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Meeting the needs of rural Veterans through rapid implementation of pharmacist-provided telehealth management of diabetes during the COVID-19 pandemic

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Title: Meeting the needs of rural Veterans through rapid implementation of pharmacist-provided telehealth management of diabetes during the COVID-19 pandemic

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Title: Meeting the needs of rural Veterans through rapid implementation of pharmacist-provided telehealth management of diabetes during the COVID-19 pandemic

Abstract

Background: The rapid implementation of telehealth care due to the COVID-19 pandemic allowed clinical pharmacist practitioners (CPPs) within the Veterans Health Administration (VA) to continue to provide diabetes management to Veterans with healthcare disparities, including rural Veterans.

Objectives: This project aimed to describe the change in hemoglobin A1c (HbA1c) in telehealth naïve Veterans with types 1 or 2 diabetes mellitus (DM) before and after the rapid implementation of CPP-provided telehealth DM management due to the COVID-19 pandemic. The project also sought to describe potential healthcare disparities which may be addressed by the increase in telehealth use and the impact of metformin sustained action (SA) recalls.

Methods: Analysis included patients receiving face-to-face DM-focused visits with a CPP prior to the COVID-19 pandemic (06/01/2019 – 12/01/2019) who transitioned to telehealth care via telephone or VA Video Connect (VVC) during the COVID-19 pandemic (06/01/2020 – 12/01/2020). One or more HbA1c readings within each timeframe was required for inclusion. Patients were excluded if previously enrolled in VA telehealth DM management.

Results: The rapidly implemented telehealth management of DM provided by VA CPPs was observed to maintain or improve HbA1c control in 84.2% of patients. During the same timeframe, 10.9% of patients were taken off metformin SA secondary to national drug recalls. In total, 76% of patients were from rural communities and over 52% of patients traveled greater than 50 miles round-trip to receive face-to-face DM care prior to the pandemic.

Conclusion: Glycemic control was improved or maintained for a majority of patients who were rapidly converted to pharmacist-provided telehealth DM management during the COVID-19 pandemic. A large

majority of rural patients were reached as a result of CPP-provided telehealth care. This provides evidence to support the continued widespread telehealth utilization to effectively manage DM and reach Veterans with healthcare disparities, particularly rural communities.

Keywords: Diabetes Mellitus, Telemedicine, Rural Health, Clinical Pharmacist Practitioner, United States Department of Veterans Affairs

Key Points:

What was already known:

- Telehealth is used as an effective tool to manage chronic disease states, including diabetes mellitus (DM)
- Underserved populations, including rural patients, benefit from the use of telehealth
- Clinical pharmacist practitioners (CPPs) have been shown to improve patient care through comprehensive medication management of disease states such as DM, particularly within the Veterans Health Administration (VA)

What this study adds:

- The COVID-19 pandemic created a unique urgency to quickly use telehealth exclusively for outpatient care provided by CPPs within the VA
- Large portions of rural Veterans may quickly receive access to effective DM management when telehealth care is rapidly implemented by CPPs
- CPPs provide effective DM care through telehealth

Article Text

Abbreviations

- Centers for Medicare and Medicaid Services (CMS)
- Clinical Pharmacist Practitioners (CPPs)
- Department of Defense (DoD)
- Diabetes Mellitus (DM)
- Hemoglobin A1c (HbA1c)
- Immediate Release (IR)
- Institutional Review Board (IRB)
- Rural-Urban Commuting Area (RUCA)
- Sustained Action (SA)
- VA Video Connect (VVC)
- Veterans Health Administration (VA)
- Western North Carolina VA Health Care System (WNCVAHCS)

Background

The Veterans Health Administration (VA) has been utilizing telehealth to successfully manage patients with chronic diseases, including diabetes mellitus (DM), since 2003 with the establishment of VA's Telehealth Services department.[1] In more recent years, VA has increased the impact of telehealth through the use of VA Video Connect (VVC) technology which provides scheduled and on-demand synchronous audio-video healthcare visits.[2] Although the VA was early to explore telehealth options, the degree of implementation increased significantly because of the COVID-19 pandemic. Weekly telehealth video appointments increased from 10,000 in February 2020 to 120,000 in May 2020, representing an increase of over 1000%.[3]

Since the pandemic, the use of the terms telehealth, telecommunications, and telemedicine have become more commonly used in healthcare settings.[4] The Centers for Medicare and Medicaid Services (CMS) defines telemedicine to include interactive telecommunication using both audio and video equipment.[5] During the COVID-19 pandemic, CMS issued a waiver to allow reimbursement for audio-only telehealth care of certain services, including evaluation and management from a qualified healthcare provider.[6] This CMS waiver allowed for telephone visits to be included under the umbrella term "telehealth" and become a more common means for conducting clinic visits during the first year of the pandemic.

