Title

Implementing an Enhanced Continuum of Care (ECC) Model for Patients with Diabetes and a History of COVID-19 Infection (DAHOCI)

Author

Wasonga-Agak, Jacobett Naomie O

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Implementing an Enhanced Continuum of Care (ECC) Model for Patients with Diabetes and a History of COVID-19 Infection (DAHOCI)

A dissertation submitted in partial satisfaction of the

requirements for the degree

Doctor of Nursing Practice

by

Jacobett Naomie O Wasonga-Agak

2024

ABSTRACT OF THE DISSERTATION

Implementing an Enhanced Continuum of Care (ECC) Model for Patients with Diabetes and a History of COVID-19 Infection (DAHOCI)

by

Jacobett Naomie O Wasonga-Agak

Doctor of Nursing Practice

University of California, Los Angeles, 2024

Professor Holli A. DeVon, Chair

Background: Despite the increasing cardiovascular risks (microcoagulation, hyperlipidemia, hypertension, and hyperglycemia), there is currently no standard continuum of care for patients with type 2 diabetes (T2DM) complicated by COVID-19. **Objectives:** The purpose of this quality improvement project was to evaluate the implementation of a 3-month enhanced continuum of care (ECC) model, including four pre-scheduled post-discharge appointments, education support, and medication reconciliation, and how it impacts cardiovascular risks in patients with diabetes and a history of COVID-19 infection (DAHOCI) following hospital discharge. **Methods:** Participants were adults with T2DM admitted to a community hospital

compared to age and sex matched patients admitted prior to the beginning of the project. Exclusion criteria were minors, pregnant women, prisoners, employees, and patients admitted to the Intensive Care Unit (ICU) due to prognosis. Appointments took place in person and over the phone. Primary outcomes were a reduction in HgA1C, PT/PTT, lipids, and blood pressure. Secondary outcomes were patient adherence to diabetes self-care behaviors measured with the Hill-Bone Adherence Scale, hospital readmission for any reason, provider adoption, and nurse engagement. **Results:** Nine patients were enrolled in the intervention group. Average age for the intervention group was 50.6 years (51.6 years for non-equivalent group), 55% were female, 88.9% were Hispanic-White. LDL (p=0.04), PT (p=0.027), and PTT (p=0.038) decreased in the intervention group at baseline compared to non-equivalent group. Patients were more likely to miss their appointments (37.5%; p=0.055) at study completion. There was no difference in level of sodium intake, likelihood to keep appointments and adherence to medications at completion. Adherence to appointments varied with 88%, 22%, 55%, and 77% of patients attending post discharge visits at time 1, 2, 3, and 4 respectively. Readmission rate was 66%, provider adoption was 55.6%, and nurse engagement and 88.9%. **Conclusion:** Findings provide preliminary evidence for the establishment of an enhanced continuum of care model for patients with diabetes and a history of COVID-19 infection (DAHOCI) and that multiple follow-up appointments for patients with diabetes following COVID infection can reduce LDL, PT, and PTT levels.

Key words: Diabetes; COVID-19; Follow-up Care; Microcoagulation; Cardiovascular Risks.

The dissertation of Jacobett Naomie O Wasonga-Agak is approved.

Carol L. Pavlish

Denice Economou

Holli A. DeVon, Committee Chair

University of California, Los Angeles

2024

Dedication

This dissertation is dedicated to my mother, Damaris, a single parent and accomplished educator who embodied the essence of resilience and excellence, and to my aunt, Rosemary, who inspired the nurse I am today by being the nurse's nurse.

To every girl-child with the heart to make a difference and a dream to fulfil – it's never too late. With determination, sacrifice and love, every dream is realized.

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Lastly, I honor my precious ABC sons for their sacrifice, love, and support through my academic pursuit; my extended family and friends for their prayers and practical support that my husband and boys needed during my academic journey. Most importantly, I give God the glory for His faithfulness through every step.

VITA

JACOBETT WASONGA-AGAK, MSN, MSHCM, RN, PHN, AGCNS-BC

POSTER PRESENTATION AND RESEARCH PARTICIPATION

- Wasonga-Agak, J., Pavlish, C., Economou, D., DeVon, H., (2024, May) Implementing an Enhanced Continuum of Care Model for Patients with Diabetes and a History of COVID-19 Infection (DAHOCI), Valley Presbyterian Hospital, UCLA 20th Annual UCLA Nursing Science and Innovation Conference, & 28th Sigma SoCal Odyssey Conference 2024.
- Horkay, M.C., Recalde, V., Wasonga-Agak, J., & Cordova, J., (2023, May 9), HOUDINI Protocol: Acculturation of nurse-driven intervention for reduction of CAUTI and indwelling catheter utilization, Professional Poster Symposium, Valley Presbyterian Hospital
- Wasonga-Agak, J & Laboy, M., (2023, May 9), Implementation of ESAR program: improving patient participation, Professional Poster Symposium, Valley Presbyterian Hospital
- Wasonga-Agak, J., (2023, May 9), Evaluation of barriers impacting timely patient discharge: Pilot study, Professional Poster Symposium, Valley Presbyterian Hospital

PROFESSIONAL EXPERIENCE

Valley Presbyterian Hospital: Van Nuys, CA **11/2021 – Present**

Clinical Nurse Specialist – Acute Care Services (Two Telemetry and Five Medical Surgical Units)

- Clinical Expert – Serve as clinical expert in translation of research to practice, contact for care of complex non-critical patients, represent acute care services in interprofessional leadership councils.
- Leadership – Active participation in Clinical Leadership Council, Quality Steering Council, Clinical Scientific Inquiry, Interdisciplinary Practices Committee, Patient Safety Committee, Clinical Practice Committee (Chair), Education Committee, Restraints committee (Co-Chair), among other leadership teams as needed. Review, revise, and formulate organizational policies and procedures.
- Collaboration – Collaborates with executive leadership, medical team, informatics specialists and nursing representatives in patient care initiatives and quality improvement projects.
- Consultation – Participate as Clinical expert on clinical practice policies and regulatory, assist with Diabetes Education consults, Support clinical nurses with complex patient care coordination/advocacy at bedside.
- Research – Development and presentation of EBP projects for new grads and new hire. Mentor for research proposal for new grads, project co-lead for three systemwide projects
- Education – Collaborative development of the New Grad Curriculum and utilization of HealthStream, Development and presentation of education for the nursing team for new projects.

Providence St. Joseph Medical Center: Burbank, CA **04/2018 – 06/2022**

ICU Registered Nurse IV ***04/2021- 06/2022***

- Provide nursing critical care to patients with Neuro, Cardiac, Respiratory and Multi-system complications
- Manage and deliver critical care to patients with COVID-19 complications.
- Implement patient education, palliative care, and end-of-life support to patients and patient families.
- Leadership & Shared Governance Roles (ICU): Diabetic Resource Nurse, Diabetic Council Member, and Early Mobility Champion

Med-Surgical Registered Nurse II ***04/2018-04/2021***

- Provide acute care and patient education to medical surgical patients with focused care of post-op bariatric patients, COVID-19 patients, and other medical/surgical complications of abdominal cavity.
- Provide patient and family inpatient and discharge education.
- Serve as Safety Officer during COVID Pandemic – support Caregivers in infection prevention.
- Function as Crisis-RN to support ICU & Telemetry RNs provide care in critical care units.
- Leadership & Shared Governance Roles (Med-Surg): Diabetic Resource Nurse, Diabetic Council Member, and Preceptor for new hire, new grad nurses and student nurses

JACOBETT WASONGA-AGAK, MSN, MSHCM, RN, PHN, AGCNS-BC

Brandman Centers for Senior Care - LAJH: Los Angeles, CA **01/2015 – 12/2017**

Medical Records Coordinator/Health Plan Associate

- Obtained, recorded, and retrieved clinical documentation; Facilitated ICD9 to ICD10 transition.
- Converted paper records to EMR; & Performed compliance & Documentation integrity audits.
- Provided EMR training; & initiated lean-process improvements; Generated state required reporting.
- Health Plan Management &Invoicing; & Process and Reconcile health claim status on IBNR.
- Verify Medicare/Medicaid eligibility; Maintain 820 DHCS & Medicare payment records.

Emanuel Morez, Inc.: Los Angeles, CA **06/2006 - 08/2011**

Administrator/Office Manager

- Executive admin, Customer Service, Contract negotiations, & Conflict resolution.
- Project management, personnel file management, HR generalist, recruitment/training, & payroll
- Accounts payable/receivables, bank reconciliations, financial reports, and shipping logistic

Institute of Primate Research.: Nairobi, Kenya **02/2001 - 10/2002**

Graduate Research Associate

- Supervised internship students
- Managed and performed laboratory/scientific experiments,
- Completed data and sample collection & analysis, sorting, labeling, and storage.
- Scientific Peer-reviewed published author – Prepared manuscript for publication, published author.

ACADEMIC ACHIEVEMENT

University of California – Los Angeles, CA	**Doctor of Nursing Practice**	Sept 2024 (Expected)
California State University – Dominguez Hills, CA	**MSN-CNS (Adult-Gerontology)**	Dec 2020
Los Angeles Pierce College: Woodland Hills, CA	**Associates (AS) in Nursing**	Dec 2017
West Coast University: Los Angeles, CA	**MS in Healthcare Management**	Dec 2012
Los Angeles Pierce College: Woodland Hills, CA	**AA in Business Management**	June 2009
University of Nairobi: Nairobi, Kenya	**Bachelor of Science (Biology)**	Nov 2000

LEADERSHIP AND PROFESSIONAL AFFILIATIONS

• National Association of Clinical Nurse Specialist (NACNS)	Sept 2019 to Date
• California Association of Clinical Nurse Specialist (CACNS)	Nov 2019 to Date
• American College of Healthcare Executives (ACHE)	2013 to date
• Health Care Executives of Southern California (HCE)	2013 to date
• American Nurses Association (ANA)	June 2018 to date
• Nursing Program Class President – LA Pierce College	Spring 2016 to Spring 2017

HONORS AND ACADEMIC AWARDS

• Gorman Centennial Fellowship in Nursing Recipient	March 2024
• Vice President (2023-2025) – Sigma Theta Tau Int (Xi Theta Chapter)	July 2023 to Date
• Membership Involvement Chair (2021-2025) – Sigma Theta Tau Int (Xi Theta Chapter)	May 2019 to Date
• Los Angeles Pierce College Full-time Honors Dean List	Spring 2009 & 2007
• Los Angeles Pierce College Part-time Honors Dean List	Fall 2008 & Fall 2007

LICENSURE AND CERTIFICATIONS

• RN – Registered Nurse CA License (#95157691)	Valid through 06/30/25
• CNS – Clinical Nurse Specialist CA License (#4920)	Valid through 06/30/25
• AGCNS-BC – Adult Gerontology Clinical Nurse Specialist Board Certified (#2021028064)	Valid through 08/17/26
• Public Health Nurse (#PHN562273)	Valid through 06/30/25
• ACLS for Healthcare Providers (American Heart Association)	Valid through 07/31/25
• BLS for Healthcare Providers (American Heart Association)	Valid through 04/30/25

CHAPTER ONE: INTRODUCTION

Aligning care to the disease process is becoming the norm that facilitates patient-centered and value-based care especially in chronic disease management. Diabetes Mellitus (Type 1 and Type 2) is a chronic disease reliant on patient's self-management practices and guided by continuum of care plan prescribed and recommended by providers. Evidently, chronic disease management thrives in collaborative effort of the patient, providers and other interprofessional team members. However, diabetes-related cardiovascular complications make management of diabetes more burdensome and complex for the patient and the health systems. The onset of Coronavirus Disease 2019 (COVID-19) further complicated diabetes care and increased the cardiovascular risks for the patient population. COVID-19 is identified as a diabetogenic agent contributing to new onset diabetes and exacerbating hyperglycemia (Lima-Martínez et al., 2021). The unique treatment regimen during acute COVID-19 resulted in steroid-induced hyperglycemia leading to higher insulin dosage and hypoglycemia risks (Amiel et al., 2019; Khanam, 2021; Knight et al., 2022). The lack of follow-up to adjust medications post COVID-19 infection further exposed patients to hypoglycemia, lingering microcoagulation, and increased cardiovascular risks. The microcoagulation in post COVID-19 infection lingers up to 48 weeks later, further increasing cardio-vascular risks for stroke and myocardial infarction (MI). In addition, diabetes is a verified independent risk factor for cardiovascular disease and increases the severity of COVID-19 infection (Lima-Martínez et al., 2021). This simultaneous impact of COVID-19 and diabetes leads to a synergistic relationship where both facilitate increasing cardiovascular risks and influence severity of both disease processes.

Problem Statement

Despite evidence of increasing cardiovascular risks (microcoagulation, hyperlipidemia, hypertension, and hyperglycemia), there is currently no standard continuum of care or updated guidelines for patients with type 2 diabetes (T2DM) complicated by COVID-19 (Abe et al.,2022). Improving health outcomes for type 2 diabetes involves the collaborative efforts of a provider's transition of care regimen and patient adherence to the follow-up regimen. The current cardiometabolic related standard of care recommends a yearly follow-up for cholesterol and electrocardiogram testing as part of the self-management (American Diabetes Association Professional Practice Committee, 2022). Microcoagulation has been shown to be present in patients with diabetes and a history of COVID-19 infection (DAHOCI) up to nine months post COVID-19 infection, further increasing cardiovascular risks (Knight et al., 2022). Further studies on readmissions rates related to these complications and the potential for reducing the financial burden for both the patient and facilities are recommended (Rubin & Shah, 2021). A translation of research to evidence-based practice addressing the identified practice gap and further inquiry in this population is warranted.

The complexity of management of chronic diseases poses a significant burden to both the patient and the facilities that care for them. Furthermore, social determinants of health (SDoH) have an identified impact on the management of chronic diseases which are highly reliant on the adherence of the patient to the treatment and self-management regimen as is with diabetes. Some patients do not keep up with the self-management and recommended appointments resulting in readmissions and increased risk for other associated comorbidities like diabetic related cardiovascular complications. In addition, the recommended patient support on continuum of care has not adjusted to mitigate these increasing cardiovascular risks.

One of the strategies to reduce the impact of diabetes-related cardiovascular risks involves improving patient engagement in adherence to the follow-up schedule for their self-management regimen. Therefore, implementing a nurse-led or nurse driven program to support the treatment and self-management regimen in patients with diabetes is vital to improving health outcomes. Virtual inpatient consultation and management of diabetes was successfully utilized at the height of the COVID-19 pandemic and incorporated in the enhanced follow-up care model for patients with DAHOCI to support an improved continuum of care. To bridge the continuum of care clinical practice gap, an advanced practice nurse-led enhanced continuum of care model with integrated telehealth was initiated to 1) identify patients while admitted in the hospital, 2) provide appropriate and enhanced discharge education resources, and 3) confirm a follow-up appointment has been scheduled, (Cheung et al., 2022; Lim et al., 2020). Studies have demonstrated the success of a nurse-led initiative for the adolescent population, but extensive studies on the impact of utilizing nurse-led telehealth on adult population with diabetes are lacking (Lim et al., 2020).

