary care clinicians for best practices and enhance SGLT2i initiation and monitoring for high-risk patients (Firkus et al., 2022; Milder et al., 2022). Including SGLT2i as the key performance indicator for diabetic patients with an established status in atherosclerotic cardiovascular disease and CKD was recommended (Ng et al., 2022). Additionally, the pharmacy e-consult mechanism could help primary practitioners confidently engage in shared decision-making with patients concerning initiating SGLT2i therapy (Firkus et al., 2022). Pharmacists have been part of valuable mitigation strategies to enhance medication barriers and adherence collaboration.

An established multifaceted intervention could increase relevant guideline awareness and implementation (Milder et al., 2021). The expansion of multidisciplinary efforts incorporating pharmacy e-consult within the primary care model could improve patient follow-ups, better monitoring, enhance prescribing confidence, and improve medication management's quality and efficiency (Firkus et al., 2022; Milder et al., 2021).

Limited Access

Several studies found a deviation in the prescription pattern of SGLT2i among patients with socioeconomic and sociodemographic disadvantages (Marasinghe et al., 2022; Monaco, 2022; Vasti et al., 2022). Patients that are women, Black, Asian, and Hispanic, with lower income, low education attainment, and lower socioeconomic status were observed with lower odds of receiving SGLT2i treatment (Marasinghe et al., 2022; Monaco, 2022; Vasti et al., 2022). The primary reasons explaining the lower SGLT2i prescribing pattern in under-served populations were the lack of continued access to medications, restriction to government subsidization for SGLT2i, and the high cost of the medicines (Hao et al., 2022; Milder et al., 2021; Monaco, 2022). One study found that clinicians with a lower rate of prescribing SGLT2i also had similar racial, gender, and ethnicity disparities as patients. For example, female clinicians and Black patients had lower odds of SGLT2i prescriptions (Vasti et al., 2022).

These findings called attention to prioritizing equity in care, addressing socioeconomic disparities, and enhancing access to SGLT2i therapy. Extending and promoting government subsidization for SGLT2i treatment without restriction or preauthorization were recommended solutions to minimize the impeding medication access (Hao et al., 2022; Milder et al., 2021; Monasco, 2022).

Clinical Decision Support

Supported by expert consensus in the American Diabetes Association, American College of Cardiology, and American Heart Association and endorsed by the National Kidney Foundation, the guideline algorithm advocated initiating SGLT2i therapy for patients with T2D and CKD. The algorithm approach with current guideline that allowed clinicians to identify patients eligible for SGLT2i was based on comprehensive risk assessment with various comorbidities and risk factors. The guideline-based algorithm was a quick reference guide to provide clarity and indication for patients with the most significant benefit from SGLT2i therapy (Colling et al., 2021; Dennis et al., 2022; Li et al., 2020; Yau et al., 2022). The features of holistically assessing cardiovascular, kidney, and metabolic risks were the major strength of the guideline-based algorithm (Li et al., 2020). The algorithm can used as realtime decision support for clinicians considering SGLT2i as the optimal treatment. It allowed clinicians to formulate strategies and proactively mitigate risks of adverse effects associated with SGLT2i (Colling et al., 2021; Dennis et al., 2022; Li et al., 2020). The electronic health record (EHR) embedded algorithm can accurately identify qualifying criteria and serves as a potential precision medicine that guides clinical decisions by taking into consideration weight changes, medication tolerability, glycemic response, and patient preference and adherence when selecting SGLT2 inhibitor therapy (Colling et al., 2021; Dennis et al., 2022; Hao et al., 2022). However, one article reported that general practitioners have mixed opinions about the usefulness of guideline algorithms because information can be confusing and complicated to engage in (Milder et al., 2021).

Setting, Stakeholders, and Systems Change Setting

Setting

The clinical setting for this scholarly project was the primary care clinics at the VA. The clinic is a federally funded facility founded in 1943 (U.S. Department of Veterans Affairs, 2022a). Its mission follows President Lincoln's affirmed government obligation statement: "To care for him who shall have borne the battle and for his widow and his orphan" (U.S. Department of Veterans Affairs, n.d.-a). The patient population is exclusively veterans. A primary care team is based on the Patient Aligned Care Teams (PACT) model (U.S. Department of Veterans Affairs, 2022b). A total of 32 PACTs provided primary care services to eligible veterans. Each PACT team consisted of a clinician (a physician or nurse practitioner), two care managers (one registered nurse and one licensed vocational nurse), a pharmacist, and a social worker. Every

PACT oversees about 1000 to 1200 veterans with arrays of physical and mental medical problems (U.S. Department of Veterans Affairs, 2022b). The clinic provided same-day access, immunizations, health education, disease prevention, and chronic disease monitoring and management (U.S. Department of Veterans Affairs, n.d.-b).

The PACT teams are the first point of contact for all veterans enrolled in the VA health care system (U.S. Department of Veterans Affairs, n.d.-b). Given that veterans with T2DM are primarily managed in primary care, primary care clinicians can greatly expand the use of SGLT2i by understanding its clinical benefits and implications. Enriched with advanced knowledge and following the algorithm pathway of the current guideline, primary care practitioners can maximize the advantages of SGLT2i in conjunction with or without first-line therapy for high-risk T2DM patients independent of their baseline HbA1C or targets (Xu et al., 2022).

Stakeholders

The stakeholders for this DNP scholarly project included the medical center director, chief of primary care, quality improvement team, primary care practitioners, IT informatics, subspecialty providers, pharmacy, laboratory, microbiology, and patients and families. A stakeholder analysis was conducted to appreciate the stakeholders' priorities and expectations of this scholarly project (see Appendix C). The medical center director and the chief of primary care were the key stakeholders with the highest interest and power in leading this project to success as the project implementation would positively impact patient outcome measures, ambulatory care sensitive condition (ACSC) quality indicators, hospital admissions rate, and service reimbursement. Primary care clinicians had the highest power for the project because they translated the knowledge of SGLT2i into their prescribing practice. They sought support or guidance from collaborating specialties to safeguard the patients while meeting therapeutic goals.