Literature has shown that using telehealth to manage DM is both safe and effective. A systematic review and meta-analysis reviewed 13 randomized controlled trials to "assess the impact of telemedicine interventions on change in hemoglobin A1c (HbA1c), blood pressure, low-density lipoprotein cholesterol, and body mass index."[7] Marcolino and colleagues determined that telemedicine, including video or audio-only telephone follow-up, in addition to usual care showed improved glycemic control compared to usual care alone.[7] A multi-center randomized controlled trial evaluated glucose control in 338 patients with type 2 DM who received telemedicine, telemonitoring, or conventional care from an endocrinologist over the course of 24 weeks; results demonstrated equivalent glucose control with synchronous audio-video telemedicine care compared to usual face-to-face care.[8]

Patients living in rural locations, defined by the United States Census Bureau as open country or settlements with fewer than 2,500 residents, have the opportunity to benefit from increased use of telehealth.[9] Research conducted for rural patients outside of the VA has added to the understanding that HbA1c is better controlled when telehealth measures are implemented for follow-up care of DM.[10-12] Additionally, studies have emphasized the importance of telehealth technology for providing care to vulnerable populations, including the elderly, racial minorities, and rural Veterans who may not otherwise be able to receive timely in-person clinical care. [13-16]

Over several decades, VA has been a leader in pioneering the use of clinical pharmacist practitioners (CPPs) to manage chronic disease states, including DM.[17] CPPs within the VA are authorized by their facility as advanced practice providers and function as collaborative practitioners according to their clinical scope of practice, functioning with a high level of clinical autonomy to provide comprehensive medication management.[18,19] Clinical studies indicate that when CPPs provide comprehensive medication management for patients with DM, significant improvements in clinical outcomes are noted.[20-21] CPPs are in a unique position to combine pharmacotherapy expertise, patient-friendly education, and clinical flexibility to improve patient care.

In the spring of 2020, the COVID-19 pandemic increased the urgency to use telehealth for outpatient care. Due to social distancing recommendations to prevent the spread of COVID-19, many providers quickly began using telehealth to care for their patients safely and effectively.[22-24] The rapid implementation of telehealth care provided the opportunity for VA CPPs to quickly reach Veterans with healthcare disparities. Rural Veterans previously traveling extensive distances for outpatient appointments benefited from the switch to virtual care by saving time, income, and/or the coordination of transportation assistance.

This project aimed to examine the impact of rapidly implemented CPP telehealth clinics during the COVID-19 pandemic at the Western North Carolina VA Health Care System (WNCVAHCS), specifically evaluating HbA1c control in VA telehealth-naïve patients with types 1 or 2 DM. The hypothesis was HbA1c would be maintained during the abrupt conversion to CPP-provided telehealth visits. Given the variability with the use of the term telehealth for the purposes of this project the term includes outpatient clinic visits conducted by CPPs over either telephone (audio-only) or synchronous audio-video modalities. Authors also describe the potential impact of increased telehealth utilization on healthcare disparities, including Veterans previously traveling from rural distances to receive DM care by face-to-face CPP clinic visits.

During the timeframe included in this project, widespread metformin sustained action (SA) recalls impacted many patients receiving care at this facility. WNCVAHC made a facility-wide decision to discontinue all use of metformin SA in the Spring of 2020 due to difficulty procuring the formulation. Given the evidence of metformin's ability to provide improvement in HbA1c, due diligence was warranted to review this potential impact during the same timeframe.

Objectives

This project sought to identify Veterans impacted by the rapid change from face-to-face DM management to telehealth care provided by CPPs. The primary objective was to compare the change in average HbA1c in telehealth naïve patients with type 1 or 2 DM before and after the rapid implementation of CPP-provided telehealth DM management.

Additionally, secondary objectives outlined the impact of metformin SA recalls and potential healthcare disparities which may be addressed by the increase in telehealth use. Potential healthcare disparities included: age, race, ethnicity, rurality, and travel distance to VA facility prior to conversion to telehealth. As a result of the widespread metformin SA recalls, this VA facility discontinued all use of metformin SA between June 1 through December 1, 2020. Given the timeframe of this factor, evaluation of metformin SA impact was included in the project analysis.