Purpose and Objectives

The purpose of this evidence-based practice (EBP) quality improvement (QI) project was to evaluate the implementation of a three-month enhanced continuum of care model and how it impacts cardiovascular risks in patients with type 2 diabetes and a history of COVID-19 infection (DAHOCI) following hospital discharge. In addition, evaluate the engagement of clinical providers during the implementation of the enhanced continuum of care model. The continuing objectives of the project explores how the enhanced follow-up and supportive care impacted patient outcomes by reducing the risks for cardiovascular complications, reducing readmissions associated with these complications, improving patient adherence with the self-

management regimen, preventing avoidable complications associated with limited comprehension of post-discharge instructions, promoting adoption of the enhanced continuum of care protocol by providers and engaging nurses in the project.

Clinical Question

The population/problem-intervention-comparison-outcome-time frame (PICOT) clinical question for this Doctor of Nursing Practice (DNP) Scholarly project is, in patients with diabetes and a history of COVID-19 infection (P), does implementing an enhanced follow-up care model within three months of hospital discharge (I) compared to the standard of practice of a single follow-up every three months (C) impact the risk for and management of cardiovascular complications including microcoagulation, hyperlipidemia, and hypertension (O) within three months (T)?

The enhanced follow-up care included four visits in the first three months following hospital discharge, impacts biomarkers of cardiovascular risk (i.e., Glycated Hemoglobin (HgA1C), blood pressure (BP), prothrombin time (PT), activated partial thromboplastin time (APTT), and lipid panel and hospital readmission. Other secondary outcomes evaluated were improvement of patient adherence with the self-management regimen, reduction of avoidable medication errors associated with limited comprehension of post-discharge instructions, and promotion of practice adoption of the enhanced continuum of care model by providers.

Background

The patient population with diabetes has been growing from 10.3 million in 1999 to over 37.3 million in 2023 with 8.5 million more undiagnosed (Centers for Disease Control and Prevention [CDC], 2020; 2022). According to the CDC (2020), over 97 million adults in America are also overweight, increasing their risk for diabetes. Ninety percent of the diabetes

population has type 2 diabetes (T2DM), representing an enormous opportunity to improve health status by optimizing interventions to reduce risk factors (CDC, 2020; Joseph et al., 2022). The patient population with diabetes was adversely impacted by the COVID-19 pandemic. Research indicates that there is a synergistic relationship between diabetes and COVID-19 infection, further increasing the cardiovascular risk factors for this patient population (Khanam, 2021; Khunti et al., 2021; Profili et al., 2022). The synergistic relationship is accounted for due to patients with diabetes having an increased risk of cardiovascular complications while simultaneously, the COVID-19 typifies a diabetogenic agent (Lima-Martínez et al., 2021). The virus "binds to the ACE2 beta cells of the pancreas resulting in an acute dysfunction and changes to glucose" (Lima-Martínez et al., 2021, p. 156). The COVID-19 treatment regimens also impact the severity and expression of hyperglycemia and the care plan after COVID-19 infection for the patient with diabetes (Khunti et al., 2021; Nassar et al., 2021; Widjaja et al., 2019).

About a third of the patients admitted to hospitals and 39.7% of hospitalized COVID-19 survivors have diabetes, therefore increasing the burden of care for health systems and patients (American Diabetes Association [ADA], 2021; Gold et al., 2020). Diabetic management is highly reliant on the provider-guided treatment regimen and the patient's adherence to the self-management schedule and model of care. However, the guidelines for diabetes continuum of care for those with a history of COVID-19 infection have not evolved despite the impact of COVID-19 on diabetes. Patients with diabetes have a threefold increased risk for stroke and a doubled risk for cardiovascular events when coupled with hypertension (Joseph et al., 2022). The risks of sudden cardiac death and unrecognized myocardial infarction (MI) are greater due to painless ST-segment depression MI and masked symptoms in patients with diabetes (Joseph et al., 2022). The cardiovascular risk factors have also increased the readmission rates from 14.7%

in 1999 to 22% in 2022 for patients with diabetes in comparison to 13.5% for the general patient population in 2022 (Beauvais et al., 2022; Hsieh, 2019). Studies indicate that microcoagulation risk post COVID-19 infection remain significantly higher with a risk of 22 times a week post-COVID-19 recovery, four times higher at about 20 weeks and 1.8 times higher at about 48 weeks, increasing the risk for stroke (Knight et al., 2022). In addition, chronic hyperglycemia increases the risk of hypercoagulation by 80% and prothrombin time (PT), activated partial thromboplastin time (APTT), and fibrinogen have been identified as effective hemostatic marker for assessing microcoagulation risk in patients with diabetes (Agarwal et al., 2019; Widjaja et al., 2019).

The average readmission rate at the clinical project site was 12.5% in July 2023. The cost associated with the readmission for patients with diabetes based on a 20% readmission rate was estimated at $24.6 billion nationally and $15,200 per admission (Beauvais et al., 2022; CDC, 2020). Evidence recommends that implementing early interventions improved health outcomes and reduces the reutilization of acute care facilities especially in patients with a high risk for 30-day readmission such as those with diabetes (Akbari et al., 2022; Rubin & Shah, 2021; Soh et al., 2020). The reported financial impact of management of diabetes is over 39 billion in California each year (American Diabetes Association, 2021). Cardiovascular complications add to the financial burden that impacts the target patient population and the facilities. Return on investment is reflected by cost-avoidance associated with readmissions. Translation into practice of the outcomes from this project plays a vital role in embracing the quadruple aim of care models (Nundy et al., 2022).

CHAPTER TWO: THEORETICAL FRAMEWORK

Every established discipline is validated by the proven concepts and principles that govern the specific clinical practices within the discipline. Nursing discipline is the science of human beings. It involves the intellectual, cognitive, behavioral, social, psychological, physiological, and spiritual nature of human beings which is impacted and influenced by the interaction of each of these facets with the changing environment the human being lives in and adopts to. This unique nature of nursing practice builds the premise for nursing principles to have reciprocal relationships with other disciples. This unique utilization of organized framework of concepts to guide practice develops and validates theories and theoretical frameworks in nursing. Nursing theories are developed by nurses or in collaboration with other disciplines but are validated by nurses as research is translated into practice or in data generated during routine care that yields similar results over a significant period, population, behavior, or process.

The implementation of the enhanced continuum care model constitutes a change in practice and Kurt Lewin's Change Theory guided the organizational change in practice (Appendix A). The Iowa Revised Model Evidence-Based Practice to Promote Excellence in Health Care provided the critical evidence-based steps to effect the necessary change in process on all levels of care and with interprofessional partnerships (Hussain et al., 2018; Iowa, 2017). These theoretical frameworks supported planning, implementation, and evaluation of the more frequent follow-up plan for the patient population to ease the complexity of care and self-management post COVID-19.

Lewin's Change Theory

Among the evolving nursing theories, Kurt Lewin's Theory of Change is utilized in many aspects of a DNP by the CNS in their role as a change agent focused on research, education,

consultation as a clinical expert and nursing leadership. The theory of change evolved in response to a need for effective ways to resolve religious and racial prejudice by the father of social psychology Kurt Lewin, in the 1940s. This theory involves the replacement of prior behavior and adoption of new behavior by analyzing all the concepts of the current practice, evaluating meaning options and then establishing a new premise to support the change.

Lewin's change theory constitutes a balance of three stages – unfreezing, moving, and refreezing (Butts & Rich, 2022). In addition, the framework interacts with three concepts involving the driving forces, restraining forces and equilibrium. The driving forces push towards change while restraining forces away for the change. The goal is to find an equilibrium especially in the change process. An inclination toward the driving forces yields change. Identifying the driving forces and aligning interventions with the designed change in practice is warranted.

The first stage, unfreezing process, involved the providers re-evaluating current practices and frequency of follow-up especially relating to the patient's cardiovascular outcomes and readmission burden. The evidence of increasing cardiovascular risks related to extended exposure to microcoagulation and increasing follow-up appointments from one per year to more frequently was evaluated and recommended. The model involved a departure from the norm, and adoption of a patient-centered care based on results of coagulation tests and the institution of anticoagulant maintenance therapy at discharge rather than waiting for complications or readmissions for cardiovascular complications (Joseph et al., 2022; Knight et al., 2022).

The second stage, moving process, involved activities related to transition to the practice change, evaluating any modification that were warranted and beginning adoption of the practice as a standard of care (Butts & Rich, 2022). Once the practice model was established, the third

stage, the refreezing process, was established with new practice guidelines. To facilitate change in the model, a policy or guideline was recommended to support the change and provide a framework for sustainability. Inter-professional collaboration and partnerships are vital during the change process.

In Lewin's theory of change, the three stages and concepts interact to produce desired outcomes. Each stage involves strategies for increasing the driving forces and reducing the restraining forces to facilitate early adoption and buy-in to the change. Nursing theories have a symbiotic relationship with clinical practice. As nurses utilize theories that support the desired outcome of behavior, the theories are validated to guide practice towards a certain outcome by applying specific, systematic, scientific strategies and processes. In addition, nursing theories cannot work in isolation but integrate philosophical principles of ethics to guide practice when faced with ethical dilemmas revolving around autonomy, justice, beneficence, and protection of vulnerable populations. Since behavior is influenced by belief systems, to achieve sustainable change, the provider or the patient must find meaningful value in implementing the change for improving health outcomes (Turrise, et al., 2019). Such global views and healthcare strategies are tenets of the Doctor of Nursing practice.

Review of the Literature

Theoretical frameworks are supported by evidence-based practices to identify and incorporate driving forces in a process, program or practice. The evaluation of past evidence that reinforced the need for the change was assessed to validate that the change would be successfully applied in a similar or varied setting, validated through multiple replications, and that the reproducible outcomes reliably indicated necessity for improving the practice. Evidence for mitigating and overcoming the restraining forces was also identified in literature to provide a

framework for research and influence changes clinical practices and nursing academia change (Avery-Desmarais, et al., 2021; Flanagan, et al., 2021; Shelby, et al., 2020; Turrise, et al., 2019). Kurt Lewin's Theory of Change was utilized in these articles to frame practice change.

The DNP-prepared leader was integral in fostering this translation of research into practice. The DNP leader designed and led the measurement and evaluation of outcomes incorporating the required scientific inquiry process to collect and analyze data. Nursing was vital in providing the data and validation of the theoretical framework for its intended application. Utilization of theory provided the framework for reproducible and replicable work that builds nursing knowledge and development of theoretical framework that guides future practices. to frame their project and influence change in nursing academia and practice.

Flanagan, et al. (2021) explored the lagging gap of adoption of nursing theories and framework in daily practice despite evidence that inclusion of theoretical frameworks improves health outcomes and advances nursing as a discipline. One of the aspects to promote sustainability of practice change is to advocate for inclusion of the change in practice in policy (Rocafort, 2020).

The DNP role is evolving in the nursing practice and Shelby, et al. (2020) affirmed the complexity science that organizations have to adopt in the organizational systems, processes and policies. As the DNP-prepared leader takes leadership in the organizations, it "disrupts linear traditional leadership" and brings evidence-based practice to the forefront of care delivery and leadership. The theoretical framework guided the identification of the practice gap and provided strategies to address practice change, therefore setting precedence for advances of nursing knowledge framed by nursing theories (Tenaglia, et al., 2022).

Application of the Theoretical Framework

The theoretical framework was validated by the associated data and outcomes. As the nursing principles aligned with the theory were applied in the practice through theory-framed evidence-based practices and projects, the breadth of nursing science and knowledge is advanced. This EBP QI project exemplified the application of theoretical framework in complex care and management of patients with DAHOCI that is reliant on effective adherence of a patient with their self-management plan which impacts the severity of the complications associated with diabetes. Given the evident need to evaluate and update the continuum of care plan for patients with DAHOCI, Kurt Lewin's Theory of Change was applied to frame the project process. Kurt Lewin's Change theory dictated that change should happen on all levels and not on a single perspective. The theory supported the change to an enhanced or more frequent follow-up plan for the patient population with diabetes to mitigate the complexity of care and self-management post-COVID-19 infection.

This project integrated concepts of Kotter's change model to mitigate constraints of Kurt Lewin's change theory. Kotter's 8 step process for change is a related and evolving model from Lewin's change theory and include: 1) create an urgency, 2) complete a strength-weakness-opportunity-threat (SWOT) analysis, form a team, 3) foster a culture of trust and commitment, 4) develop a vision and strategy that aligns with organization priorities and communicate the vision for change, 5) remove obstacles, 6) set short term goals, keep the momentum, 7) make the change stick, and 8) eliminate old norms that do not align with new practices (Butts & Rich, 2022). Kotter emphasizes the need for leadership and management in the change process that leverages the concept of mind and heart by engaging leadership perspective and willingness, assigning few and diverse opportunities for leadership, training the trainer, developing champions, and fostering perspective for "want to" and "have to". The integration and

advancement of the change theory is an integral collaboration of how nursing theories influence organizational models of change.

One of the constraints of the change theory, according to Kotter, is inadequate sense of urgency for the change (Butts & Rich, 2022). Data analysis of readmissions related to cardiovascular events in patients with diabetes post COVID-19 infection provided a basis for the sense of urgency (Beauvais et al., 2022; Rubin & Shah, 2021; Soh et al., 2020). A second constraint involved the need for coalition with stakeholders. To address this constraint, the preliminary data analysis and evidence-based research was disseminated to key stakeholders for their support and adoption of the clinical change in practice to facilitate system wide practice modification and sustainability (Hussain et al., 2018). A dedicated team during the change process was created to eliminate the identified barriers and enable the change guided by the theoretical frameworks. A well-articulated multidisciplinary co-management of care between the inpatient and outpatient settings was aligned using the Iowa Revised Model for change sustainability and quality improvement (Iowa, 2017; Rubin & Shah, 2021).

Criticism of the change theory is that it does not account for environmental influences on the dynamic changing environment at the bedside. Therefore, to account for these dynamics in the environment, the change theory was paired with the QI model, the Iowa Model (2017), to strengthen the continual adoption of practice founded on the basic principles of the change theory. The Iowa model utilizes a systematic algorithm to guide implementation of the change (Iowa Model, 2017). Lewin's change theory laid the foundation for the change process, the Iowa model defines the process map for implementation. The pilot steps in the Iowa model dictated the activities involved in the moving phase of Lewin’s change theory and facilitated transition to refreezing as the change is hard wired.