IT informatics was essential in the project because it supported data collection, stratification, and integration of the algorithm prompt within the e-prescribe function. Patients and their families were directly affected, as their health outcomes were the direct results associated with SGLT2i therapy. QI improvement teams and subspecialty providers, such as cardiology, endocrinology, nephrology, and pharmacy, were indirectly impacted because their care for high-risk patients could be enhanced when primary care clinicians manage patients promptly and safely manner by considering SGLT2i therapy. The stakeholders with the lowest power and interest in the project were the education department, laboratory, and microbiology. A system change required continued collaboration among all stakeholders to drive advocacy for the project goals and support the execution and sustainment of this project.

System Change

The system change process of this scholarly project involved the meso-micro level as it occurred in the outpatient setting within the organizational level (see Appendix D). At the meso level (Nelson et al., 2011), the change focused on multidisciplinary collaboration among key stakeholders to support clinical decisions and care delivery to high-risk patients in the context of the prescribing practice of SGLT2i. At the micro level (Nelson et al., 2011), the patients and families interacted and connected with all their healthcare providers to learn about their health status, seek health advice, be medically managed, and be monitored for adverse events.

A strength, weakness, opportunities, and threats (SWOT) analysis (see Appendix E) was performed to evaluate the potential of this project. Internal strengths included federal funding, strong organizational/leadership support, robust IT infrastructure, and cost-effectiveness. Weaknesses comprised providers' resistance to the change, lack of time to learn the proposed change, lagging in seeking consultation, and poor algorithm design that caused more confusion. External opportunities included increasing awareness of the importance of multidisciplinary collaboration. In addition, this project could be adaptable across specialties within the VA healthcare system as clinical practice guidelines are highly relevant in every healthcare specialty to support the best practice. Threats to the project encompassed mismanagement and complications due to patient refusal of treatment, non-compliance, or lost follow-ups.

Implementation Plan with Timeline and Budget

This evidence-based practice project was aimed at improving primary care clinicians' prescribing compliance with the new ADA guideline in expanding the use of SGLT2i. The algorithm bundle was designed to reflect the current guidelines, intended to enhance primary care clinicians' prescribing confidence in SGLT2i and guide better decision-making. Taking an active role and aggressively assessing patients with DM and CKD for SGLT2i therapy was the critical step in primary care to mitigate risk factors, minimize vascular and kidney complications, reduce the progression of CKD related to DM, and improve patients' quality of life and outcomes.

There were three objectives this project planned to achieve:

- Among clinicians who were identified to have lower than 10% of SGTL2i prescriptions, at least 20% of their qualified patients with DM and CKD would be given SGLT2i prescriptions by the end of week four with the support of the algorithm bundle.
- Increased knowledge and awareness among PACT clinicians of updated ADA guidelines would be observed with a higher prescription rate than baseline (10%) by the end of week ten of the project implementation.

• By week 10, PACT clinicians' prescribing confidence would be enhanced by using an algorithm bundle.

Unfreezing

Lewin's change theory guided each process of the project and helped identify the strengths to sustain the project (Errida & Lotfi, 2021). During the unfreezing stage, clinicians' awareness and understanding of the need for change were established. The algorithm bundle was designed to resonate with ADA's latest recommendation to redefine and widen indications of SGLT2 to optimize the management of patients with DM and CKD. The algorithm bundle was approved by the medical chief of Nephrology and proven to meet face validity and reliability as an interventional tool.

The algorithm bundle comprised the physical laminated algorithm card, embedded reminder in the e-Prescribing menu, and focused education session. Physical algorithm cards were disseminated to identified PACT providers at the beginning of the implementation phase. The algorithm card was lamented in 8X10 inches size card which demonstrated the guideline pathways to allow clinicians to critically assess and determine patients' eligibility for SGLT2i therapy (see Appendix F). An electronic version of the algorithm was also emailed to the selected clinicians.

The bundle included a statement prompt in the clinicians' e-Prescribing menu. Upon selecting the "diabetes medications" category in the e-Prescribing menu, a statement populated as follows:

"Per the 2022 ADA guideline, consider SGLT2i (Empagliflozin) to improve glycemic control and reduce CVD risks and mortality in patients with HF and DM. Criteria: eGFR >30, proteinuria uACR > 300, BMI >40. Side Effects: acute kidney injury (AKI), bone

fracture, hypersensitivity, hypotension/volume depletion, infection, ketoacidosis, lower limb amputation. Contraindication: severe hypersensitivity to SGLT2i, eGFR <30, Endstage renal disease. E-consult to the pharmacy or referral to endocrinology, nephrology, and cardiology are appropriate as collaboration efforts to optimize DM management and reduce CVD risk factors ".

Change

The next change step of Lewin's change theory involved increasing the driving force to overcome resistance (Errida & Lotfi, 2021). Enhancing clinicians' decision-making confidence for prescribing SGLT2i was the project principle for developing algorithm bundle intervention. Providers' low prescribing confidence was reflected in a lower SGLT2i prescription rate. To examine each provider's prescribing pattern, a patient data dashboard was created in collaboration with the IT team to collect, extract, and stratify relevant data specific for this evidence-based practice project. The patient data was built on the patient population with active ICD-10 coding for type 2 DM and CKD who are under the care of assigned primary care PACT teams at the VA. The dashboard provided SGLT2i prescription data that was prescriber and time-specific. Utilizing the patient data dashboard, the DNP student was able to accurately identify and target clinicians who had the lowest prescription rate implying a lack of knowledge and low confidence (resistance) in prescribing SGLT2i with a focused one-on-one education (driving force). A ten-minute education session covered a brief overview of the guideline algorithm, benefits, indications, patient selection criteria, possible adverse reactions, contraindications, and the guideline recommendation for widening the use of SGLT2i. The education session can be provided via face-to-face or Microsoft Teams meetings.

Refreezing

The SGLT2i prescription rate was the key measure for the effectiveness of the algorithm bundle intervention. The project goal was to achieve at least 20% of SGLT2i prescriptions given to qualified patients under each identified clinician's panel upon completing the implementation phase in week 10. Leveraging multidisciplinary expertise from subspecialties such as endocrinologists, cardiologists, nephrologists, and clinical pharmacists improved clinicians' confidence, accelerated the uptake of SGLT2i therapy, ensured adherence to guideline-directed monitoring and treatment, and facilitated extended practice compliance (Honigberg et al., 2020). Routine audit and continued efforts in educating clinicians were essential tools to address potential knowledge gaps and ensure new prescribing practice remains the standard of care. VA's substantial financial resources, strong leadership support, robust IT infrastructure, and research-friendly environment was advantageous to support the project's success. Nevertheless, the project's success and sustainment required collaboration and support from all stakeholders. **Budget**

The total cost to support the proposed project was \$ 6,624.80 (see Table 1). A considerable amount of the project incurred cost was the pharmacy personnel supporting medication consultations and chart audits. The estimated time necessary for their tasks required approximately two eight-hour shifts per month to complete. The approximate fixed costs of \$2500 and \$384 covered the equipment and supplies, respectively. The indirect cost for the project was estimated to be \$2000 for the utility, electricity, overhead, and room to facilitate the project.