Methods

The project was conducted as a quality assurance retrospective chart review with permission from the VA facility Institutional Review Board (IRB). Included patients were referred to a CPP for focused management of type 1 or type 2 DM by June 1, 2019. CPP practice encompassed all elements of comprehensive medication management authorized by the VA Pharmacy Benefits Management Clinical Scope of Practice Guidance.[19] CPP management of DM varied based on individual CPP practice

autonomy and use of primary literature and guideline-directed therapeutic interventions. Typically, these CPPs provided medication management, recommended dietary and lifestyle interventions, and applicable monitoring and education of DM. Additionally, CPPs managed associated comorbidities such as hypertension, heart failure, and dyslipidemia. CPPs at this facility practiced clinical independence regarding DM management with access to other healthcare professionals, including primary care physicians, mental health providers, and endocrinology specialists for consultation or referral, as needed.

Patients included in this review had a minimum of two face-to-face clinic visits with a CPP prior to December 1, 2019. Patients had to be subsequently transitioned to telehealth care between June 1 through December 1, 2020 with at least one CPP telehealth visit during that timeframe. Telehealth care was defined as either telephone (audio-only), VA Video Connect (VVC), or other secure form of synchronous audio-video visit (i.e. Doximity). Patients received DM-focused visits with a CPP only via telehealth during this timeframe as all in-person CPP DM clinics were closed in attempts to minimize the spread of COVID-19. Included patients also required one or more HbA1c readings during each review timeframe (06/01/2019-12/01/2019 and 06/01/2020-12/01/2020). Patients were excluded if they had been previously enrolled in telehealth DM management or if they were not receiving insulin prior to June 1, 2019. Patients not receiving insulin prior to the pandemic were excluded in order to avoid potential confounding created if administration education was delivered only via telehealth.

Evaluation of the primary outcome was conducted by defining change in average HbA1c as maintained, improved, or worsened. These categories were established as: a 0-1% change in average HbA1c considered “maintained” DM control; >1% increase in average HbA1c defined as “worsened” control; and >1% decrease in average HbA1c considered “improved” control. The 1% margins were defined by taking into consideration both potential HbA1c laboratory margin of error and clinically insignificant change in HbA1c which is defined in the literature as ≤0.5%.[25, 26] The VA/Department of

Defense (DoD) clinical practice guidelines reference that laboratory margin of error related to HbA1c readings may contain up to a 0.5% difference, which is considered an insignificant difference for margin of error.[27] Ultimately, allowing for a 1% discrepancy in HbA1c change took into account both the potential laboratory error (0.5%) as well as any insignificant change in HbA1c (≤0.5%).

Patients included in the primary outcome were subsequently reviewed for the defined secondary outcomes. Data pulled directly from the VA electronic medical record identified the following: age, residential zip code, diabetes diagnosis code, total number face-to-face CPP visits between June 1 through December 1, 2019, total number telephone CPP visits between June 1 through December 1, 2020, total number synchronous audio-video CPP visits between June 1 through December 1, 2020, average HbA1c during each timeframe (06/01/2019-12/01/2019 and 06/01/2020-12/01/2020), race, ethnicity, and metformin SA or immediate release (IR) prescriptions filled between June 1 through December 1, 2019 and June 1 through December 1, 2020. Distance traveled to VA facility was determined via GoogleMaps evaluation of patients' residential zip code and VA facility zip code. Rurality was determined by assessing the U.S. Department of Housing and Urban Development track and Rural-Urban Commuting Area (RUCA) code of each Veteran's residential zip code. All results were evaluated using descriptive analysis.

Results

Five hundred and twenty-two patients met inclusion criteria. Background and demographic data is summarized in **Table 1.** A majority of patients were between the ages of 65-74 years, with approximately 79% of patients categorized as elderly. Most patients identified as white (n=469, 89.8%) and non-Hispanic/Latino (98.9%), this was consistent with the distribution of race and ethnicity among WNCVAHCS Veterans. The distribution of type 1 and type 2 DM diagnoses was as expected for the patient population with a mere 16 patients (3%) who had type 1 DM. Prior to the implementation of

telehealth visits, over 52% of patients were traveling greater than 50 miles round-trip to receive face-to-face DM care. The majority of patients included in this analysis (76.6%) were traveling from rural locations before they were quickly converted to telehealth visits.