The Iowa Revised Model

The project also adopted the Iowa implementation for sustainability framework involving refining the project purpose: developing a team; completing the literature review and synthesis, budget analysis, and proposal; gaining institutional review board (IRB) approvals; implementing a model project; evaluating the project; disseminating results; and recommending adoption of a practice change. The Iowa Revised model, a validated evidence-based model for sustainable quality improvement (QI), was applied to the project to guide sustainable process improvement (Appendix A) (Iowa Model Collaborative [Iowa], 2017).

The model involved a stepwise flowchart that guided each of five major process and incorporated: 1) evaluating the process, 2) establishing decision points and next steps to frame a sustainable plan of creating an awareness of and significance of the project, 3) building knowledge and commitment from stakeholders, 4) promoting action and adoption, and 5) pursuing integration and sustained use. These stages complement and intersect with Kurt Lewin's Theory of Change steps of unfreezing, change process, and refreezing that impact the practice change while addressing the constraints in Lewin's theory. The Iowa model incorporated three major decision points assessing priority of the project, evaluating sufficient evidence for the project, and deciding whether the change is appropriate for adoption, therefore guiding implications for practice (Iowa, 2017). The intermittent steps include: 1) identifying the change opportunities, 2) formulating the study purpose, 3) establishing an interdisciplinary team, 4) reviewing, appraising, and synthesizing the literature, 5) designing, and modeling the practice change, 6) integrating and sustaining the practice change, and 7) disseminating the results and validating the change (Iowa, 2017). Implementing a model program during the change process grounded the moving and refreezing steps of Lewin's change theory to facilitate system-wide

change and communicate the clear vision and plan as articulated in the PICOT statement. This clarified the strategies and goal of the change in practice.

It is important to note that every patient encounter is guided by a framework of a nursing theory or a combination of models. Nursing theorists attempt through the core elements for nursing theories to "explain, predict and describe" the elements of practice. The theorists also draw from their clinical experience and expertise as well as their academic background therefore correlating the critical role of the DNP leader in nursing theory development and implementation to further advance the science of nursing. Theory is also influenced by past theories and practices and as they are modified in practice to align with patient-centered care, they yield a framework and new approach for care.

The DNP-prepared was well equipped to recognize and reconcile these theories and practices, integrate them in care, and influence the necessary practice change that impacts patient health outcomes. The project lead, a clinical nurse specialist (CNS) in adult and geriatric specialty was responsible for translation of research into practice. During this project, outcomes were shared reflecting the impact of the change in practice and validating the new practice. This consistency of acculturation of nursing theories and utilizing theoretical framework in nursing practice is the foundation and mandate of the DNP and has proven to advance nursing knowledge and improve health outcomes. Implementation of the project integrated the DNP essentials of leadership, interprofessional partnership, and ethical practices grounded by evidence-based practices.

CHAPTER THREE: REVIEW OF LITERATURE

Literature Search

The literature search was performed using PubMed and Google Scholar databases. The following keywords were utilized singularly and in combination: diabetes, diabetic management, COVID-19, post COVID-19, cardiovascular complication, microcoagulation, and stroke. An initial total of 899 articles were retrieved. In refining the search by using contractuals and booleans such as “and”, “or” with parentheses, resulted in 128 articles. The abstracts were reviewed for content and relevance. Duplicate articles and articles that did not meet the inclusion criteria for the population, interventions, standard of care, or outcomes were eliminated. Literature review inclusion criteria included primary and secondary sources, peer reviewed and randomized controlled trials (RCT) within the last five years of publication. This criterion ensured current evidence was utilized for translation into practice for validity and relevance. The articles were also evaluated for levels of evidence as well as the frequency of citations. A summary of evidence is detailed in the Table of Evidence.

Evidence-based practice facilitates sustainability of new initiatives, provides rationale for practice, and supports the translation of research into practice. Rubin et al., (2021) conducted a systematic review of six RCTs at multiple sites. The authors included papers with sample sizes ranging from 44,203 to 105,974, with Diabetes Early Readmission Risk Indicator (DERRI) prediction models, and management care involving follow-up. The article identified the bidirectional relationships between COVID-19 and diabetes, and the increased risk of cardiovascular complications. The article also reviewed the impact of learning models, readmission rates, and the post follow-up plan of care, including virtual follow-up and statistical significance in utilizing readmission prediction models. The prediction models were validated but learning models were not, therefore revealing a gap in practice in this study. There was also a gap in practice relating to lack of follow-up post discharge. This evidence supported the

evaluation of readmission rates and enhanced post hospital discharge follow-up model as outcome criteria in the project study.

The Lim et al., (2020) article was selected for the implementation of the nurse-led telehealth pilot with a small sample of 60 patients. The telehealth follow-up appointment was initiated after hemoglobin A1C data for the patients had resulted. Findings indicated a significant reduction of time spent completing virtual or telehealth follow-up versus an in-person follow-up. Lim et al., (2020) also completed a RCT assessing the utilization of telehealth in the management of diabetes, COVID-19 related complications, and follow-up care. The study showed an estimated reduction in hospital utilization from 175 minutes for in-person follow-up model to 75 minutes for the telehealth follow-up model. Limitations in this study included a small sample size and study on adolescent population only. The evidence in this study supported consideration of including telehealth options for participants unable to attend an in-person follow-up session.

Abe et al., (2021) conducted a RCT evaluating the risk of cardiovascular complication for patients with and without diabetes and COVID-19. The sample size included 142 patients with a mean age of 58 years with new onset atrial fibrillation and new onset diabetes. The authors applied the multivariable logistic regression in data analysis and reported higher cardiovascular risks for patients with diabetes and COVID-19 at 73.3% versus without diabetes and COVID-19 at 40.6% with $p<0.0001$. The results also indicated a 12.7% and 1.4% new onset a-fib, a 9.9% and 1.4% of acute MI, and a 25.3% and 5.6% of acute heart failure for patients with and without diabetes, respectively. The sample demographic included 80% of African American participants posing a limitation that impacts generalizations to other populations. This study suggested that the advanced practice registered nurse (APRN) led project design with multiple follow-up

appointments was warranted and, contingent on project finding, a recommendation of adopting a nurse-lead program would be valid for practice change and applicable to the patient population and project.

Profili et al., (2022) highlights the incidences of first cardiovascular events in a sample size of 46,152 COVID-19 patients and 4,597 who survived COVID-19 infection. A 1:1 matched control group by age, gender and diabetes diagnosis was utilized for an observational retrospective study. The authors applied the multivariable logistic regression model for readmission for first hospitalization for MI, stroke and/or death. Findings showed a two-fold higher risk for cardiovascular complications for the diabetes population with an incidence rate ratio of 67% versus 17% for patients without non-diabetes. Patient education at discharge showed no statistical significance in reducing readmissions. Limitations in the study included restriction to participants with no prior hospitalization for cardiovascular event and the short follow-up period of 6 months. To mitigate the impact and burden of diabetes-COVID-19 related cardiovascular complications, preventive measures to implement an enhanced continuum plan of care was pursued for the DNP project.

Agarwal et al. (2019) evaluated correlation between diabetes markers with coagulation variables in 60 participants with diabetes, with or without microvascular complication. The case control study with a control group of 30 suggested the need for routine assessment of PT, APTT, and fibrinogen to identify coagulation impairment and mitigate cardiovascular risks in patients with diabetes. T-test, ANOVA, and Mann-Whitney U tests were applied to analyze correlation by age and diabetes and indicate statistical significance of $p<0.0001$ and $p=0.038$ for lower APTT and higher fibrinogen respectively. A higher coagulation profile was noted for patients with microvascular complications. Evidence in the study indicated that a shortened duration for

PT/APTT and longer fibrinogen was an important hemostatic biomarker for higher cardiovascular complications among persons with diabetes. Small sample size and duration of study were identified limitation of the study. This evidence supported utilization of PT and APTT as outcome criteria for cardiovascular risks in the DNP project study.

Cheung et al. (2022) explored and implemented a virtual inpatient diabetes management system to evaluate the impact of timely follow-up care on hyperglycemia management in 40 participants and 112 encounters. A daily follow-up care over six weeks was completed with glucose values posted on a dashboard in real-time to facilitate timely identification hyperglycemia, medication administration, intervention, and patient education. The study indicated a quarter of the admitted patients had a diabetes diagnosis, 16.7% had hyperglycemia incidences, there were limited staff to provide in-person care, therefore, video conferencing was utilized to support follow-up care. The lack of staff and single site were identified limitations in the study. The study recommended video conferencing to be the future of diabetes follow-up management providing evidence for utilization of telehealth follow-up in the DNP project.

Literature Synthesis

The validity, reliability, and applicability of the studies reviewed included peer-reviewed articles, both primary and secondary sources relating to the impact of diabetes-COVID-19 relationships on cardiovascular risks, management strategies of the complications and the incorporation of telemedicine in care and follow-up models (Abe et al, 2021; Lim et al., 2020, Rubin et al., 2021). The overall themes emerging from the articles included the bidirectional relationship between COVID-19 and diabetes, and the increased cardiovascular risk in patients with diabetes (Lima-Martínez et al., 2021; Rubin et al., 2021). In addition, the incidence of hyperglycemia and new-onset diabetes cases post COVID-19 was reported (Agarwal et al., 2019;

Khunti et al., 2021; Widjaja et al., 2019). There was no sufficient evidence to guide revision of the current standard of practice (ADA Professional Practice Committee, 2022) for patients with diabetes and COVID-19. Evidence also indicated that follow-up care (in-person or virtually) post COVID-19 infection emerged to be important and deserved further study (Cheung et al., 2022; Khunti et al., 2021; Lim et al., 2020).

Gaps in Research and Practice

Evidence outlined that further research with validated tools and protocols specific for patients with diabetes post COVID-19 infection was essential. No evidence-based guidelines to support continuum of care for this patient population currently existed despite the increasing cardiovascular risk to the population and the largely unknown and potentially precarious long-term impact of COVID-19 among patients with diabetes. Research indicated that non-adherence to follow up appointments increased cardiovascular risks and was further impacted by steroid therapy patients received during COVID-19 acute phase treatment plan (ADA, 2022; Khanam, 2021; Knight et al., 2022). In addition, the lack of follow-up to adjust insulin administration and other diabetes medication increases hypoglycemia episodes due to higher insulin dosage. The hypoglycemia episodes mimic MI and increased readmissions rates (Joseph et al., 2022). Studies have shown that microcoagulation persists up to nine months post COVID-19 infection but no guidelines for follow-up or treatment regimen were instituted (Knight et al., 2022). Furthermore, hyperglycemia increases hypercoagulation, therefore increasing the cardiovascular risks. Palpably, PT/APTT tests were identified as appropriate hemostatic markers appropriate for monitoring microcoagulation risks (Agarwal et al., 2019; Knight et al., 2022; Widjaja et al., 2019). Follow-up studies in adolescent populations had shown positive impact on health outcomes but no guidelines for adult follow-up studies were identified, therefore, prompting the

need for further research in adults (Lim et al., 2020). The cited evidence-based limitations in clinical practice provided the rationale and significance for this project.

Impact on Project Intervention

Evidence in select studies indicated that having scheduled follow-up appointments improved patient compliance and reduced readmission rate (Agarwal et al., 2019; Beauvais et al., 2022; Soh et al., 2020). Recommendation to reduce hypertension and incorporate prophylactic anticoagulant regimen post-COVID-19 infection was supported for reducing cardiovascular risks (Joseph et al., 2022). In addition, the use of telehealth for follow-up care also improved patient adherence and improved their health outcomes. Therefore, including telehealth to deliver the follow-up care in the project was implemented (Cheung et al., 2022; Lim et al., 2020).

CHAPTER FOUR: METHODS

Ethical Considerations

The DNP project was reviewed and approved by the Western Institutional Review Board (WIRB)-Copernicus Group (WCG IRB) affiliated with the community hospital designated as the project site in Southern California (Appendix B) and the University of California, Los Angeles IRB (Appendix C). The WCG IRB, accredited by Association for the Accreditation of Human Research Protection Program (AAHRPP), ensured compliance of informed consents and Health Insurance Portability and Accountability Act (HIPAA) documentation. Other sponsorship and approvals obtained prior to project implementation included Information technology (IT) approvals for updates on documentation templates and access to chart review during the planning phase; access to a designated venue for the follow-up appointments; provider and laboratory board approval for post-intervention lab draws; and interdisciplinary collaboration for practice change post-intervention.

Design

The project design was a quasi-experimental longitudinal study including an intervention group exposed to the program intervention over a three-month period and a non-equivalent comparison group. The non-equivalent comparison group was utilized to compare baseline retrospective data and the standard of practice; a single recommendation for follow-up appointment in three months to the intervention group.

Sample

We enrolled a convenience sample of patients with a diagnosis of diabetes and a history of COVID-19 infection. The participants were 18 years or older and admitted to the acute care service. The sample size included 18 participants with nine enrolled for the intervention group and nine matched by age and sex for the non-equivalent control group. With an alpha of 0.05, and a medium effect size, a sample size of 35 participants was needed to achieve 90% power.

Setting

The setting was at a single site acute care facility located in a community with a high prevalence of diabetes. The setting served a robust population with diabetes diagnosis which accounted for about 33% of hospitalized patients and was consistent with the community demographics served by the acute care facility.

Protocol

Clinical nurses received an in-service on the eligibility process and interdisciplinary engagement. Other providers received a presentation at the medical staff meeting. An informational resource was emailed, and a copy kept at the nursing station for reference (Appendix D). The project leader rounded daily with clinical nurses in order to identify eligible patients and held weekly meetings with provider champion for provider-driven interventions.

Recruitment occurred at a single acute care hospital while patients were still hospitalized. Participants meeting the inclusion criteria provided written informed consent after assessment by the clinical nurses and a referral for an advanced practice nurse consult was initiated.

An enhanced and focused patient educational resource was provided to participants (Appendix E). In addition, basic diabetic educational resources were provided to all consulted patients with diabetes as a standard of care within the selected site for the project. Four follow-up appointments (in-person and telehealth) were prescheduled by the project lead in collaboration with the providers, case managers and social workers. Discharge instructions with prescheduled appointment information was provided to the participants prior to hospital discharge (Appendix F). The first appointment was scheduled for 2-7 days following discharge, at four weeks, eight weeks, and at 12 weeks. The four appointments were designed to coincide with the monthly wellness community class held at the selected project site. The classes were part of the community needs assessment benefit that prioritized patients with diabetes. Interprofessional team (diabetic educator, pharmacists, dietician, and CNS) support was provided to the patients who attended these classes as a standard of practice. Participants received supplemental education and subsequent opportunities to ask questions, clarity on their care during their follow-up care and to guide their expectations of the continuum of care model of care. Studies indicated that education had no impact on readmissions rates and this project did not explore the impact of education. Opportunities to evaluate the impact of education on patient adherence and participation were identified. Baseline and demographic data were retrieved from the electronic medical records (EMR), and deidentified. The age and sex matched control group was identified in an EHR review.