Timeline

Four weeks prior to implementation, all stakeholders were identified, the patient data dashboard was created and finalized, the pocket cards were printed and laminated, and the baseline prescription reports were evaluated. Disseminating printed pocket cards and arranging one-on-one education on identified low-prescription providers were completed within two weeks. The implementation phase was allotted four weeks before the post-intervention evaluation took place. Post-implementation assessment and compiling data were completed in two weeks post-intervention. The timeframe for the entire project, from planning, and implementation to post-intervention evaluation, was approximately eight to 10 weeks. The project schedule provided a comprehensive overview of the project process and activities. A detailed project timeline is outlined in Appendix H.

Results

This scholarly project aimed to enhance clinician adherence to ADA 2022 guidelines by including SLGT2i in their treatment plan for patients with diabetes and CKD. The project goal was to increase SGLT2i prescriptions by greater than 10% from the baseline post-intervention over a 4-week implementation time frame. The effectiveness of the algorithm bundle intervention was also evaluated. Effectiveness was defined as increasing the rate of SGLT2i prescriptions.

Patient Data Selection

Inclusion criteria for the participants consisted of veterans, aged 40 years and older, who were assigned to the PACT team, with active problems of T2DM and CKD III. Patients were excluded from data analysis if they had type 1 DM, CKD beyond stage III, and/or with eGFR

less than 30. Six PACT team providers with a baseline of lower than 10% of SGTL2i prescriptions were identified and selected for algorithm bundle intervention.

Data Details

The patient data dashboard was the main source for data collection and stratification. The dashboard generates acquired data based upon specific selections of medication, PACT teams, month, and year. Empagliflozin 10 milligrams and 25 milligrams were the approved formulary SGLT2i agents at the VA; their prescription rates were monitored for this project. Therefore, empagliflozin 10 and 25 milligrams, the chosen PACT provider participant, and August 2023 were the key selections utilized to generate the prescription rate per provider within the given time frame. The resulting output also displayed the names of the providers/PACT team, number of prescriptions, number of patients, and patients' last names.

One week prior to implementation, a baseline measurement of the rate of prescribed empagliflozin per PACT team provider was established to enable post-intervention comparison. The rate of prescriptions was collected and monitored throughout the four weeks of the implementation phase.

Outliers

There was no concern about missing data. However, the charts of qualified patients without therapy were viewed individually for possible outlier exclusion. Outliers consisted of those patients who were qualified but not on SGLT2i treatment due to absolute contraindication; patient's refusal to initiate; poor compliance; history of intolerance or allergic to SGLT2i; loss in follow-up with the PACT team; or expired prescriptions. Absolute contraindication to SGLT2i included those patients with a history of frequent urinary infection, diabetic ketoacidosis, foot ulcers or amputation, or Fournier gangrene (DeSantis et al., 2022).

Data Integrity

All medication data were obtained from the patient's EHR without unique patient identifiers. The collected information was stored in the computer inside a highly secured VA facility. All VA computers could only be accessed by a federal employee's personal identity verification (PIV) card with unique password protection.

The algorithm and educational interventions did not cause any physical or emotional harm. In addition, some threats to patient privacy and data were considered. Compliance with HIPPA when handling patient information was reinforced to protect patient information. This evidence-based practice project was deemed a practical intervention for the facility and was approved by the Institutional Review Board (IRB) at the VA.

Data Analysis

The prescription data and its corresponding prescriber's *pre*-implementation and *post*implementation were organized and entered into an Excel spreadsheet (see Figure 2). Statistical analysis was performed using the Intellectus Statistics program (Intellectus, 2022). The data was assessed using the paired *t*-test to evaluate its statistical significance before and after intervention (Beavans, 2022). The project outcome of the two-tailed paired samples *t*-test showed statistical significance based upon an alpha value of .05, t(5) = -5.10, p=.004 (see Table 2). When the confidence interval is 95%, the result is considered statistically significant if the *p*-value reported from the t-test is less than 0.05. On the contrary, if the *p*-value exceeds 0.05, the result would not be considered statistically significant (Beavans, 2022).

Given the patient data dashboard's data collection and stratification capability, Cronbach's alpha coefficient was used to test the internal consistency reliability of the patient data dashboard in collecting prescription data. The range for Cronbach's alpha coefficient is from zero to one. A high and desirable reliable value would be 0.8 or higher (Sylvia & Terhaar, 2018). The result had Cronbach's alpha coefficient of 0.99, indicating excellent reliability (see Table 3). Hence, the patient data dashboard met the necessary criteria of face validity as an evaluation tool (Middleton, n. d.).

The finding of this scholarly project suggested the difference in the mean of the *pre-* and *post-* was significantly different. The pre-implementation mean of 29.33 was significantly lower than the post-implementation mean of 34.50 (see Table 2). The project outcomes reflected that the algorithm bundle had clinical significance in improving prescribers' knowledge of SGLT2i agents and practice compliance, as evidenced by a rise in SGLT2i prescriptions.

Impact

Heightened awareness and understanding of the importance of SGLT2i supported by the algorithm bundle was the vital driver in achieving primary care providers' practice change, which was the goal of this project. The implementation of the algorithm bundle was shown to effectively improve the overall utility of SGLT2i therapy, which positively impacted patient populations with DM and CKD. Optimizing the use of SGLT2i would ultimately impact patient outcome measures, lower ambulatory care sensitive condition (ACSC) quality indicators, reduce hospital admissions rate, and increase service reimbursement.

Barriers

Time constraints are a common challenge for primary care clinicians. Primary care providers spent a considerable amount of time to document, review lab or imaging results, and fulfill other administrative tasks in addition to serving patients. Therefore, during the implementation phase, not all identified providers for this project participated in the in-service session. Out of six participating providers, only three were able to review the SGLT2i algorithm with the DNP student and ask questions during the dissemination of the algorithm pocket card. The other three providers opted out of the in-service session because of lack of time due to attending meetings, conferences, or other tasks. Clarification during the follow-up could only be provided via messages and emails to the participating providers.

