

Dynamic Diffusion Network (DDN) QUERI Program: a quality improvement project to compare strategies for implementing the advanced comprehensive diabetes care program at VA medical centers

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| Submission date 09/12/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 19/12/2022 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 17/11/2023 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Healthcare systems face the challenge of delivering care of the highest possible quality while at the same time ensuring broad access to services and responsible use of resources. Without thoughtfully designed implementation strategies, the impact of evidence-based practices cannot be fully realized. This quality improvement evaluation seeks to implement and test two different implementation support strategies to better address the needs of Veterans with persistently poor type 2 diabetes control.

The Veterans Affairs (VA) Dynamic Diffusion Network (DDN) QUERI Program is designed to support quality improvement efforts and provide information to VA to continue to better understand different implementation support strategies, especially for spreading complex clinical evidence-based practices (EBPs) beyond successful earlier adopters across the VA healthcare system.

Who can participate?

Facilities in the United States Veterans Health Administration (VHA) with a Home Telehealth Program which are seeking to implement ACDC - a telehealth-based program for patients with persistently poorly controlled type 2 diabetes - as part of a quality improvement program.

What does the study involve?

Participating facilities that have a Home Telehealth Program and are, or will be offering, ACDC - a telehealth-based program for patients with persistently poorly controlled type 2 diabetes - are assigned to one of two implementation support strategies. One of the support strategies involves participating in a Dynamic Diffusion Network and the other support strategy consists of technical assistance. The Dynamic Diffusion Network was developed as a method for implementing and adapting complex clinical interventions. It is designed to enhance the evidence-based implementation of clinical EBPs that utilize existing structures within facilities.

The DDN recognizes the need to: 1) have engaged facilities; 2) plan to link quality goals and EBP components to the workflow; 3) facilitate rapid cycle quality improvement and 4) plan for sustainment and further spread. The DDN QUERI Program will evaluate the DDN with selected VA facilities in comparison to providing information about diabetes self-management and responding to facility questions about the process of delivering self-management modules, along with telemonitoring patient glucose levels and specialist-guided medication management (i.e., technical assistance).

What are the possible benefits and risks of participating?

This non-research quality improvement project seeks to understand how to help VA facilities improve the quality of care provided to Veterans who are experiencing persistently poor diabetes control.

Where is the study run from?

The Durham Veterans Affairs Health Care System (USA)

When is the study starting and how long is it expected to run for?

October 2020 to September 2025

Who is funding the study?

United States Veterans Affairs Quality Enhancement Research Initiative (USA)

Who is the main contact?

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Study website

https://www.durham.hsrdr.research.va.gov/Dynamic_Diffusion_Network_DD_N_QUERI_Program.asp

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

QUE 20-012

Study information

Scientific Title

Dynamic Diffusion Network (DDN) QUERI Program: a randomized quality improvement evaluation comparing a network-based implementation facilitation strategy to technical assistance for the implementation of advanced comprehensive diabetes care among veterans with persistently poorly controlled type 2 diabetes mellitus

Acronym

DDN QUERI – ACDC QI Evaluation

Study objectives

The purpose of this project is to conduct a randomized quality improvement evaluation comparing two strategies, the Dynamic Diffusion Network (DDN) and technical assistance, for the implementation of the Advanced Comprehensive Diabetes Care (ACDC) evidence-based practice among a group of VA Medical Center sites. The DDN strategy operationalizes the EPIS (exploration, preparation, implementation, sustainment) Implementation Framework. ACDC combines telemonitoring with self-management support and specialist-guided medication management for diabetes. All participating sites will implement ACDC using existing VA Home Telehealth (HT) staffing and infrastructure, with assistance from a medication management specialist at the site.

The primary outcome of this quality improvement evaluation will focus on successful clinical intervention implementation as measured by the delivery of an appropriate intervention dose (fidelity). Secondary implementation outcomes include the use of core and adaptable components of the clinical intervention (i.e., ACDC) and rapid improvement processes. Secondary clinical outcomes, specifically diabetes control as measured by a change in hemoglobin A1c (HbA1c), will focus on the clinical impact of the ACDC program. The researchers will also conduct: 1) a mixed-methods evaluation of factors influencing outcomes at each EPIS stage based on the Consolidated Framework for Implementation Research (CFIR) and 2) a detailed examination of budget impact to examine the potential business case.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Per regulations outlined in VHA Program Guide 1200.21, this evaluation has been designated a non-research quality improvement activity by the Director of the VHA Office of Healthcare Innovation and Learning via a memorandum dated 07/05/2021

Study design

Multicenter hybrid type 3 randomized quality improvement evaluation

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Persistently poorly controlled type 2 diabetes in veterans receiving care in the United States Veterans Health Administration system