During the four follow-up appointments, medications were reviewed, insulin administration techniques evaluated and reinforced, and nutrition and lifestyle recommendations were addressed. On the final appointment blood for glycated hemoglobin (HgA1C), lipid panels and coagulation studies were collected to assess health status. Participants were provided access to their laboratory results post intervention with provider input. Transportation was arranged for any participants that required transportation to the appointments (Department of Health Care Services [DHCS], 2022). Transportation resources are part of the Medi-Cal strategies to improve access to care for patients. Parking fees and meals were also provided to facilitate attendance in the class.

Instruments and Measures

Demographic and Clinical Data

Retrospective data for the non-equivalent group was retrieved from the electronic medical records (EMR) between December 1, 2022, to November 30, 2023. Readmissions during the study period (3 months) were recorded (ADA, 2022; Rubin et al., 2021; Ssentongo et al., 2022).

Provider Adoption and Nurse Engagement

Provider adoption and nurse engagement of the continuum of care model as a practice change were assessed during the intervention. The practice change involved initiating referrals for recruitments, prescheduling for appointments, incorporating prophylactic anticoagulant on discharge for eligible patients, and including more frequent follow-up schedules. The current ADA recommended standard of care was enhanced with the continuum of care model during the project implementation (Appendix G).

Hill-Bone Adherence Scale

Participant adherence to the follow-up schedule and self-care behaviors were assessed using the Hill-Bone adherence scale during the initial appointment and repeated during the last appointment (Kim et al., 2000). The Hill-Bone adherence to diabetes therapy tool (Appendix H), a 14-item scale and part of the Hill-Bone scales, was adopted from the HillBone compliance to high blood pressure therapy scale (HB-HBP) (Appendix I) with permission (Appendix J). The scale assessed patient adherence in three main patient practices: reduction of sodium intake, appointment keeping and medication taking (Kim et al., 2000). The HB-HBP was validated with patients with high blood pressure (Lambert et al., 2006). Further validation of the scale was adopted to measure adherence with medication and therapy for chronic diseases such as diabetes.

Data Analysis

Outcome variables included cardiovascular risk markers, compliance of attendance of the participants to follow-up appointments, and adoption of providers to the enhanced continuum of care. Dependent variables were low density lipoprotein (LDL), high density lipoprotein (HDL), triglycerides and cholesterol, HgA1C, PT/PTT, blood pressure, and readmission rates. Independent variables included age, sex, and race (Table 1).

Table 1: *Outcome Variables*

Variables	**Dependent**	**Independent**	**Level of Measure**
Cardiovascular Risk Markers			
Lipid Panel			
LDL	X		Continuous
HDL	X		Continuous
Cholesterol	X		Continuous
Triglycerides	X		Continuous
HgA1C	X		Continuous
PT/PTT	X		Ordinal
Blood Pressure	X		Continuous
Readmissions	X		Categorical
Attendance	X		Nominal
Age		X	Continuous/ Ratio

Sex	X	Nominal/ Categorical
Race	X	Nominal/ Categorical

We explored the health outcome impact difference between the enhanced follow-up care and the current ADA single follow-up in three months (standard of care). Data analyzed was presented as descriptive statistics. Standard deviation (SD) and measure of central tendency were applied as appropriate to describe the participant demographic and cardiovascular risk markers at baseline, within the pre and post data collected for each variable. Outlier and missing data were accounted for where appropriate. Baseline difference between groups on demographics, cardiovascular risk biomarkers, patient adherence and readmissions were analyzed using the chi square and t-test as appropriate for distributional characteristics of variables and outcomes measures: chi squares to analyze frequencies of the categorical variables, and t-tests to analyze continuous variables between groups. The Mann Whitley U test was utilized to accommodate for small sample size.

In addition, patient adherence reflected by attendance and pre-and-post assessment of self-reported adherence by the Hill-Bone adherence scale was also analyzed. Outcome measures for provider adoption of practice and nurse engagement was evaluated at the end of the interventions by analyzing the percentage of providers that adopted the practice during the project phase and number of missed referrals for recruitment. Baseline differences of groups were computed for each variable. Project data was recorded and computed using the International Business Machines Corporation Statistical Package for the Social Sciences (IBM® SPSS®) version 29.0.0.0 (241) and in consultation with a University of California – Los Angeles, School of Nursing, approved statistician.

Threats to Validity

Internal and external validity for sampling were assessed and addressed. The exclusion criteria involved patients admitted to the intensive care units (ICU) and emergency department (ED) that do not transition to the inpatient areas to mitigate the internal validity of participant traction and retention. The sampling considered that the patients in the ICU more likely had a poor prognosis and may not complete the time allocated for the study - three months. The patients seen in the ED that do not transition to the inpatient areas had a limited exposure to the initiation of the intervention that involved screening, consults, specified patient education and prescheduling of the four-follow-up sessions.

A convenience sample was recruited and sample randomization in future studies addresses this internal threat. The use of non-equivalent comparison group posed an internal threat to validity influenced by the alternative factors for cause-and-effect relationship between the independent and dependent variables within the study (Flannelly et al., 2018). Each participant had varying confounding factors related to medical history that may have impacted the study. The selected setting was an acute care facility located in a community with a demographic of patients identified with a high prevalence of diabetes. The external threat to validity was the small sample size and the short timeframe for the study that yielded the sample size, therefore not reflective of the generalized population. The use of statistical measures to determine the minimum sample size for statistically significant analysis was applied to mitigate the validity threat.

The recruitment of the target population was completed in hospital. Providers received in-service sessions on the enhanced follow-up care model to mitigate confounding factors and external threats to the study. The in-service sessions were limited and not all providers

participated, an information flyer was distributed to provide references for providers that did not participate in the in-service.

In addition, patient literacy threatened study validity given that the inclusion criteria focused on English-speaking participants. Patient education process was initiated during recruitment to assess patient education risk factors and incorporated during the follow-up appointment. Furthermore, patient resources were aligned at fifth and below grade reading level. Future implication to research would incorporate sample randomization to address validity issues.

Project Timeline

The implementation of the project commenced after the written proposal was approved and accepted, the oral exam passed, and IRB approval received. Project timeline was from mid-January 2024 with completion of project including data analysis and dissemination by end of June 2024.

CHAPTER FIVE: RESULTS

Project results focused on reduction of cardiovascular risks evidenced by lipid panels, HgA1C, PT/PTT, and blood pressure values. Secondary outcomes involved improving patient adherence to self-care, reducing readmission rates, and engaging provider adoption as well as nurse engagement to practice change

Participant Demographic Characteristics

The sample size included 18 participants, nine in the non-equivalent group and nine consented for the intervention group. One participant in the intervention group did not participate and therefore their data were not analyzed. The average age for participants was 50.6 years (±15.2). Fifty-six percent of participants were female and 88% were Hispanic-White (Table 2).

Table 2: *Demographic Characteristics of Participants*

Characteristics	**Non-equivalent Grp n (%)**	**Intervention Grp n (%)**
Age (in years)		
Mean ±SD	51.6 (14.3)	50.6 (15.2)
Sex		
Male	4 (44.4%)	4 (44.4%)
Female	5 (55.6%)	5 (55.6%)
Race/Ethnicity		
Hispanic-White		8 (88.8%)
Non-Hispanic		1 (11.1%)

Note: SD=Standard deviation; n=Number of participants; % = percentage of participants; Grp = group

Cardiovascular Risk Markers

Cardiovascular risk markers of the nonequivalent and intervention group are presented in Table 3. LDL (p=0.040), PT (p=0.027), and PTT (p = 0.038) were significantly lower in the intervention group at baseline. These values were consistent with the literature on the lingering cardiovascular risks post COVID-19 recovery and demonstrated mostly similar levels for the matched group. The non-equivalent group members were in the acute phase of COVID-19 infection during their admission.

Table 3: *Cardiovascular Risk Markers: Exploratory Data at Baseline*

Variables	**Matched Non-equivalent n=9**	**Intervention n=9**	**P Value**
LDL	115.9 (43.5) [64-200]	74.4 (30.7) [36-128]	0.040*
HDL	48.1 (29.3) [27-122]	44.5 (31.7) [26-122]	0.810
Chol	206.9 (40.5) [139-273]	159.8 (54.5) [89-236]	0.059
Trigly	215.8 (142.4) [62-459]	204.8 (176.2) [92-624]	0.888
A1C	6.8 (2.3) [4.2-10.9]	7.8 (2.3) [4.8-11.6]	0.384
PT	14.4 (0.7) [12.9-15.4]	13.1 (1.4) [10.3-14.5]	0.027*
PTT	32.7 (5.5) [22-41.6]	28.3 (1.9) [25-31.7]	0.038*
BP_Sys	127.6 (16.8) [98-158]	122.9 (13.9) [102-141]	0.530
BP_Dia	71.2 (6.4) [56-77]	67.8 (11.1) [52-82]	0.431

Note: Mean (Standard Deviation) [Minimum-Maximum]. Sys is systolic. Dia is diastolic.
**Denotes statistical significance (P<0.05), P value computed using the independent sample t-test*

The average HgAIC was higher for the intervention group although not significant and may reflect lack of randomization to group. Consideration of the patient adherence behaviors and the small sample size may have impacted results. Analysis of the comparison data affirmed that the non-equivalent group was similar to the intervention group.

The distribution of each cardiovascular risk marker in the intervention group (at baseline and completion of project) was evaluated using the independent samples nonparametric Mann-Whitney U test (Table 4). No statistical significance was noted on the cardiovascular risk markers in the intervention group. Five participants (55.6%) completed the post intervention lab work.

Table 4: *Cardiovascular Risk Markers: Descriptive Summary for Intervention Group*

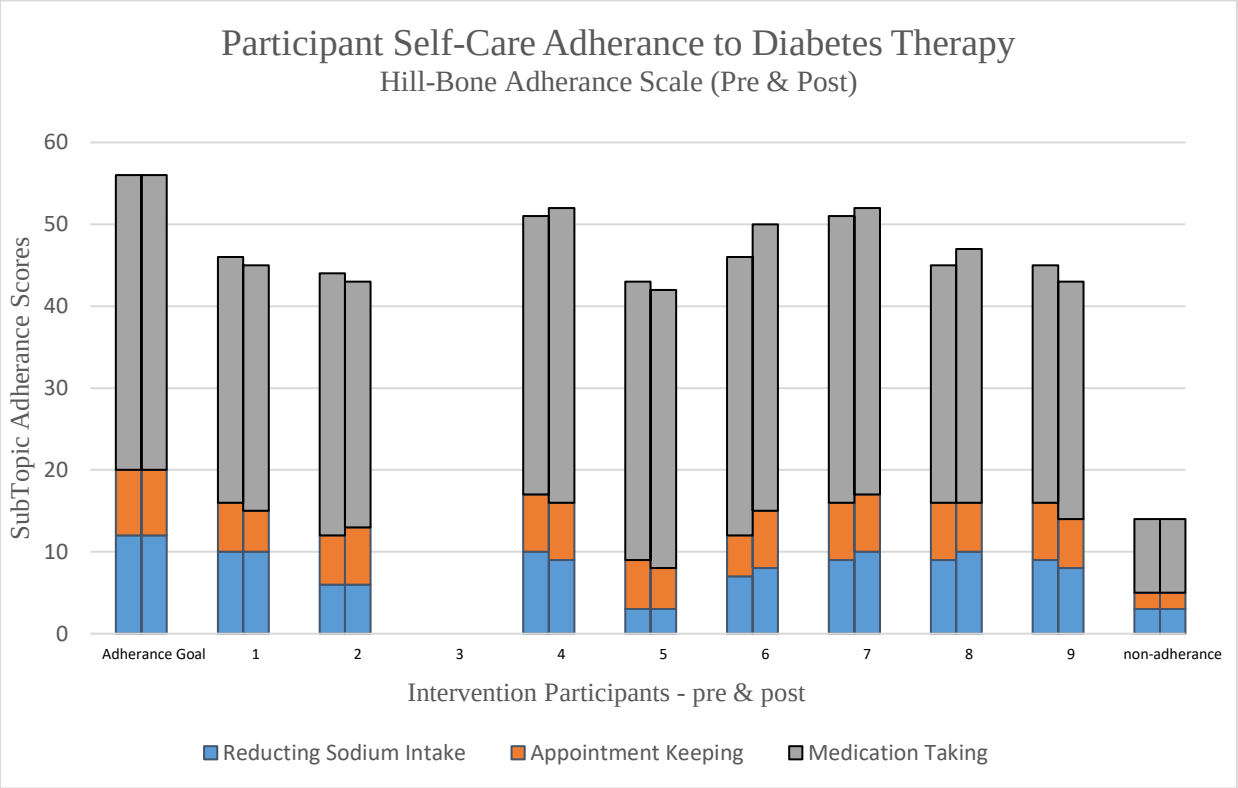
Variables	**Baseline n=9**	**Completion of Project n=5**	**P Value**
LDL	74.4 (30.7) [36-128]	86.0 (51.8) [27-128]	0.833
HDL	44.5 (31.7) [26-122]	34.2 (10.2) [26-50]	0.524
Chol	159.8 (54.5) [89-236]	162.6 (46.7) [92-213]	0.943
Trigly	204.8 (176.2) [92-624]	314.8 (206.2) [102-532]	0.524
A1C	7.8 (2.3) [4.8-11.6]	8.8 (2.9) [5.7-12]	0.524
PT	13.1 (1.4) [10.3-14.5]	14.3 (1.5) [12.3-16.4]	0.190
PTT	28.3 (1.9) [25-31.7]	29.6 (2.1) [26.7-31.7]	0.240
BP_Sys	122.9 (13.9) [102-141]	150.8 (29.5) [116-182]	0.083
BP_Dia	67.8 (11.1) [52-82]	72.2 (17.2) [55-95]	0.699

Note: Mean (Standard Deviation) [Minimum-Maximum]
P value computed using the nonparametric Mann-Whitney U Test

Participant Adherence to Self-care

Pre and post data evaluation of the self-reported adherence to diabetes therapy scale for the intervention group was compared (Figure 1).

Figure 1: *Participant Self-Care Adherence to Diabetes Therapy – HillBone Scale*



Pre and post intervention analysis for the *Hillbone Adherence to Diabetes Therapy Scale* demonstrated little to no change over time (Table 5). There was a 37.5% increase in missed scheduled appointments by study completion (from "some of the time" to "most of the time").