Another limitation was that another alternative may have been dismissed or overlooked when SGLT2i was over-emphasized. The new ADA guideline calls for SGLT2i and GLP-1 to have the same cardiorenal protection. Although SGLT2i was the considered approach for this project, its use was restricted to those with eGFR greater than 30. However, GLP-1 would have been an essential alternative without restriction for advanced CKD patients with an eGFR of less than 30.

Sustainability

After the data was collected, the DNP student continued to consult with staff to examine the safety profile of SGLT2i treatment and guide providers to initiate treatment on qualified patients. Continued monitoring of the progression of the SGLT2i prescription rate and present results via emails to each provider were conducted weekly.

The future sustainability plan is to present updates of SGLT2i utilization at the semiannual virtual "lunch-and-learn" session in primary care, which is anticipated to start in November 2023. The refresher information session reminds providers to adopt the prescribing practice of SGLT2i and automatically screen all diabetic patients with the SGLT2i algorithm on all clinical encounters. The future implication for this practice change includes incorporating the SGLT2i utility rate as one of the critical quality improvement metrics and integrating the SGTL2i algorithm into artificial intelligence (AI) within the EHR to adapt user preference, personalize treatment recommendations, enhance patient experience, and improve clinical outcomes.

Dissemination Plan

The dissemination of this scholarly project was performed through different modalities. The weekly progress reports and graphs were shared with the participating PACT providers via emails, the Microsoft TEAM messaging system, and PACT's interdisciplinary team (IDT) meetings. The project findings were made available to internal stakeholders, the medical chief of primary care and nephrology, quality improvement members, and other interested members and audiences. Other avenues for the project result submission include the annual Office of Nursing Service Research & EBP Poster Presentations in March 2024 and the New Knowledge & Innovations Poster Fair in April 2024 at the VA Long Beach, California, for evidence-based practice focusing on similar professional topics: improving clinical outcomes of patients with DM and CKD.

This manuscript will be published in the Scholarship and Open Access Repository (SOAR) at the University of St. Augustine for Health Sciences Library Portal. The Journal of Family Medicine and Primary Care will be considered for manuscript submission, as its peerreviewed, open-access publication covers a broad spectrum of clinical topics and academic needs relevant to this project's subject matter.

Conclusion

This change project intended for early detection and management of DM and diabetic kidney disease in primary care showed their significance in reducing future health challenges and healthcare expenditure related to its complications. The literature review demonstrated the clinical benefit of SGLT2i therapy in improving renal and cardiovascular outcomes, minimizing

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complications, and enhancing patients' quality of life. The evidence uncovered common underuse of SGLT2i therapy: limited knowledge, prescribing disparities, and restricted medication access among primary care clinicians.

The algorithm bundle intervention in this project resonates with ADA's latest recommendation to widen indications for using SGLT2 in optimizing the management of patients with DM and CKD. The evidence supported using a guideline-based algorithm to guide clinicians with a comprehensive assessment of high-risk patients and a better decision-making tool. The JHNEBP model and Lewin's change theory were chosen as a framework to guide this change project. Nevertheless, the focus of this change project relied on multidisciplinary collaboration among key stakeholders to support the new prescribing practice of SGLT2i. Continued efforts in educating and auditing are essential tools to assess potential knowledge gaps and sustain the prescribing practice of SGLT2i as part of the standard of care.

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Table 1

Implementation EBP Project Budget

Direct Costs Only											
Personnel	<u>Number</u>	<u>Total</u>		<u>Salary</u>	<u>Fringe</u>		<u>Total</u>		<u>otal</u>	<u>Funding</u>	
<u>(Title of Position)</u>	<u>Needed</u>	<u>Hours</u>			Bene		<u>Salary</u>		<u>ost in</u>	<u>Source</u>	
		_			<u>(28%</u>	-			ollars		
Pharmacy/Auditor	1	8		85	190.		870.4	-	70.4		
<u>Pharmacist</u>	<u>1</u>	<u>8</u>		<u>85</u>	<u>190.</u>	4	<u>870.4</u>	<u>8</u>	<u>70.4</u>	<u>In-Kind</u>	
<u>Subtotal Cost</u>								<u>1</u>	740. <u>8</u>	In-Kind	
										-	
<u>Equipment</u>	<u>Number N</u>	<u>leeded</u>	<u>C</u>	Cost per Ur	<u>nit</u>	-	<u>al Cost in</u>		Fundir	ng Source	
						<u>Doll</u>					
<u>Computers</u>	<u>1</u>			.500		<u>150</u>			In-Kind		
Printers	<u>1</u>		1	.00		<u>1000</u>			In-Kind		
Subtotal Cost						<u>250</u>	0		<u>In-Kinc</u>	<u>1</u>	
<u>Supplies</u>	Number	•	<u>C</u>	Cost per Ur	<u>nit</u>		<u>al Cost in</u>		<u>Fundir</u>	ng Source	
	Needed				<u>Doll</u>		<u>ars</u>				
<u>Paper</u>	<u>4 ream</u>		+	. <u>5</u>	<u>60</u>					In-Kind	
<u>Pens</u>	12		<u>7</u>		84				In-Kind		
lamination	<u>40</u>		6	<u>)</u>		240			In-Kind		
<u>Subtotal Cost</u>	+					<u>384</u>			In-Kind	<u>1</u>	
Total of Subtotal Co						200	0				
Indirect Cost (25%)						<u>200</u>					
TOTAL COST						<u>662</u>	<u>4.80</u>				
REVENUE											
Billing											
<u>Grants</u>											
Institutional budge	<u>t support</u>										
NET BALANCE											

Table 2

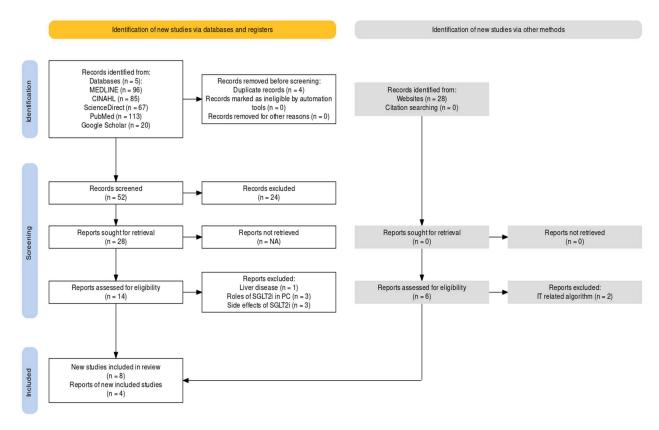
Two-T	Two-Tailed Paired Samples t-Test for the Difference Between Pre and Post										
Pre Post											
M	SD	M SD t p d									
29.33	29.33 16.23 34.50 17.85 -5.10 .004 2.08										
Note. N	N = 6. [Degrees	of Free	edom for the <i>t</i> -sta	tistic = 5. d re	presents Cohen's d.					