Interventions

Participating facilities that have a Home Telehealth Program and are, or will be offering, ACDC - a telehealth-based program for patients with persistently poorly controlled type 2 diabetes - are assigned to one of two implementation support strategies. One of the support strategies involves participating in a Dynamic Diffusion Network and the other support strategy consists of technical assistance. The Dynamic Diffusion Network was developed as a method for implementing and adapting complex clinical interventions. It is designed to enhance the evidence-based implementation of clinical EBPs that utilize existing structures within facilities. The DDN recognizes the need to: 1) have engaged facilities; 2) plan to link quality goals and EBP components to the workflow; 3) facilitate rapid cycle quality improvement and 4) plan for sustainment and further spread. The DDN QUERI Program will evaluate the DDN with selected VA facilities in comparison to providing information about diabetes self-management and responding to facility questions about the process of delivering self-management modules, along with telemonitoring patient glucose levels and specialist-guided medication management (i.e., technical assistance).

The total duration of ACDC implementation for both arms will be approximately 2.5 years (preparation phase approximately 6 months, implementation phase approximately 12 months, and sustainment phase approximately 12 months).

Stratified sites are randomized 1:1 into one of two implementation support strategies (i.e., network-based structured implementation facilitation called, Dynamic Diffusion Network, or technical assistance). Randomization will be stratified based on sites' Home Telehealth enrollment with categorization of 6 low and 4 high enrollment sites (low and high sites identified by having less or more than a mean calculated enrolled population of 392)

Intervention Type

Other

Primary outcome measure

Appropriate dose/adherence to the ACDC clinical intervention as determined by nurse-led tracking indicating that a patient completed 80% or more of the intended phone calls and associated modules at the end of the study.

Secondary outcome measures

1. Successful delivery of core and adaptable components of ACDC measured using self-reported information on quarterly and phase reports, qualitative interviews conducted with team members before and after the beginning of implementation, and examples/descriptions of group materials and processes provided by participating facilities over approximately 1.5 years of implementation (e.g. preparation and implementation phases).
2. Intervention clinical effectiveness measured using HbA1c change from baseline to 6 months (HbA1c values pulled from EHR).
3. Process evaluation utilizing survey (Organizational Readiness for Change) and qualitative data from semi-structured qualitative interviews conducted at the start and completion of the 1-year implementation phases to capture components of the Consolidated Framework for Implementation Research (CFIR).
4. Cost of the implementation strategy and intervention will be measured based on self-reported participant activities captured using reports of both implementation and intervention activities conducted by specific individuals over the course of the Dynamic Diffusion Network or technical assistance. The cost of the implementation strategy and intervention will be measured

based on self-reported participant activities captured using reports of both implementation and intervention activities conducted by specific individuals over the course of the Dynamic Diffusion Network or technical assistance.

Overall study start date

01/10/2020

Completion date

30/09/2025

Eligibility

Key inclusion criteria

Healthcare facilities with a Home Telehealth Program in the Veterans Health Administration serving Veterans with persistently poorly controlled type 2 diabetes, as indicated by having an HbA1c $\geq 8.5\%$ despite receipt of clinic-based services or standard telehealth approaches will be randomly assigned as part of this quality improvement evaluation. The work of these facilities will be led by teams of individuals who are:

1. VHA-employed telehealth nurse working in collaboration with a medication manager (e.g. clinical pharmacist, nurse practitioner)
2. Willing and able to deliver the ACDC self-management support modules according to a schedule to Veterans with type 2 diabetes (nurse)
3. Willing and able to receive and review phone encounters for any recommended changes to patient medications (medication manager)
4. Willing and able to be randomly assigned to one of two implementation support conditions (technical assistance or network-based structured implementation facilitation)
5. Willing and able to obtain clinic-level leadership and facility-level leadership support and approval to participate
6. Invited by DDN QUERI staff to participate in the QI program

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

10 healthcare facilities

Key exclusion criteria

Must meet all inclusion criteria noted, including being invited to participate in the QI program by DDN QUERI staff

Date of first enrolment

19/12/2022

Date of final enrolment

15/03/2023

Locations

Countries of recruitment

United States of America

Study participating centre

Durham VA Health Care System

508 Fulton St

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Organisation

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Funder(s)

Funder type

Government

Funder Name

Quality Enhancement Research Initiative

Alternative Name(s)

VA Quality Enhancement Research Initiative, QUERI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publications in high-impact peer-reviewed journals

Intention to publish date

30/04/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are not expected to be made available due to the quality improvement/operations nature of the project and regulations of the United States Department of Veterans Affairs.

IPD sharing plan summary

Not expected to be made available