Table 5: *Hillbone Adherence to Diabetes Therapy Scale for the Intervention Group*

Variables	Baseline n (%)	Completion of Project n (%)	Pearson Chi-Square
1. Forget to take Meds			0.580
All of the time	0	0	
Most of the time	0	1(12.5%)	
Some of the time	6 (75%)	5(62.5%	
None of the time	2(25%)	2(25%)	
2. Decide to not take Meds			1.000
All of the time	0	0	
Most of the time	0	0	
Some of the time	1(12.5%)	1(12.5%)	
None of the time	7(87.5%)	7(87.5%)	
3. Eat salty food			0.766

All of the time	3(37.5%)	2(25%)	
Most of the time	1(12.5%)	2(25%)	
Some of the time	4(50%)	4(50%)	
None of the time	0	0	
4. Shake salt on food before you eat			0.744
All of the time	1(12.5%)	1(12.5%)	
Most of the time	0	1(12.5%)	
Some of the time	2(25%)	2(25%)	
None of the time	5(62.5%)	4(50%)	
5. Eat fast food			1.000
All of the time	1(12.5%)	1(12.5%)	
Most of the time	2(25%)	2(25%)	
Some of the time	5(62.5%)	5(62.5%)	
None of the time	0	0	
6. Make next appointment before you leave provider office			0.574
All of the time	4(50%)	5(62.5%)	
Most of the time	3(37.5%)	3(37.5%)	
Some of the time	1(12.5%)	0	
None of the time	0	0	
7. Missed scheduled appointment			0.055
All of the time	0	0	
Most of the time	0	3(37.5%)	
Some of the time	8(100%)	5(62.5%)	
None of the time	0	0	
8. Forget to fill prescriptions			
All of the time	0	0	
Most of the time	0	0	
Some of the time	0	0	
None of the time	8(100%)	8(100%)	
9. Run out of medication			0.614
All of the time	0	0	
Most of the time	0	0	
Some of the time	5(62.5%)	4(50%)	
None of the time	3(37.5%)	4(50%)	
10. Skip med before Provider appt			1.000
All of the time	0	0	
Most of the time	0	0	
Some of the time	3(37.5%)	3(37.5%)	
None of the time	5(62.5%)	5(62.5%)	
11. Miss taking meds because you feel better			0.572
All of the time	1(12.5%)	0	
Most of the time	2(25%)	1(12.5%)	
Some of the time	3(37.5%)	3(37.5%)	
None of the time	2(25%)	4(50%)	

12. Miss taking meds because you feel sick			0.513
All of the time	0	0	
Most of the time	0	1(12.5%)	
Some of the time	2(25%)	1(12.5%)	
None of the time	6(75%)	6(75%)	
13. Take someone else's diabetes pills			1.000
All of the time	0	0	
Most of the time	0	0	
Some of the time	2(25%)	2(25%)	
None of the time	6(75%)	6(75%)	
14. Miss taking diabetes pills when you are careless			1.000
All of the time	0	0	
Most of the time	0	0	
Some of the time	3(37.5%)	3(37.5%)	
None of the time	5(62.5%)	5(62.5%)	
Adherence to Therapy Subtopics: Summary			
Reduction of Sodium (questions 3,4,5)			0.521
Appointment Keeping (questions 6, 7)			0.766
Medication Taking (questions 1, 2, 8, 9, 10, 11, 12, 13, 14)			0.544

Note: Significance computed with Pearson chi-square - asymptotic significance (2-sided)
**Denotes statistical significance*

Self-care practices varied from pre to post intervention for some behaviors. There were no changes on items 2 – decision on taking medications, 5 – eating fast food, 10 – skipping medications before appointments, 13 – taking someone else's meds, and 14 - miss taking pills when careless. None of the patients reported missing filling their prescriptions. There were no significant changes with the three subscales of reducing sodium intake, appointment keeping, and medication taking.

Aligning participant perception of their self-care practices and validated practices is critical in improving health outcomes and patient engagement in care. Self-report on the adherence rate of appointments and the actual attendance at follow-up appointments showed a discrepancy between the participant's perception of their follow-up behaviors and the actual practice. The first appointment adherence was at 88.9%, the second at 22.2%, the third at 55.6%

and the fourth appointment at 77.8 % and included both in-person and virtual appointments with the provider or APRN (Table 6).

Table 6: *Continuum of Care Model Adoption and Participant Adherence Rates*

Variable	**n (%)**
Follow-up Appointment Adherence	
1st Appointment (2-7 days)	8 (88.9%)
2nd Appointment (Week 4)	2 (22.2%)
3rd Appointment (Week 8)	5 (55.6%)
4th Appointment (Week 12)	7 (77.8%)
Readmission Rate	6 (66.7%)
Provider Adoption	5 (55.6%)
RN Adherence	8 (88.9%)

Note: n=Number of participants; % = percentage of participants

Readmission Rates

Financial impacts of patient care and the associated health outcomes is a consideration for health systems. One measure of fiscal impact is readmission rates. Sixty-six percent of the participants were readmitted within 30 days of hospital discharge. This finding presents an important opportunity to improve care.

Provider Adoption and Nurse Engagement

Implementing an enhanced continuum of care model required interdisciplinary collaboration. The provider adoption (55.6%) was lower than the registered nurse's engagement (88.9%) and is a target for improvement. More registered nurses completed the preliminary criteria assessment and initiated a referral to the advance practice nurse (CNS) as compared to the number of providers that captured specific follow-up discharge instructions in the discharge summary for the participants.

CHAPTER SIX: DISCUSSION

Implementation of a continuum of care model requires a multifaceted approach. The validation of the outcomes, identification of opportunities, and appraisal of limitations of the project laid the foundation for future research and evidenced-based projects. The project implementation highlighted challenges and opportunities in three main areas: patient-related, provider-related, and system-related.

Intervention Participants Demographic Characteristics

Nine participants were enrolled in the intervention arm of the project. The average age of the participants in the sample was 50.6 years. Studies showed a greater cardiovascular risk for adults 65 ≥years (Joseph et al., 2022; Profili et al., 2022). The project site location is comprised of more than 870,000 people, with over 62% being of Latino or Hispanic heritage. Our sample had a higher proportional of Hispanic White patients.

Cardiovascular Risk Markers

Secondary prevention by aligning care to disease process requires that cardiovascular risk markers are monitored and evaluated. Cardiovascular risk markers in diabetes patients are reflected in hypoglycemia, microcoagulation, hypertension and hyperglycemia-induced microcoagulation. Cardiovascular risk markers were compared between the non-equivalent group and the interventional group at baseline. There was a statistical significance in the LDL, PT, and PTT values were significantly lower in the intervention group at baseline. Then cardiovascular risk markers were compared in the intervention group at baseline (pre-intervention) to project completion (post-intervention) and there were no significant differences.

LDL has been known to be a marker for cardiovascular health among other lipid panel markers (Grundy at al., 2019). The recommended LDL level for patients with diabetes is less

than standard of care less than 70mg/dL (Grundy et al., 2019). The average LDL for the intervention group was 73.75mg/dL which is slightly higher than desired. Patient education addressing the importance of a healthy LDL is vital for this patient population. Studies showed that it takes about six weeks to three months to reduce LDL with lifestyle changes and even earlier if pharmacological inventions are included (Janse Van Rensburg, 2018). The timeframe for our project may have been too short to see reductions in LDL and cholesterol. Further studies on the impact of diet adjust should be incorporated in the management and reduction of cardiovascular risks.

Studies show that PT and PTT are suitable hemostatic markers for monitoring and guiding care for patients with DAHOCI (Agarwal et al., 2019; Widjaja et al., 2019). The differences between the non-equivalent group and intervention group were consistent with studies that show the lingering coagulation problems post COVID-19 infection. It is critical that providers adopt a monitoring practice to ensure patients are not further exposed to the risk of clotting disorders following COVID infection. Studies have suggested the inclusion of an anticoagulant beyond acute infection with monitoring, within the first year following infection.

The average PT /PTT for the intervention group was 13.1/28.3 and 14.3/29.6 in the pre-post. The recommended PT and PTT levels for patients are 11-13.5 and 25-25 seconds respectively. Some of the patients were not within the recommended levels and interventions may be indicated. One of the participants encountered a readmission related to a DVT post-surgery that may be attributed to the residual impact of COVID-19 infection. Patients in the matched group had an active infection and the passage of time aligned with expected improvement of the coagulation levels.

Participant Adherence to Self-care

The Hillbone Adherence scale was utilized to assess patient adherence habits/behaviors on three main practices – sodium intake, appointment keeping and medication intake. Patients self-reported their adherence to therapy behaviors and pre and post responses were evaluated to measure any significance in change of self-care behaviors. Patients may obtain a maximum score of 12 in sodium intake, 12 in medication adherence and 36 in appointment keeping for highest adherence and 3, 3, 6 score for non-adherence. The highest adherence score on reducing sodium intake, appointment keeping and medication taking was 10, 7, and 35 respectively and the lowest adherence scores were 3, 5, 29 respectively. The sample was too small to conduct statistical analyses but there was a slight improvement in sodium reduction, appointment keeping, and medication adherence. Incorporating an assessment of patient adherence to self-management plans is integral in the follow-up care to promote awareness for the patient and guide providers in partnering with patients to improve their adherence to practice the treatment plan.

Patient Participation

A higher percentage of participants completed the first appointment. There was a significant drop by the second appointment and participation increased at the third and the fourth appointment. The results indicated a bias in self-reporting of appointment keeping at baseline which did not accurately reflect patients' actual appointment keeping. Patients were more likely to report keeping appointments at baseline and then changing their response to "missing" appointments at completion. Patients cited challenges that contributed to missed appointments. Some of the challenges reflected SDoH. Small sample size may have impacted the results on patient participation and further studies on perception of patient self-adherence and actual adherence is warranted.

Readmission Rate

Readmission in patients with diabetes is a known risk and increases the financial burden on health facilities. Diabetes-associated comorbidities contribute to the readmission rate and increasing cardiovascular risk accounts for the added financial burden to patients and systems that provide care. Sixty-six percent of the intervention group were readmitted within 30 days of discharge with cardiovascular related complications. Implementing strategies that engage the quadruple aim of improving health systems, patient care experiences, provider experiences, and population health at reduced costs are integral to health (Nundy et al., 2022; Racey et al., 2022). Follow-up care post- discharge may help reduce readmission rates. Further study with larger samples is necessary in the future.

Provider Adoption and Nursing Engagement

Patient advocacy begins with providers and caregivers identifying a need for practice change that may improve care. Implementation of the continuum of care model for patients with DAHOCI is a patient advocacy measure to improve health outcomes. Provider adoption was 55.6% for discharge instructions and willingness to include specific follow-up instruction in the discharge summary. A total of 88.9% of the patients that participated in the program were referred by the nursing team.

Aspects of project design enhancements presented an opportunity to standardize and support sustainability of the follow-up discharge instructions. This involved collaboration with the IT team in creating a nurse driven inclusion of discharge follow-up instructions in consultation with the providers. The template created is due to be implemented and involved specific instructions and educational content for nursing to include in the discharge summary of patients identified with DAHOCI.

Identified Opportunities

Implementation of the EBP QI project focused on three main areas of opportunities: patient, provider, and systems that are related to improving care outcomes.

Patient-Related

Patient outcomes are highly impacted by SDoH. Lack of insurance, lack of transportation, caregiver challenges, and English as a second language all impact patient well-being. The recruitment challenges highlighted that SDoH need to be addressed when improving patient adherence to appointments and reducing cardiovascular risks in this vulnerable population. Health literacy and language barriers were also noted. Translation services were utilized in the discharge process as a standard of practice at the project setting, however, the printed resources were in English and English was a second language for many patients. Finally, adherence to follow-up visits was only 22.2% and 55.6% for visits two and three. Therefore, facilitating follow-up visits is critical to improving patient outcomes.

We found that providers scheduled the next appointment less often than needed to meet the target for four follow-up visits. This gap in practice prompts further studies on improving patient adherence with prescheduled appointments. More than 75% of the participants observed their appointments in the study, a plausible indication that prescheduled appointments contribute to patient adherence with follow-up care. In addition, the HillBone adherence scale indicated that over 50% of patients self-reported rarely missing a scheduled appointment.

Impact of SDoH on DAHOCI

The intersection of health care systems and delivery of personalized care for individuals and communities' challenges leaders to reassess the impact of SDoH, then recommend and adopt care models to bridge the SDoH disparity gaps (Gagnon et al., 2022; Thornton et al, 2020). The COVID-19 pandemic significantly impacted the patient population with diabetes, triggering a

review of the care models to mitigate the increased risk for diabetic-related cardiovascular complications (Joseph et al., 2022).

A focused evaluation of the SDoH is vital. This includes but is not limited to education access and quality care, neighborhood and built environment, social and community context, health care access and quality, and economic stability (Joseph et al., 2022). Access to healthcare, level of education and health literacy, and economic instability impacted the effective implementation of the DNP project for the target population.

The participants were screened for SDoH. Engaging the social workers and case managers in the plan of care from hospitalization to ambulatory care is vital. In this project, part of the discharge planning included interdisciplinary collaboration with discharge planners (DP), social workers (SW) and case managers (CM). The role of the DP, SW and CM included assessing the patient's individual, societal and community needs during participants admission to the facility. They also ensured pertinent patient information had been assessed and captured by confirming the patient's financial, insurance, and living situation as they facilitated the pre-scheduling of the appointment. Discharge planning assessment included the patient's preference for contact and attendance for the follow-up appointments. Access to virtual platforms was offered to establish whether the patient was able to attend the follow-up appointment virtually or in person. Given that SDoH does not influence care outcomes in isolation, knowing the patient's literacy and education level as well as access to the internet was vital. The need for transportation was evaluated during the disposition planning to facilitate post-discharge follow-up appointments.

Access to transportation: Patients needed transportation to attend the pre-scheduled appointments. This required time away from work, and often utilization of bus transportation

thereby increasing time away from family or work obligations. Currently, Medi-cal insurance covers transportation to medical appointments and the facility's community health benefit intervention for the patients with diabetes (one of the prioritized chronic diseases), included providing transportation to and from the facility and the associated clinics to improve access to care (Community Benefit Report, 2022; DHCS, 2022).

Access to Education: Language and Literacy. The impact of language and health literacy on participant engagement in continuum of care was not measured in this project. However, language barriers were noted during recruitment and provision of care. Translation services were provided as needed and preference of utilizing telehealth was assessed. However, translated written resources for the project were lacking. Patient and family access to translation services, both written and spoken, enhanced the access and quality of education the patient received during the project. The education level, health literacy and language barriers are components of access to education vital to improving health outcomes (Showstack, 2019). In person and over the phone appointments were utilized to mitigate access to care, family dynamics that impact childcare, work schedules and transportation issues (Lim et al., 2020).