Table 3

Reliability Table for Rx rate									
Scale	No. of Items	α	Lower Bound	Upper Bound					
Rx rate	2	.99	.99	1.00					
<i>Note</i> . The lower interval.	and upper bounds of Ci	conbach's α	were calculated using a 9	5.00% confidence					

Figure 1

PRISMA Flowchart



Note. Prisma flow chart diagram from "Preferred Reporting Items for Systematic Reviews and Meta-analyses: The PRISMA Statement," by D. Moher, A. Liberati, J. Tetzlaff, & D.G. Altman, 2009, *Annals of Internal Medicine, 151*(4), p.267 (<u>https://doi.org/10.7326/0003-4819-151-4-</u> 200908180-00135). Copyright 2009 by The American College of Physicians.

Figure 2

Prescription Data Pre- and Post-intervention

	A	В	С
1	Participant	Pre-intervention	Post- intervention
2		7/24/2023	9/4/2023
3	1	37	46
4			
5			
6	2	40	45
7			
8			
9	3	25	28
10			
11			
12	4	50	56
13			
14			
15	5	5	7
16			
17			
18	6	19	25
19			
20	Participant 1	Eagle 5 PACT/Alvin R. NP	
21	Participant 2	Alpha 5 PACT/Dr.Hoang	
22	Participant 3	Laguna 1 PACT/Janessa C. NP	
23	Participant 4	Charlie 4 PACT/Sandy F. NP	
24	Participant 5	VTC 1 PACT/Jan V. NP	
25	Participant 6	VTC 2 PACT/ Alvita L. NP	
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Appendix A

Summary of Primary Research Evidence

Citation	Design, Level Quality Grade	Sample Sample size	Intervention Comparison	Theoretical Foundation	Outcome Definition	Usefulness Results Key Findings
Banjara et al., 2022 https://link.gal e.com/apps/do c/A733465477 /AONE?u=lirn 55718&sid=eb sco&xid=1f3e 87c6	A cross- sectional, web- based discrete choice experiment (DCE) questionnaire survey Level III, A	A sample size of 176 patients aged 19 years or older, diagnosed with T2DM, and proficient in English in May 2021	Web-based discrete choice experiment (DCE) questionnaire survey was used.	None	Six attributes: 1. the route and frequency of administration, 2. chance of reaching target HbAlc in six months 3. the percentage reduction in the risk of major adverse cardiovascular events (MACE) 4. the chance of gastrointestinal side effects 5. the chance of genital infection 6. out-of-pocket cost per month	Key findings: 1. when the initial treatment (i.e., metformin) alone did not help patients with T2DM achieve their treatment goal, SGLT2i or GLP-1RA would be the preferred alternative treatment In Mix model: 1. SGLT2i (oral route) > preference than GLP- 1 (injectable) 2. GLP-1 > SGLT2i reaching HA1C target, lower chance of urosepsis, lower GI SE, lower cost. In the Latent Class Model: 1. Older patients with more comorbidities did not prefer the addition of the second-line treatment: SGLT-2is and GLP-1 but the reverse preference for younger patients with comorbidities. 2. Older patients prefer oral, once-daily, once-a- week treatment, but younger patients are more flexible. Usefulness: Different ages and comorbidities have other preferences.
Colling et al., 2021. https://doi.org/ 10.2337/dc21- 0013	Quantitative appraisal study with multiple variables Level II, A	Sample size: 13,350 adults with type 2 diabetes (T2D).	The study used data from electronic health records (EHR) from the Primary Care Practice-Based Research Network (PBRN) at Massachusetts	None	To use the 2021 ADA guidelines algorithm to identify patients for whom a GLP- 1 RA or SGLT2i would be recommended.	Key findings: 1- EHR algorithm identified one-third of primary care patients with T2D as meeting the criteria for SGLT2i and GLP-1 RA 2- 13% of patients met the criteria for an SGLT2i based on heart failure or albuminuric chronic kidney disease (CKD), 3- 18% of patients met the criteria for either agent based on atherosclerotic cardiovascular

			General Hospital in Boston, MA.			disease or CKD with an albumin-to-creatinine ratio of ≤300 mg/g. PCP barriers: 1- lack of time and resource 2- lack of confidence in the knowledge 3- uncertain clinical responsibilities Usefulness: The algorithm approach helps identify patients eligible for these medication classes that could be used in real-time decision support.
Dennis et al., 2022. <u>https://doi.org/</u> 10.1016/S2589 - <u>7500(22)0017</u> <u>4-1</u>	Retrospective cohort study Level II, A	41807 study- eligible participants initiating SGLT2 or DPP-4 inhibitors Between Jan 1, 2013, and July 1, 2019	Data extraction from the UK Clinical Practice Research Datalink (CPRD) from 2013- 2019 And Individual participant data from 14 multi- country randomized clinical trials of SGLT2i and DPP4-I therapies	None	HA1C value and weight after six months of drug initiation in data from CPRD HA1C value after 3-6 months of drug initiation in data from trials studies	Key findings: The algorithm is potential precision medicine that allows the selection of optimal treatment based on the glycemic response, weight change, and tolerability outcomes when choosing between SGLT2 inhibitor or DPP-4 inhibitor therapies. Usefulness: The selection algorithm supports informed discussion between patients and clinicians on the benefits and risks of SGLT2i and DPP-4 inhibitors for individual
Gao et al., 2020. https://doi.org/ 10.1016/j.ahj.2 020.03.017	An experimental, qualitative study Level III, B	Convenience sampling 43 providers in endocrinolo gy, 357 in primary care, and 109 in cardiology at the Duke University Health System	Questionnaires were administered between May 17, 2018, and June 11, 2018 Using Research Electronic Data Capture (REDCap).	None	Identify providers' perspectives about prescribing GLP1RA and SGLT2i.	Key findings: Barriers: 1. Cost and procedural burden of prior authorization were significant barriers for endocrinology providers and PCPs 2. limited knowledge about these medications, worries of confusing current patient care, and discomfort in prescribing diabetes medications found in cardiologists. Usefulness: Educating clinicians would be critical to increase the use of these evidence-based therapies
Ghazwa et al. 2022.	Cross-sectional Analysis, non- experimental design	Patients with T2DM, 18 years or older, had received	Data collection from electronic medical records from two centers in Riyadh,	none	1. Proportion of patients who were or were not	Key findings: 1. High rate (81%) of under-prescribing SGLT2i or GLP-1 RA among patients that are likely to benefit from them. Older age and a history of