Effective communication in health care is at the core of effective care, impacts the continuum of care, and is a driver for patient safety. Patient comprehension of discharge instructions on medications and aftercare is a component of the reportable public accessed core measures on patient safety (Liang et al., 2018). Furthermore, adopting patient education resources to a readability level of fifth grade or less aligned with the Healthy People 2030 language and literacy goals (Healthy People, 2022).

Provider-Related Factors

Providers are responsible for the patients' plan of care. Provider participation in the project was 55.6% as compared to nursing engagement which was 88.9%. Provider adoption was lower than anticipated and may have been related to lack of established guidelines for patients with DAHOCI was a limitation in the project. Only 55.6% of the participants had a scheduled follow-up appointment in their discharge instructions exclusive of the project protocol. A collaboration with Information Technology (IT) was made to update a provider template in the discharge instructions to include the intervention protocol. The provider adoption to the pre-scheduled appointment is now supported. We would recommend gaining the provider perspective in order to implement the project. Providers play an integral role in planning and supporting patients with diabetes.

Nurses provide the daily assessment of patients and play a vital role in identifying at risk patients. They are also integral in providing patient education, discharge instructions, and assessing SDoH that impacts the patient's adherence to follow-up care. Engaging nurses in the continuum of care model was key for initiating referrals and patient discharge to ensure follow-up instructions are documented and provided to the patient. Engaging clinical nurses in the EBP QI project process facilitated organizational strategies and promoted share governance with patient care and outcomes (Lal, 2020; Rao et al., 2022; Wright, 2020).

Systems-related

We encountered organizational challenges including balance of liability, culture, and leadership changes. Evaluating the strengths, weakness, opportunities, and threats (SWOT) of the program indicated the chance to improve care while optimizing the resources allocated (Appendix K). Implementation of the project also aligns with the organization's strategic planning that identifies diabetes as the second greatest community need. Addressing system

challenges begins with strategic planning for the project setting. Organizational mission, vision and values guide the operational decisions and focus for the organization and define what facilities stand for and strive to be. They also echo the needs the organization plans to meet and how they intend to meet these needs. Mission, vision, and values are the tenets that brand the organization culture and the fiber that guides the risks and benefits of prioritizing and engaging in different projects. A clear understanding of the organizational mission, vision and values as well as the strategic goals when planning for a DNP project is critical in analyzing approval, adoption, and sustainability of projects.

Varied staff with changing shifts was a weakness and threat to the DNP project, therefore effective provider training is an anchor goal in the facility as well as with the DNP project. We noted an opportunity to address the incomplete or not updated admission records necessary for effective prescheduling of follow-up with primary providers. Financial responsibility was a significant part of the project consideration and was elaborated in the nursing strategic planning. Every project needed to integrate direct and indirect financial impact of the project. However, as a non-profit facility, CHNA programs are also prioritized, therefore aligning the project to the organizational strategies and goals is critical. Obtaining approval and buy-in from key stakeholders on the organizational chart was critical to implementation and sustainability of the project.

The contractual scope of practice for providers within the acute care and the out-patient settings was a consideration. Consultation with legal representatives and executive leadership was instrumental in overcoming this challenge. Future implication in practice requires collaboration between the inpatient and outpatient settings to facilitate seamless interfacility continuum of care and bridge the separation of inpatient and outpatient care process.

Limitations

We encountered limitations in sampling design, recruitment, retention, the setting, participant comorbidities, provider adoption to change, and project timeline. Participants were not randomized to groups so it was possible that they varied on demographic or clinical variables that may have influenced their responses to diabetes, self-management interventions or adherence to follow-up visits. An interdisciplinary team of clinicians provided patient care, including diabetes education and monitoring of the clinical lab data and interpretation so the protocol may have varied from patient to patient. In addition, the patients had other comorbid conditions that may have impacted their response to the intervention.

Use of a single setting was a limitation to the project. Multi-site cohorts would increase the generalizability of the findings. Multi-site cohorts increase the power to detect differences if they exist. Eligibility was limited to the English-speaking population. This was only a small percentage of the community and remains a limitation of the project. Further research is required to evaluate the impact of enhanced continuum of care in reducing risks for cardiovascular complications. Other considerations for extending the study time frame and increasing the sample size would mitigate the control of retention.

Recruitment was a significant problem. Many eligible patients declined to participate and stated the inability to attend multiple appointments, travel to the appointment, caregiver responsibilities, or need to be at work. These SDoH present a barrier for improving healthcare outcomes and deterred enrollment in the project (Gagnon et al., 2022).

Program implementation and effectiveness was assessed by measuring the adoption compliance rate for providers (nursing and medical teams) as well as patient adherence to follow-up appointments. Provider adoption rate was lower than expected.

The financial burden for both the patient with diabetes and the health system drive the models of care associated with management of chronic comorbidities. Rubin & Shah (2021) stated that the financial burden for health systems is associated with readmission within 30 days. The readmission rate within 30 days for the population with diabetes was between 14-22% and associated with an estimated $24 billion per year (Hsieh, 2019, Sol et al., 2020).

Implications for Future Clinical Practice and Research

This clinical project provided a basis for further review of the standards of practice for patients with DAHOCI. Implications for future clinical practice and research include increasing the sample size for a fully powered statistical analysis and expanding the project to multiple settings. From a clinical perspective, addressing electronic health record (EHR) constraints, adopting to the stakeholders' priorities, and emphasizing the key role of the DNP-prepared leaders on the project will be needed in the future.

Eligibility was limited to English-speaking patients and those able to self-consent. Incorporating measures to accommodate all levels of consents. This process will require diligent ethical considerations and approvals as well as incorporate sample randomization. The care model initiated with the project and subsequent expansion of the project on different health settings and cohorts would create basis for validation and reliability. The body of evidence built from this study would guide the recommended change in practice.

Ongoing analysis on the continuum of care model required retrospective data review which proved to be very cumbersome. Redesign of the discharge planning documentation template for providers and nurses was the identified start point for enhancements. IT and medical team stakeholders were engaged, and templates approvals are pending.

Continuously SWOT analysis was completed regularly over the scope of the project to facilitate timely realignment with changing executive leadership and organizational strategic priorities. The key is the ability to adapt to the continual changes of identified strengths, weakness, opportunities, and threats for adjusting the project to align to the organizational strategies. It is therefore vital for the DNP leader to plan any project with the organizational goals in mind. It is also important to foster interdisciplinary collaborations, identify key stakeholders, and design protocols congruent with organizational priorities.

Role of the DNP-Prepared Leader

The role of the DNP in integrating a theoretical framework to improve health outcomes is vital and involves the clinical expertise, the leadership skills, the nurse scientist training, the educator experience, and characteristics that define and align with CNS specialty. The DNP leader applies the frameworks of the Iowa evidence-based practice model to improve quality of care, to design and implement research and EBP projects, and incorporate learning theories to plan and educate the target audience. Therefore, the DNP leader also serves as a mentor in the implementation of the theoretical framework in academia and practice (Shannon, et al., 2021). It is important that as nursing practice evolves, DNP leaders engage in building nursing knowledge and developing nursing theories that have proven to support nursing practice. Research highlights the need for furthering nursing theories by nursing scientists (Rocafort, 2020). A DNP provider has multiple avenues to advance nursing theories.

The CNS embodied the function of a change agent in the clinical and organizational settings and utilizes the theoretical framework of change management in the translation of research into practice. One vital step in this translation is the utilization of the PICOT statement to clarify and communicate the strategies and goals of the change of practice. As a DNP-CNS,

interdisciplinary collaboration is critical in team formation and elimination of barriers to facilitate the desired practice change and impact health outcomes. As practice change occurs with translation of research, disseminating outcomes to the teams with each milestone revitalizes the team and helps with advancing practice changes.

CONCLUSION

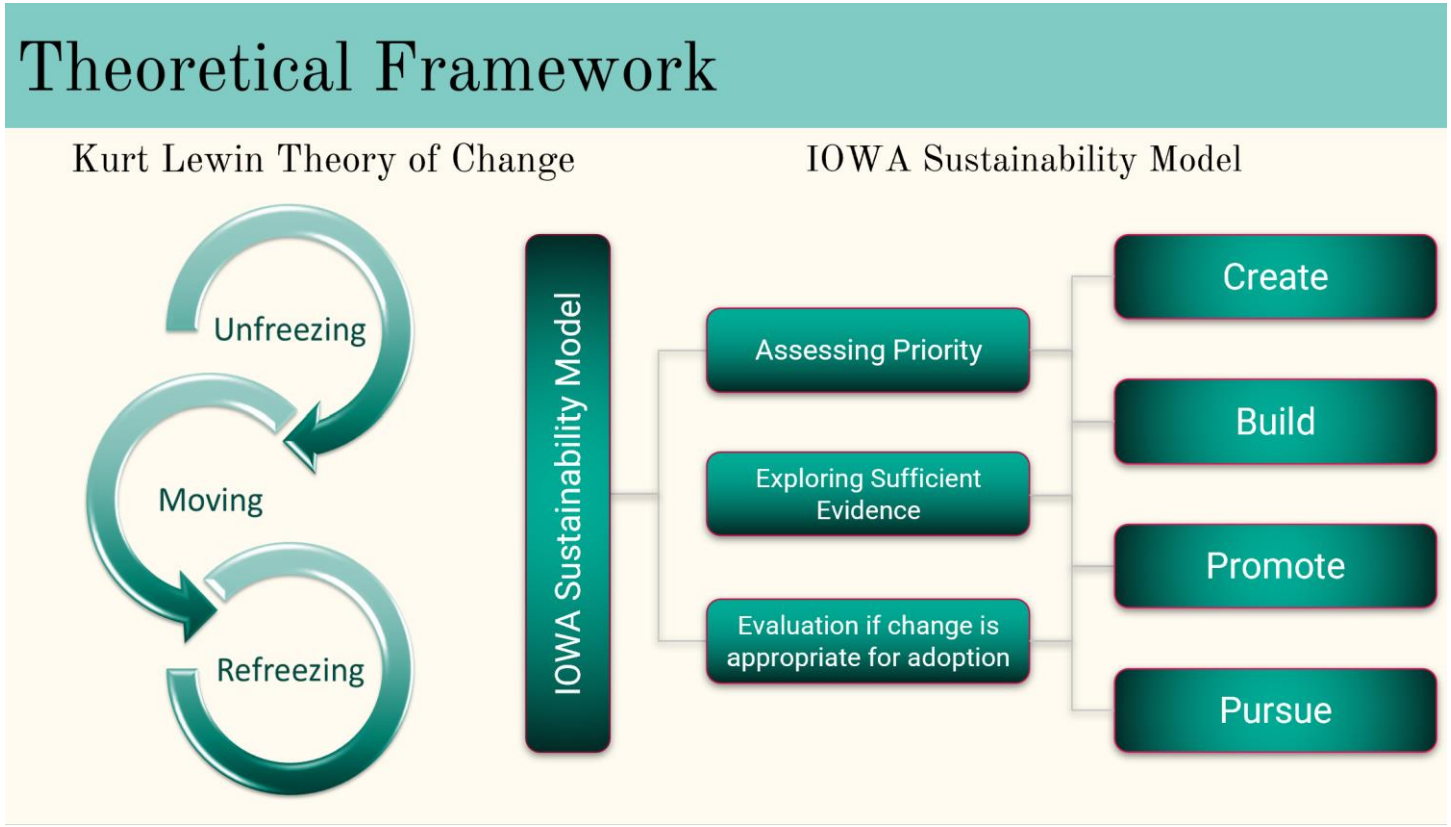
Despite limitations, findings provided preliminary evidence for the establishment of an enhanced continuum of care model for patients with DAHOCI and the associated updates of ADA and AHA care guidelines incorporating reduction of risks for cardiovascular complications, improvement of patient adherence to self-care, and the reduction of readmissions rates. The project was the first to explore the impact of follow-up care on cardiovascular risk markers at the institution.

Reducing the cardiovascular risk factors for patients with DAHOCI is key to improving health outcomes and evaluating alignment of care to disease process in this patient population. Since the management of diabetes is reliant on the patient adherence to a recommended follow-up regimen, implementing an enhanced follow-up schedule is more likely to reduce cardiovascular risks, improve patient adherence and reduce readmission rates.

Future research would include replicating the project with a larger sample size, a more heterogeneous sample, multiple settings, and a longer time frame to validate data and model of care. Clinical implication would incorporate strategies to address systemic and organizational barriers, response to SDoH and evaluation of the financial impact of the project. A nurse-led enhanced follow-up program is significant in evidence-based quality improvement projects that impact patient outcomes, health care operational systems and change in clinical practice paradigms.

APPENDICES

Appendix A: Theoretical Framework



Adopted from:

Hussain, S. T., Lei, S., Akram, T., Haider, M. J., Hussain, S. H., & Ali, M. (2018). Kurt Lewin's change model: A critical review of the role of leadership and employee involvement in organizational change. *Science Direct, 3*(3), 123–127. https://www.sciencedirect.com/science/article/pii/S2444569X16300087?via%3Dihub

Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing, 14*(3), 175–182. https://doi.org/10.1111/wvn.12223

Appendix B: IRB Approval

wcg™

Certificate of Action

Investigator Name: Jacobett Wasonga-Agak, MSN, RN, PHN	**Board Action Date:** 01/08/2024
Investigator Address: 15107 Vanowen Street Van Nuys, CA 91405, United States	**Approval Expires:** 01/08/2025 **Continuing Review Frequency:** Annually
Sponsor: Hannah Grossman – Valley Presbyterian Hospital **Institution Tracking Number:**	**Sponsor Protocol Number:** None **Amended Sponsor Protocol Number:**
Study Number: 1366885	**IRB Tracking Number:** 20235775
Work Order Number: 1-1726195-1	
Protocol Title: Implementing an Enhanced Continuum of Care (ECC) for Patients with Diabetes and a History of COVID-19 Infection (DAHOCI)	

THE FOLLOWING ITEMS ARE APPROVED:
Investigator
Protocol (source: protocol irb_v20231215)
Tables, Discharge Instructions, and Subject Questionnaires #39346634.0 - As Submitted
Consent Form [IN0-0]

Please note the following information:
The Board found that for the retrospective data collection for non-equivalent group the research meets the requirements for a waiver of consent under 45 CFR 46.116(f) [2018 Requirements] 45 CFR 46.11(d) [Pre-2018 Requirements].

The Board requires that all adult participants must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable adult participants who require enrollment by consent of a legally authorized representative.