https://doi.org/ 10.3389/fpubh. 2022.1031306	Level III, A	care in one of the two centers between January 1, 2020, and December 31, 2020. Sample size: 1220	Saudi Arabia: a secondary care hospital, King Abdullah bin Abdulaziz University Hospital, and a tertiary care center, King Abdulaziz Medical City.		prescribed GLP-1 RA or SGLT2i 2. Factors associated with under-prescribing GLP-1 RA or SGLT2i and the distribution of prescriber specialties.	 stroke/TIA were significantly associated with higher odds of under-prescribing SGLT2i or GLP-1 RA. 2. Odds of under-prescribing were significantly lower among patients with T2DM who were receiving insulin 3. Endocrinologists were the most frequent specialty prescribing SGLT2i or GLP-1 RA (60.6%), followed by internal medicine (IM) physicians (11.4%). Cardiologists were responsible for only 9.8% of the SGLT2i or GLP-1 RA prescriptions, and nephrology for 2% Usefulness: Characteristics of patients who were eligible but not prescribed for SGLT2i
Hao et al., 2022 <u>https://doi.org/ 10.1186/s1287</u> <u>5-022-01731-</u> <u>w</u>	Cross-sectional study Level III, A	Adult patients> or =18 years old with DM (HbA1C > or = 6.5%) who visit the PC clinic between 1/1/2018 – 6/30/2019. Sample size: 7,168 patients	Data extraction from Alberta Primary Care Research Network (EMR) examined characteristics of patients with DM, the prevalence of cardiorenal indication for SGLT2i or GLP-1 RA, and the rate of SGLT2i and GLP-1 RA prescribing in high-risk patients relative to other DM patients	None	Guideline concordant targets: Blood pressure <130/80 mmHg, LDL-C < 2.0mmol/L, and HbA1C < 7%	Key findings: 56.8% met HA1C < or = 7.0% 62.1% met Blood pressure <130/80 45.3% met LDL-C < or = 2.0 4377 patients on glycose lower medications, Metformin commonly used 77.7%, insulin 24.6%, insulin secretagogues 23.6%, SGLT2i 19.7%, PD4-inhibitor 19.3%, GLP-1 RA 9.4% Barriers for SGLT2i rx: 1- access to new medication 2. clinician knowledge gaps 3. patient preferences, adherence 4. contraindications 5. clinician uncertainty of risk vs. benefit in high-risk populations, discomfort discussing AE of newer and less familiar medication, the belief that benefits observed in clinical trials do not translate into clinical practice Usefulness: Suggest increasing access, enhancing clinician knowledge, and assessing patient preference and adherence.

						Guideline variation makes quality improvement more complicated.
Marasinghe et al., 2022. <u>https://doi.org/ 10.1016/j.jcjd.</u> 2022.02.002	Cross-sectional Analysis, non- experimental design Level III, A	Patients with T2 DM that had at least one encounter with PCP from 12/31/2018 – 12/31/2020 Sample size: 11,939 patients	Electronic medical records review: 1- identify high-risk T2DM patients 2- Determine % of these patients are eligible for SGLT2i or GLP-1 RA in Primary Care	None	The proportion of persons with T2DM who were eligible to receive new treatment within either primary or secondary prevention according to 2020 updated guidelines.	GLP-1 RA and SGLT2i have cardiovascular and renal benefits for patients with T2DM 66% show indications, but <25% were prescribed Factors for low use: 1. Restricted access for PCP to prescribe these agents (special authorization or only restricted to specialties) 2. Lack of public coverage 3. One study observed that females and lower socioeconomic status are barriers to receiving appropriate care Usefulness: Consider economic analysis to explore the costs and value of expanded use of SGLT2i and possible difference in the Rx pattern.
Milder et al., 2021. <u>https://doi.org/</u> 10.1016/j.dabr <u>es.2021.10903</u> <u>6</u>	An experimental, qualitative study Level III, B	Purposive sampling approach 15 GPs and 12 Endocrinologis ts working in diverse areas of Sydney and New South Wales region.	Semi-structured interviews were conducted via online, phone, or face-to-face meetings. Interviews were recorded. An iterative general inductive approach was used for analysis by two researchers who independently reviewed transcripts and coded the data.	None	1-GPs' perspective regarding initiating SGLT2i 2- the support provided to GPs by endocrinologists in relation to rx of type 2 DM medications	 Key findings: Barriers to GPs prescribing SGLT2i 1- Less aware of the cardiovascular and renal benefits of SGLT2i 2 – GPs preferred Endocrinologist to decide 3- Patients' experience of adverse effects due to SGLT2i use contributed to a reluctance to rx SLGT2i 4- GPs had varied opinions about the usefulness of guidelines and difficulty engaging with this source of information 5- Endocrinologists had limited time to educate and support GPs Usefulness: Increase access to medications Less confusing guideline algorithm Multifaceted intervention is needed Address socioeconomic disadvantage and clinician's prescribing patterns.
Ng et al., 2022.	An experimental,	Purposive sampling approach	Used in-depth semi- structured interviews and The Consolidated	Theoretical Domains Framework (TDF)	To explore factors affecting PC doctors'	Key findings: Knowledge

http://dx.doi.or g/10.1186/s12 875-022- 01928-z	qualitative study Level III, B	Sample size: 17 primary care doctors in the Department of Family Medicine and Primary Health Care in Hong Kong	Criteria for Reporting Qualitative Research (CQREQ) checklist to guide the reporting of this study Interview questions are six open-ended and non-leading. All interviews were audio-recorded without repeat interviews.		prescribing of SLGT2i in patients with DM and established ASCVD/CKD	 1-Generally aware of the cardio-renal benefit of SGLT2i and recommendation 2- perceived benefits of SGLT2i mainly for glycaemic improvement, not independent of glycaemic efficacy 3- uncertain safety profile of SGLT2i Balancing risks/benefits 1-rx SGLT2i for obesity and suboptimal BP control 2- Concern for elderly 3- concerns to use on patients with renal impairment 4- patients' preference Clinicians' responsibilities Most PCP acknowledged the importance of roles and the appropriated to initiate SGLT2i. System barriers 1- Lack of time to discuss and follow up 2- Concern that the cost of medication may overrun the budget Strategies: 1- Clinicians need ongoing additional training/education 2- Encourage doctors to voice concerns, 3- Patients needing education on cardio-renal risk control 4. SGLT2i should be the key performance indicator besides HA1C control in patients with diabetes and established ASCVD/CKD status
						Usefulness: Barriers were identified to formulating strategies
Vasti et al., 2022 <u>https://doi/org/</u> <u>10.10116/j.dia</u> <u>bres.2022.110</u> <u>233</u>	Quantitative appraisal study with multiple variables Level II, A	Diabetes aged 18 years or older with a clinic visit to primary care or endocrinologist between	Used Optum insurance database to include data on medical and pharmacy claims, enrollment information, inpatient	None	Association between medical and sociodemographic characteristics with the likelihood of	Key findings: 1- low rx of GLP1RA/SGLT2i therapy in older patients 2 – Women, Black, Asian, and Hispanics have lower odds of GLP1RA/SGLT2i treatment

1/1/2018 to 1/1/2019. Sample size:793,525 patients	data, and clinician characteristics across all 50 states with Clinformatics DataMart database	GLP1 RA/SGLT2i therapy, Identify disparities in patient population and clinicians' practice	 3- Clinicians that are women, Black, Asian, and Hispanic also have low odds of prescribing GLP1RA/SGLT2i 4-Patients with lower income or low education attainment had lower odds of GLP1RA/SGLT2i treatment. 5. Endocrinology had a higher odd of prescription rate on SGLT2i or GLP1RA 6. Patients with HF and a higher rate of DM- related complications were less likely to receive GLP1RA/SGLT2i therapy
			Usefulness: Characteristics of patients and clinicians associated with the use of SGLT2i

Legend:

T2DM = Type 2 diabetes mellitus

AE = Adverse effects

Rx = Prescriptions

PC = Primary care

Appendix B

Summary of Systematic Reviews (SR)

Citation	Quality	Question	Search Strategy	Inclusion/	Data Extraction and Analysis	Key Findings	Usefulness/Recommendatio
	Grade			Exclusion Criteria			n/
							Implications
Li et al., 2020 https://doi.org/ 10.2215/CJN. 02690320	review of	Compare the effectiveness of SGLT2i and GLP-1 RA.	Not reported	Not reported	trials: EMPA- REG, CANVAS, DECLARE- TIMI 58, CREDENCE, ELIXA, EXSCEL, PIONEER 6, HARMONY, etc. Comprehensive risk assessment for patients with diabetic kidney disease. Compare the effectiveness of SGLT2i and GLP-1 RA for different risk categories. Assess the strength of current evidence for using SGLT2i and GLP-1 RA.	microalbuminuria & CV events 2. SGLT2i reduced risk for sustaining CKD or ESKD 3. SGLT2i reduce risk of AKI 4. SGLT2i reduced HF hospitalization> GLP- 1RA 5. GLP1-RA reduce metabolic risks>SGLT2i 6. Adverse effects of	Usefulness: Compare the effectiveness of SGLT2i and GLP-1 RA Implication: Decision-making, the stepwise algorithm can help clinicians determine when to consider SGLT2i and GLP-1 RA for heart and kidney protection and formulate mitigation Strategies to monitor and mitigate adverse effects

Citation	Quality	Question	Search Strategy	Inclusion/	Data Extraction and Analysis	Key Findings	Usefulness/Recommendatio
	Grade			Exclusion Criteria			n/
							Implications
2022 https://doi.org/ 10.1016/j.ekir.	review of RCTs with meta-analysis Level I, A	Indications for SGLT2 inhibitors in patients: 1. with and without diabetic kidney disease 2. heart failure with or without reduced ejection fraction 3. use in patients with stage 4 CKD, and chronic glomerulonephritis.	Not reported	CKD patients in SGLT2i from clinical trials: SCORED trial: 10584 DAPA-CKD trial: 4304 EMPA-Kidney trial:6609 CREDENCE trial: 4401	trials: CREDENCE, DAPA- CKD, SCORED, EMPA- KIDNEY, etc. Data extracted from these trials are used to compare CKD participants' characteristics in using SGLT2i.	for patients with CKD without albuminuria. 2- anticipated acute	Usefulness: More indications for SGLT2i and the usefulness of the algorithm guiding the decision

Legend:

AKI = Acute kidney injury

- CANVAS = Canagliflozin cardiovascular assessment study
- CREDENCE = Canagliflozin and renal events in diabetes with established nephropathy clinical evaluation
- DAPA-CKD = Dapagliflozin and prevention of adverse outcomes trial in chronic kidney disease

DECLARE-TIMI 58 = double-blind, multinational, placebo-controlled, phase 3 trial of dapagliflozin collaboratively by the Thrombolysis in

Myocardial Infarction (TIMI) Study Group.