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Valley Presbyterian Hospital, 15107 Vanowen Street, Van Nuys, California 91405

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:
As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
  - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- For research subject to continuing review, submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
  - The protocol is permanently closed to enrollment
  - All subjects have completed all protocol related interventions and interactions
  - For research subject to federal oversight other than FDA:
    - No additional identifiable private information about the subjects is being obtained
    - Analysis of private identifiable information is completed
- For research subject to continuing review, if research approval expires, stop all research activities and immediately contact the IRB.
- Promptly (within 5 days) report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research.

When the Board approves subject materials and/or advertisements, any redline changes that were provided by the submitter or required by the Board for approval will remain visible in the outcome document(s); however, recipients are expected to accept the tracked changes in the document before using. Do not make any additional modifications (including font size and visual effects) to the approved materials.
If the IRB approved an e-consent process that involves uploading the approved consent form to an e-consent platform, please ensure that the consent form(s) approved for your site is the version of the consent form that gets uploaded to the platform.

If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by WCG IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement.

If this study includes data monitoring committee/data safety monitoring board, please note that the reports of all meetings of this committee should be submitted to the IRB even if the outcome of the meeting results in no changes to the study.

For research subject to continuing review, you will receive Continuing Review Report forms from WCG IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:
Contact, Company
Katie Roemer, Valley Presbyterian Hospital
Jacobett Wasonga-Agak, MSN, RN, PHN, Valley Presbyterian Hospital
Hannah Grossman, Valley Presbyterian Hospital
Sanket Kunde, Valley Presbyterian Hospital
Holli DeVon, UCLA - School or Nursing - DNP Program

This is to certify that the information contained herein is true and correct as reflected in the records of WCG IRB. WE CERTIFY THAT WCG IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full Accreditation

Appendix C: IRB Approval

Upon review from the UCLA School of Nursing Faculty Chair, it is determined that the UCLA DNP Scholarly Project entitled:
Enhanced Continuum of Care (ECC) for Patients with Diabetes and History of COVID-19 Infection (DAHOCI) – Reducing of Cardiovascular Risks

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To be carried out by DNP student:
Student Name: Jacobett N.O. Wasonga-Agak
Institution for Project Implementation: Valley Presbyterian Hospital
Date(s) of implementation: December 2023 to June 2024

School of Nursing Faculty Chair: Dr Holli DeVon
Email: HDevon@sonnet.ucla.edu

Faculty Chair Signature: Holli DeVon

Date: 12/28/2023 **Comments**: This is a Quality Improvement project, exempt from IRB review.

If SON Faculty Chair wishes to consult REPRESENTATIVE OF UCLA OHRRP TO DETERMINE NEED FOR REVIEW, email completed form to gcirb@research.ucla.edu.

Appendix D: Interdisciplinary Engagement Flyer

VALLEY PRESBYTERIAN HOSPITAL

UCLA School of Nursing

Interprofessional Engagement in Quality Improvement Study

Implementing an Enhanced Continuum of Care (ECC) for Patients with Diabetes and a History of COVID-19 Infection (DAHOCI)

Target Population: Patients with diabetes and a history of COVID-19 infection

Interprofessional Contribution: Facilitate referral for participation in quality improvement study.

Study Location: Valley Presbyterian Hospital

Study Significance: Possibly reduce cardiovascular risks associated with diabetes and a history of COVID-19 infection by engaging in scheduled post discharge follow-up care.

Interprofessional Engagement:
Nurses - Notify clinical nurse specialist if patient assessed to have diabetes with a history of Covid-19 infection.
Providers - Assess need for baseline HgA1C, lipid panel, coagulation studies, and possibly prophylaxis anticoagulant at discharge. Referral for follow-up care.
Case Managers - Identify primary care provider for post discharge follow-up and potential need for transportation to medical appointments post discharge.
CNS/APRN - Complete study participant recruitment, provide supplemental discharge patient education, facilitate scheduled follow-up appointments, and oversee study.
Duration of Study: up to six months

Please contact Jacobett Wasonga-Agak, MSN, APRN, AGCNS-BC, PHN – Clinical Nurse Specialist - Acute Care/Telemetry Services with questions regarding this QI Study.
Ph: (818) 902-9212
VPH Clinical Mentor: Sanket Kunde, MD

Appendix E: Participant Informational Flyer

VALLEY PRESBYTERIAN HOSPITAL

UCLA School of Nursing

Voluntary Participation in a Quality Improvement Project Study

Reducing Cardiovascular Risks in Patients with Diabetes and a History of COVID-19 Infection (DAHOCI)

VPH is committed to supporting and improving your health outcomes even after you are discharged. We are studying how follow up sessions would benefit all patients with diabetes and a history of COVID-19 infection and would like to request your participation.

What to Know about Diabetes and COVID-19

Studies are showing an increase in cardiovascular risk for patients with diabetes and COVID-19 even after discharge from hospital.

- Diabetes patients have a three times higher risk for stroke,
- If a diabetic patient has a heart attack, the patient may not know because they don't feel the typical chest or left arm pain,
- The risk of having small blood clots after COVID-19 infection remains even after recovering from COVID-19, and
- The risk of high blood pressure doubles and risk of heart failure also increases.

To help reduce these cardiovascular risk factors, studies show that patients benefit from participating in a consistent follow up after being discharged from hospital. Participating in this project is voluntary and requires signed consent in accordance with the Federal and State regulations regarding studies involving patients.

What to Expect

You will attend a monthly follow up session after discharge to review your medication, take survey questions at the beginning and end of the study on management of your follow-up care for diabetes, and engage in at least one of the *Live Well with Diabetes* classes. We will monitor your blood pressure, HbA1C, coagulation studies and lipid studies at the fourth and last session.

Participation in this study is voluntary.

For more information about the project study, please contact the Project Lead, Jacobett Wasonga-Agak on (818) 902-2912.
Project Clinical Mentor: Dr. Sanket Kunde

Appendix F: Participant Preschedule Instructions

Patient Discharge Instructions

Diabetes Care After COVID-19 Infection

Why do I have follow-up appointments?

- Having COVID-19 on top of diabetes puts your heart at added risk.
- We want to ensure a provider evaluates you to prevent problems.
- During your scheduled time, your questions on diabetes and prevention of heart problems will be answered by providers including:
    - Advanced Practice Nurse / Diabetes Educator,
    - Dietician, and/or
    - Pharmacy representative
- You will meet with a nurse or provider on the following dates at the *Live Well with Diabetes* Class

Appointment One: Two to seven days after discharge

Date: _____Time: _____

Provider: _____

Appointment Two: Three to four weeks after discharge

Date: _____Time: _____

Provider: _____

Appointment Three: Eight to ten weeks after discharge

Date: _____ Time: _____

Provider: _____

Appointment Four: Three months after discharge

Date: _____ Time: _____

Provider: _____

Remember:

- You will meet with an Advanced Practice Nurse or Provider on the scheduled dates.
- To help manage your diabetes and the risks for other diseases associated with diabetes.
- **Follow-up appointments will be at the Valley Presbyterian Hospital – *Live Well with Diabetes* Community Class**
- **For questions and schedules please call study coordinator on 818-902-2912**

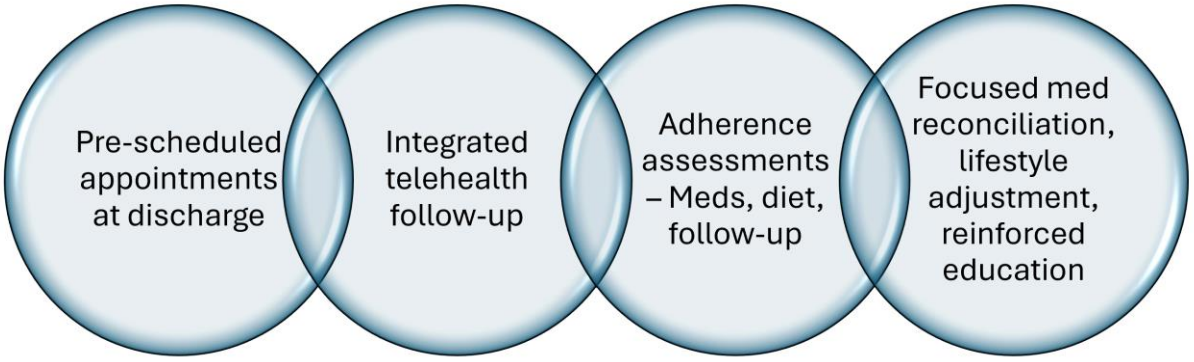
Appendix G: Enhanced Continuum of Care Model Recommendation

CARE RECOMMENDATIONS

Standard of Care Recommendation (ADA, 2022)	Frequency
Diabetic Specialist / Endocrinology	**4/year**
HbA1c Testing	**4/year**
Retinal check-up	1/year
Dental check-up	1/year
Lipid levels lab check-up	1/year
Renal check-up – specialist and lab tests	1/year
Electrocardiogram (EKG) & Cardiology check-up	1/year

Enhanced Continuum of Care

- ❑ Specified follow-up appointments with discharge instructions
  - ✓ 2-7 days post discharge,
  - ✓ 4-6 weeks post discharge
  - ✓ 8-10 weeks post discharge six
  - ✓ Quarterly check-up
- ❑ Prophylactic: Aspirin
- ❑ Coagulation Studies: 4/year
- ❑ Cardiology appointment: 2/year



Appendix H: Hill-Bone Adherence to Diabetes Therapy Scale

Hill-Bone Adherence to Diabetes Therapy Scale
Adopted from:
Hill-Bone HBP Compliance to High Blood Pressure Therapy Scale (HB-HBP)

No.	Item	Response: 1. All of the Time 2. Most of the Time 3. Some of the Time 4. None of the Time
1	How often do you forget to take your **diabetes** medicine?	
2	How often do you decide NOT to take your **diabetes** medicine?	
3	How often do you eat salty food?	
4	How often do you shake salt on your food before you eat it?	
5	How often do you eat fast food?	
6	How often do you make the next appointment before you leave the doctor's office?*	
7	How often do you miss scheduled appointments?	
8	How often do you forget to get prescriptions filled?	
9	How often do you run out of **diabetes** pills?	
10	How often do you skip your **diabetes** medicine before you go to the doctor?	
11	How often do you miss taking your **diabetes** pills when you feel better?	
12	How often do you miss taking your **diabetes** pills when you feel sick?	
13	How often do you take someone else's **diabetes** pills?	
14	How often do you miss taking your **diabetes** pills when you are careless?	

* Reverse coding

Note:
Scale and subscale scores are calculated by summing individual items.
Reducing sodium intake subscale: Items 3,4,5
Appointment keeping subscale: Items 6,7
Medication taking subscale: Items 1, 2, 8,9,10,11,12,13,14

Hillbone Scale used with Permission

Appendix I: Compliance (HB-HBP) and Adherence (HB-MAS) Instruments

Compliance (HB-HBP) and Adherence (HB-MAS) Instruments

Hill-Bone HBP Compliance to High Blood Pressure Therapy Scale (HB-HBP)

No.	Item	Response: 1. All of the Time 2. Most of the Time 3. Some of the Time 4. None of the Time
1	How often do you forget to take your **high blood pressure** medicine?	
2	How often do you decide NOT to take your **high blood pressure** medicine?	
3	How often do you eat salty food?	
4	How often do you shake salt on your food before you eat it?	
5	How often do you eat fast food?	
6	How often do you make the next appointment before you leave the doctor's office?*	
7	How often do you miss scheduled appointments?	
8	How often do you forget to get prescriptions filled?	
9	How often do you run out of **high blood pressure** pills?	
10	How often do you skip your **high blood pressure** medicine before you go to the doctor?	
11	How often do you miss taking your **high blood pressure** pills when you feel better?	
12	How often do you miss taking your **high blood pressure** pills when you feel sick?	
13	How often do you take someone else's **high blood pressure** pills?	
14	How often do you miss taking your **high blood pressure** pills when you are careless?	

* Reverse coding

Note:
Scale and subscale scores are calculated by summing individual items.
Reducing sodium intake subscale: Items 3,4,5
Appointment keeping subscale: Items 6,7
Medication taking subscale: Items 1, 2, 8,9,10,11,12,13,14

Hill-Bone Medication Adherence Scale (HB-MAS)

No.	Item	Response: 1. All of the Time 2. Most of the Time 3. Some of the Time 4. None of the Time
1	How often do you forget to take your **high blood pressure** medicine?	
2	How often do you decide NOT to take your **high blood pressure** medicine?	
3	How often do you forget to get prescriptions filled?	
4	How often do you run out of **high blood pressure** pills?	
5	How often do you skip your **high blood pressure** medicine before you go to the doctor?	
6	How often do you miss taking your **high blood pressure** pills when you feel better?	
7	How often do you miss taking your **high blood pressure** pills when you feel sick?	
8	How often do you take someone else's **high blood pressure** pills?	
9	How often do you miss taking your **high blood pressure** pills when you are careless?	

Note:
This 9-item scale has broad application across various chronic diseases and conditions for self-assessment of medication adherence. The words "**high blood pressure"** may be replaced with other conditions as applicable.

Details on scale scoring and psychometric properties are provided in the references below:

Kim, M.T., Hill, M.N., Bone, L.R., Levine, D.M. Development and testing of the Hill-Bone compliance to high blood pressure therapy scale. Progress in Cardiovascular Nursing Summer 2000, 90-96. https://www.ncbi.nlm.nih.gov/pubmed/10951950

Lambert EV, Steyn K, Stender S, Everage N, Fourie JM, Hill M. Cross-cultural validation of the Hill-Bone compliance to high blood pressure therapy scale in a South African, Primary Health Care Setting. Ethnicity & Disease 2006; 16:286-291. https://www.ncbi.nlm.nih.gov/pubmed/16599385

Tool used with permission

Appendix J: User Agreement

Hill-Bone Scales: User Agreement

Definitions:

- Hill-Bone Scales: the Hill-Bone Compliance to High Blood Pressure Therapy Scale (HB-HBP) and its medication sub-scale, the Hill-Bone Medication Adherence Scale (HB-MAS)
- Provider: Johns Hopkins University School of Nursing
- User: anyone who employs a Hill-Bone Scale in a research, clinical, educational, or other setting
- Publicly Available: the Hill-Bone Scales which are available for download at https://nursing.jhu.edu/HillBoneScales

Thank you for your interest in the Hill-Bone Scales. Please read our User Agreement carefully as we include information which applies universally to the use of our scales.

You understand and agree that the Provider gives access to the Hill-Bone Scales subject to this User Agreement. Provider reserves the right to update the User Agreement at any time. Changes to the User Agreement will apply to new users, new instruments, and to new projects created by existing users after these changes are posted.

Use of the Hill-Bone Scales, related materials, and services requires acceptance of all terms and conditions stated herein. You agree to abide by the Hill-Bone Scales: User Agreement as a condition of using the Hill-Bone Scales. No modifications or additions to these User Agreement are binding upon Provider unless previously agreed to in writing by an authorized representative of Provider.

Single Use, Reproducibility, and Distribution

- All Hill-Bone Scales are copyrighted. All English versions of the Hill-Bone Scales are publicly available for use without licensing or royalty fees for individual research or individual clinical use. Such use of the Hill-Bone Scales is "single use," meaning solely for User's research, clinical, educational, or other application per this request. Subsequent projects, research, clinical use, etc. requires a new Permission Request and new User Agreement.
- User shall not reproduce the Hill-Bone Scale(s) except as needed to conduct the authorized single use research, clinical, educational, or other activity. User shall not distribute, publish, sell, license, or provide the Hill-Bone Scale(s), by any means whatsoever, to third parties not involved with the authorized single use as stated above, without the prior written agreement of the Provider. Users must request permission to reprint the Hill-Bone Scale(s) for reasons not included in the single use case.
- Commercial Users must seek permission to use, reproduce, or distribute any Hill-Bone Scale regardless of purpose, at all times.
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for data collection. Provider may incur costs in providing the permission to integrate, and those costs may be passed along to the User.

- Users who secure license agreements to deliver the Hill-Bone Scale(s) through technological systems owned and supported by Provider do not need additional licenses to use the Hill-Bone Scale(s) provided with the technological system to which User has been granted license. If the license agreement for the technology owned and supported by Provider includes reproduction and distribution rights, the license agreement itself is sufficient permission for reproduction and distribution and covers all requirements to seek permissions or consent required herein.
- User agrees not to adapt, alter, amend, abridge, modify, condense, make derivative works, or translate the Hill-Bone Scale(s) without prior written permission from the Provider. In cases where permission is granted, User will be expected to evaluate the impact of approved modifications. User will also be expected to provide the verified translation of the Hill-Bone Scale(s) to the Provider for public use.
- User agrees and undertakes not to sell or incorporate the Hill-Bone Scale(s) into materials that could be sold without prior written consent from the Provider.
- To inquire about permissions, email son-hillbonescales@jhu.edu.

Indemnification

- User agrees and undertakes to indemnify and hold Provider harmless against any and all claims, loss or damage, including fees, penalties or fines and third-party claims, and attorneys' fees arising from User's use of any Hill-Bone Scale. Further, User shall be obliged to indemnify, defend and/or hold harmless Provider and its agents, trustees, officers, medical affiliates, employees, and their respective successors, heirs, and assignees against any liability, damage, loss or expense incurred in connection with User's use of any Hill-Bone Scale.
- Consent to User's use of the Hill-Bone Scale(s) is given 'AS IS', without any accompanying services or improvements. Provider does not accept any liability resulting from User's use of any Hill-Bone Scale. Hill-Bone Scale(s) is supplied to User with no warranties or representations of any kind as to the accuracy, currency, or the merchantability or fitness of the Hill-Bone Scale(s) for a particular purpose.
- Neither Provider nor any party involved in creating, producing, or delivering any Hill-Bone Scale shall be liable for any damages, including without limitation, direct, incidental, consequential, indirect, or punitive damages arising out of access to, use of, alterations of, or inability to use any Hill-Bone Scale, or any errors or omissions in the content thereof.

Trademarks References

- User will include Provider's trademark ownership statement on all printed copies of any Hill-Bone Scale in the same form as it appears on the document that User is downloading from this website or is receiving via email from the Provider.
- User agrees and undertakes not to remove the trademark notices which appear on any printed Hill-Bone Scale. Use of the Hill-Bone Scale(s) does not and will not create any

right, title or interest thereof for User, other than the right to use the Hill-Bone Scale(s) under this User Agreement.

Publications and Presentations

- Any publication or presentation created from research, clinical, educational, or other applicable use of any Hill-Bone Scale should include a statement that indicates which instruments were used and provide an appropriate citation.
- For precise citation, please see: *Kim MT, Hill MN, Bone LR, Levine DM. Development and testing of the Hill-Bone Compliance to High Blood Pressure Therapy Scale. Prog Cardiovasc Nurs. 2000 Summer;15(3):90-6. doi: 10.1111/j.1751-7117.2000.tb00211.x. PMID: 10951950.*

Furthering Research

- Use of the Hill-Bone Scale(s) in clinical research is encouraged, with the understanding that data collected from that use will contribute to knowledge about the validity of Hill-Bone Scale measures. USERS OF Hill-Bone Scale TOOLS ARE STRONGLY ENCOURAGED TO SUBMIT A BRIEF REPORT INCLUDING SAMPLE DEMOGRAPHIC INFORMATION, CLINICAL DATA SUFFICIENT TO characterize THE SAMPLE, AND SCORE DISTRIBUTIONS (E.G., BASELINE MEAN AND STANDARD DEVIATIONS OR CHANGE SCORES). This brief report should be submitted to son-hillbone@jhu.edu for internal review. None of this submitted information will be published without the written consent and participation of the submitter. In addition to the brief report, clinical researchers are encouraged to submit a final version of any translated scale, presentation or publication. Data ownership would remain with the submitter. Clinical researchers are strongly encouraged to collaborate with Hill-Bone Scale researchers when applying these items and banks to their research.

NO WARRANTY. Provider makes no warranties, expressed or implied, including warranties of merchantability or fitness for a particular purpose. Provider will not, under any circumstances, be liable for User's expense for delays, for costs of substitute materials, or for possible lost income, grants, profits, or any other special or consequential damages that may result from using the Hill-Bone Scales.

☐ Yes, I agree ☐ No, I do not agree

Signature: _____ Date: _____

Affiliation: _____

_____

_____

Approved version 18 May 2018

Appendix K: SWOT Analysis

SWOT Analysis

	Strengths	Weakness
INTERNAL	• Aligns with community assessment • Existing class for patients with diabetes • Contingent sample • Three months pilot • CNS - other successful project • Strong Past and current interdisciplinary collaborations - buy-in • CNS for acute care services - access to leadership and staff • Chair of clinical practice committee and member of glycemic management committee – team relations • Current working setting - established relations	• New program • Cost impact • Current working location - separation of work and project • IRB approval • Varied providers - utilization of travel nurses and registry - standardization of recruitment and patient education • Case management - competing priorities - disposition vs securing pre-scheduled appointment • Insurance verification - primary care provider verification' • Language barriers
	Opportunities	**Threats**
EXTERNAL	• IRB approval • CNO resigning - leadership change • Lack of endocrinologist team on site. Recently resigned • Identified NP champion • Identified DNP clinical mentor • New leadership relationship • Proven leadership on other projects • Collaboration with UCLA	• Providers not comfortable to order labs 3 months in advance • Insurance • Changing organizational structure • Stand alone community hospital • Competing priorities - magnet journey • Lack of resources - staffing challenge • Lack of endocrinologist team on site. Recently resigned

TABLE OF EVIDENCE

CITATION	**PURPOSE**	**SAMPLE / SETTING**	**METHODS (Design, Interventions, Measures)**	**RESULTS**	**DISCUSSION, INTERPRETATION, LIMITATIONS**
Abe, T., Egbuche, O., Igwe, J., Jegede, O., Wagle, B., Olanipekun, T., & Onwuanyi, A. (2021). Cardiovascular complications in COVID-19 patients with or without diabetes mellitus. *Endocrinology, Diabetes & Metabolism*, *4*(2), e00218. https://doi.org/10.1002/edm2.218	Compare the magnitude of cardiovascular complications in COVID-19 patients with or without DM	<u>Sample:</u> N=142 50% with COVID-19 50% w/o – control N=72 excluded – incomplete data <u>Setting</u> Grady Memorial Hospital - Georgia	<u>Design</u> RCT Patient data analyzed. Age, gender, race, comorbidities, health insurance, in hospital management, & complications (DVT, PE, AKI & AKI w RRT), resp failure, & death	<u>Statistical Analysis</u> Multivariable logistic regression Stata MP V16 for analysis <u>Results</u> Mean age: 58 CV complications - 73.3% vs 40.6% p<0.01 higher in DM patients New onset a-fib 12.7% vs 1.4% Acute MI 9.9% vs1.4% Acute HF 25.3% vs 5.6%	<u>Discussions</u> Higher rates of CV complications in DM Worse outcomes – patients with CVD hx <u>Interpretation</u>: DM contributed to worse CV complication outcome. <u>Limitation</u> Further research – understanding disease process. 80% were African American

CITATION	PURPOSE	SAMPLE / SETTING	METHODS (Design, Interventions, Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATIONS
Agarwal, C., Bansal, K., Pujani, M., Singh, K., Chauhan, V., Rana, D., & Lukhmana, S. (2019). Association of coagulation profile with microvascular complications and glycemic control in type 2 diabetes mellitus – a study at a tertiary care center in delhi. *Hematology, Transfusion and Cell Therapy, 41*(1), 31–36. https://doi.org/10.1016/j.htct.2018.05.002	Evaluate coagulation profile and analyze correlation between DM characteristics and coagulation variables. Routine assessment of PT/APTT & fibrinogen to identify coagulation impairment	Sample N=60 DM patients w/ or w/o microvascular complication N=30 Control grp Setting Department of Pathology of the Employees State Insurance Corporation (ESIC) Medical College & Hospital, Faridabad, Haryana, Delhi, India	Design Case Control Study Grouped into 2 groups – DM patients w/ or w/o microvascular complication. Record of demographic and coagulation elements (PT/APTT/fibrinogen) EMR chart review, Lab work completed, and statistical difference between groups computed	SPSS software, t-test, ANOVA, and Mann-Whitney U tests. P-value <0.05 for statistical significance. Results represented in means, SD & percentages. 33-70 yrs.; 50% =40-50-year-olds, Correlation by age and DM duration for APTT was lower: P value <0.0001; fibrinogen was higher – p=0.000; w/complication p=0.038, and ANOVA - higher coagulation profile & patient complication for w/ complication	Discussion & Interpretation Shorter PT/APTT & longer fibrinogen important indicator for hemostatic markers in DM. Limitation Small sample size Duration of study

CITATION	PURPOSE	SAMPLE / SETTING	METHODS (Design, Interventions, Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATIONS
Cheung, N. W., Hor, A., & Hng, T. M. (2022). The virtual inpatient diabetes management service: COVID-19 brings the future to inpatient diabetes management. *The Medical Journal of Australia*, *216*(6), 321–322. https://doi.org/10.5694/mja2.51456	Explore & implement virtual inpatient DM management system – (vIDMS)	Sample N=112 Median age: 62yrs Setting: Westmead Hospital, Sydney	Method 40 patients reviewed daily over 6 weeks. Record and display all glucose on dashboard. Facilitate timely and easy identification of DM complication (hyperglycemia), timely medication administration, intervention, and education. Video conferencing utilized for care management	Results Real time EMR transmission of glucose measurement to guide care and patient management. 16.7% - hyperglycemia incidences	Discussion ¼ patients report DM, but few personnel to facilitate management. Virtual management systems define the future of DM management. Limitations Single facility Lack of adequate personnel to respond. Excluded patients without COVID-19 infection.

CITATION	PURPOSE	SAMPLE / SETTING	METHODS (Design, Interventions, Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATIONS
Lim, S. T., Yap, F., & Chin, X. (2020). Bridging the needs of adolescent diabetes care during COVID-19: A nurse-led telehealth initiative. *The Journal of Adolescent Health: Official Publication of the Society for Adolescent Medicine, 67*(4), 615–617. https://doi.org/10.1016/j.jadohealth.2020.07.012	Evaluate a nurse-led telehealth program for adolescents with DM. Optimize infrastructure and limited resources to provide access to care	Sample N=60 in person N=35 – telehealth Setting Public tertiary pediatric hospital - Singapore	Design 1. Tele consults 2. Payment platforms 3. Laboratory tests 4. Medication collection Interventions HgbA1C resulted - 20–30-minute call to address insulin titration & COVID-19 related questions or complication. Text message, verbal consent, in-person for labs, electronic results, and consult	Results 80% reported in-person appt was similar to virtual. 20% reported virtual was superior to in person. 4 opted to remain in in person consults. No ER visits for diabetes related adverse effects. Estimated time in hospital deduced from 175minutes to 75minutes	Discussion Tele health well received, bridged continuum of care. CGM to compliment telehealth follow-up. No adverse effects Limitation Insight on the challenges not assessed. Small sample Statistical analysis Adolescent population

CITATION	PURPOSE	SAMPLE / SETTING	METHODS (Design, Interventions, Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATIONS
Profili, F., Seghieri, G., & Francesconi, P. (2022). Effect of diabetes on short-term mortality and incidence of first hospitalizations for cardiovascular events after recovery from SARS-CoV-2 infection. *Diabetes research and clinical practice*, 187, 109872. https://doi.org/10.1016/j.diabres.2022.109872	To review effects of diabetes and COVID-19 on new onset cardiovascular events (MI or Stroke)	Sample: - Diabetic, COVID-19 patients -45-94 years - Exclusion: Type 1 Diabetes Sample size n=46152 n=4597 survived COVID-19, 1:1 matched control group by age, gender, and DM dx Setting: Tuscany Italy	Design: Randomized control cohorts/observational retrospective study Intervention/measures: observational retrospective study & secondary administrative databases 1:1 matched control group by age, gender, and DM dx Evaluate co-existence of DM and COVID-19 at death or first CVE-related hospitalizations post COVID-19	Statistical Analysis**:** Stata version 15.0; Poisson multivariate regression model for 1st hospitalization for MI, stroke, and/or death incidence rate ratio (IRR) at 95% CI P-value of <0.05 for statistical significance Results 60% w/ DM – oral meds, 18% insulin, 22- no glucose lowering meds; Two-fold increased risk for CVE; 1st CVE incident hospitalization	Discussion & Interpretation Post-COVID-19 recovery – (6 months), increased risk for cardiovascular event. No difference in first CVE episode. DM independently – increased risk for first CVE Gender (female) & Statins reduced CVE risks. Strength – large, validated databases Limitations: observational retrospective study – no access to clinical data restricted to participants with no prior CVE hospitalization, short follow-up

CITATION	PURPOSE	SAMPLE / SETTING	METHODS (Design, Interventions, Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATIONS
				higher in DM patients (log-rank test <0.001); Comparison DM – higher IRR for death or 1st CVE hospitalizations in DM than non-DM 67% and 17% respectively – log-rank test <0.05 for both	

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Agarwal, C., Bansal, K., Pujani, M., Singh, K., Chauhan, V., Rana, D., & Lukhmana, S. (2019). Association of coagulation profile with microvascular complications and glycemic control in type 2 diabetes mellitus – A study at a tertiary care center in Delhi. *Hematology, Transfusion and Cell Therapy*, *41*(1), 31–36. https://doi.org/10.1016/j.htct.2018.05.002

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