ELIXA = randomized, double-blind, placebo-controlled, parallel-group, multi-center, phase III, event-driven trial evaluation of Lixisenatide in Acute Coronary Syndrome

EMPA-Kidney = The study of heart and kidney protection with empagliflozin

EMPA-REG = Empagliflozin in cardiovascular outcome event trial

EXSCEL = Exenatide Study of cardiovascular event lowering trial to evaluate cardiovascular outcomes after treatment with exenatide once weekly in patients with type 2 diabetes mellitus

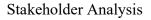
HARMONY = a randomized, double-blind, placebo-controlled trial of the effect of albiglutide on major adverse cardiovascular (CV) events in

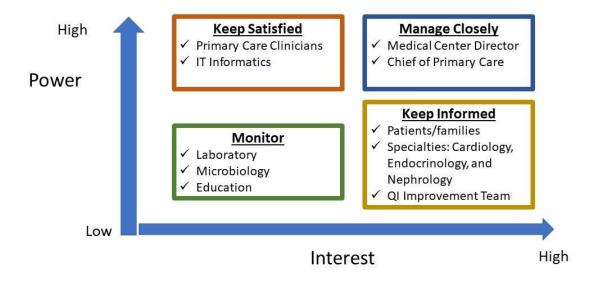
patients with T2DM and established CV disease

PIONEER 6 = Peptide Innovation for Early Diabetes Treatment, preapproval cardiovascular outcomes trial specifically designed to rule out the excess cardiovascular risk with oral semaglutide among patients with type 2 diabetes

SCORED = Trial assesses the effect of sotagliflozin on cardiovascular and renal events in participants with Type 2 diabetes and moderate renal impairment who are at cardiovascular risk

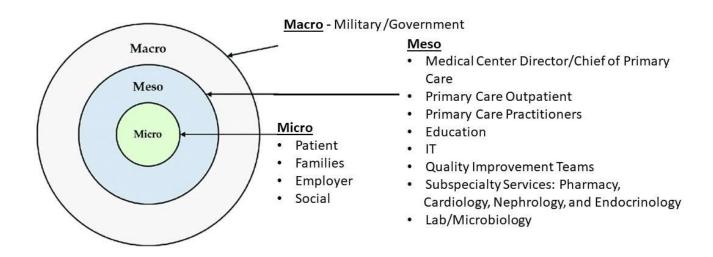
Appendix C





Appendix D

System Change



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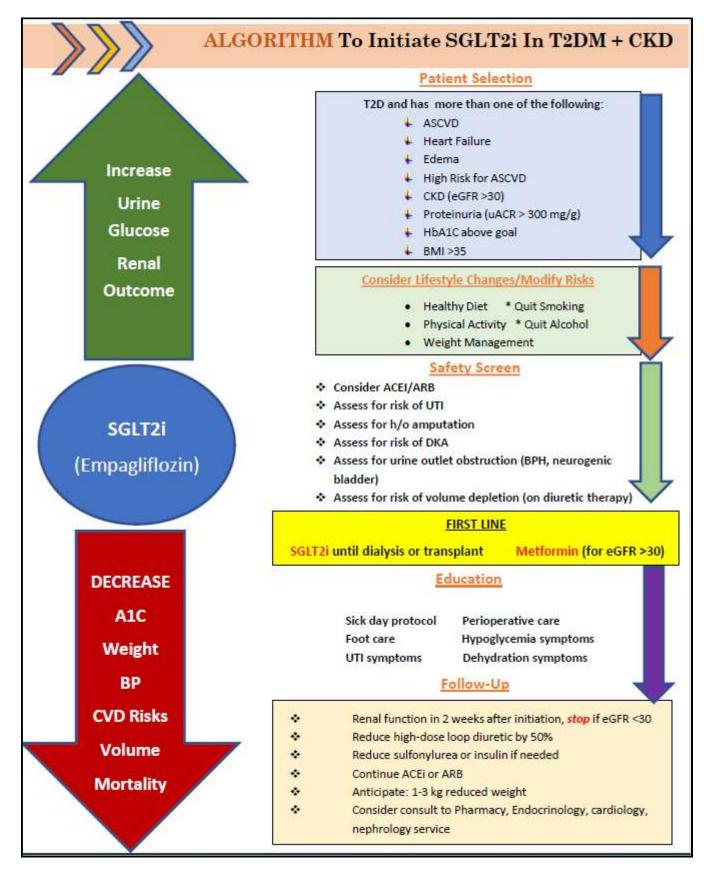
Appendix E

SWOT Analysis

Strengths	Weaknesses
 Federal funding Strong leadership/QI team support for change project Robust EMR infrastructure for data sharing across all disciplines Cost effective Efficient in care delivery 	 Provider resistance Lack of time Lagging from the correspondence Confusing algorithm pathways
Opportunities	Threats
 Increase awareness of multidisciplinary collaboration Project can be adopted across all specialties across different VA facilities Highly relevant to all specialties Increase providers/patients' confidence in VA health system 	 Patient refusal/non-compliance Complications due to lost follow up Mismanagement

Appendix F

Algorithm To Initiate SGLT2i



Appendix H

Project Schedule

	NUR7801									UR78	02						NUR7803								
Activity	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	
Meet With Preceptor	X	Х		Х				X																	
Conduct Practice Setting Assessment	X																								
Review Literature	X																								
PICO Approval	X																								
Discuss Project Proposal With Primary Care Leadership	X				X																				
Discuss Project Proposal With the Chief and Attendings of the Nephrology Department	X																								
Meet with IT for Data Extraction, Stratification	X	X		Х		X		X																	
Meet with VA IRB			Х					X																	
Evidence Search			Х	Х																					

	NUR7801									UR780	02					NUR7803								
Activity	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15
Stakeholder Analysis	X			Х	X																			
SWOT Analysis				Х	X																			
Budge Analysis					X																			
Implementation Plans					X																			
Design Intervention Tools					X																			
Finalizing Project Proposal							X	X																
Identify and Meet All Stakeholders								X	X	X	X	X	X	X	X	X	X	X						
Create and Modify Patient Data Dashboards								X	X	X	X													
Formulating/revising Algorithms								Х	X	Х	X													
Print Algorithm Pocket Cards											X													
Evaluate Baseline Prescription Reports												X	X											
VA IRB review, revise, and approval											X	Х	Х	Х										

	NUR7801									UR78	02						NUR7803								
Activity	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	Week 1	Week 3	Week 5	Week 7	Week 9	Week 11	Week 13	Week 15	
Disseminating Printed														X	X	Х	Х								
Pocket Cards																									
One-on-one Education															X	X	Х	X	X	Х	X	X	X	X	
and Consultations																									
Dissemination of the																Х	Х	X	Х	Х	X	X	Х	Х	
results/ Evaluating results																									
Revise manuscript																	Х	X	Х	Х	X	X			
Finalize manuscript																						X	Х	X	
Construct Project Poster																							Х	Х	