Results showed 72% of patients maintained DM control when transitioned to telehealth management during the COVID-19 pandemic **(Table 2).** An additional 12.2% of patients saw an improvement in HbA1c, while 15.7% experienced a >1% increase in HbA1c. The average number of face-to-face CPP visits during the 6-month timeframe in 2019 was similar to the average number of telehealth visits during the 6-months in 2020 (2.34 vs. 2.12, respectively). Further evaluation of the telehealth visits between June 1 through December 1, 2020 demonstrated a vast majority of telehealth visits were conducted via telephone compared to synchronous audio-video modalities (1.91 vs. 0.22, respectively). A small portion of patients were receiving metformin SA between June 1 through December 1, 2019 (n=82, 15.7%). Twenty-five of the 82 patients previously receiving metformin SA were successfully switched to metformin IR following the extensive drug recalls during the same time they were converted to telehealth care (06/01/2020-12/01/2020). As a result of the facility-wide decision to stop all metformin SA use, a total of 57 patients (10.9%) were taken off metformin entirely between June 1 through December 1, 2020. The loss of metformin SA was evenly distributed among primary outcome groups and did not appear to impact the results.

Discussion

The results of the primary objective were consistent with the original project hypothesis that most patients would maintain HbA1c control when converted to telehealth. Based on no change in CPP clinic availability between the two timeframes evaluated, it was expected that patients would maintain a similar quantity of follow-up visits during each 6-month timeframe. Given the small portion of patients

who required metformin discontinuation when visits were quickly switched to telehealth, the national drug recalls did not extensively impact type 2 DM care during that time.

Strengths of this project include a balanced population sample among the evaluation groups for the primary outcome which was indicative of the general population at the VA facility. The project was a cost-effective design: conducted as a quality assurance retrospective review which required no additional funding. The inclusion of potential confounders, including metformin SA drug recalls, was an additional strength of this project. Including drug recalls of metformin SA was particularly was important considering the 1-1.5% average HbA1c reduction that metformin can achieve.[20] Considering rurality and travel distance to VA clinic was important given the typically frequent follow-up visits for DM management and unique location of the facility in rural Western North Carolina. This highlights the potential time and cost savings for Veterans requiring transportation assistance and/or time off work to travel to and from clinic appointments.

The project investigators recognize the potential limitations of this project and results evaluation. The methods utilized to analyze the results were descriptive in nature and the project was unable to be powered for the primary endpoint based on consultation with a statistician. Results were not able to be further analyzed to distinguish the impact of telephone versus video visits on glycemic control due to the minimal number of video visits conducted during this timeframe. Since the first year of the pandemic, more patients have gained access to complete video visits, both with the assistance of VA-issued tablet devices and additional technology education and support from VA staff. The limitation of providing DM care and education via audio-only visits is noted and taken into consideration by excluding patients who had not received insulin administration education prior to the switch to telehealth.

In addition, inability to quantify many other potential confounders during the COVID-19 pandemic may have impacted results. Many patients living in rural settings experienced the following

inequities even before the COVID-19 pandemic with lack of nearby grocery stores containing nutritious, healthy, fresh foods, medical centers and healthcare clinics, fitness centers, and limited employment opportunities. These confounders were likely further impacted during the COVID-19 pandemic by food shortages, closing or limited access to gymnasium or other physical recreational facilities, lack of accurate evaluation of weight gain or loss during stay-at-home ordinances, and the psychological impact of the pandemic on mental health wellbeing. While the lack of evaluation for these factors may limit the results analysis, we feel the results nonetheless represent a strong indication towards the benefit of effectively managed DM provided by CPPs via telehealth. Most noteworthy is the large majority of rural Veterans, previously traveling extensive distances to receive timely DM follow-up care at WNCVAHCS, who maintained HbA1c after successfully converting to telehealth visits.

Conclusion

The rapidly implemented telehealth management of DM provided by CPPs resulted in maintained or improved HbA1c control in 84.2% of patients. This project included a large majority of rural patients (76%) who were reached because of CPP-provided telehealth care. We recognize that many of these rural Veterans face additional challenges to maintain glycemic control including minimal access to nearby nutritious food options, recreational facilities, employment opportunities, and medical centers. This project provides evidence to support the continued use of telehealth to reach a greater range of rural patients to effectively manage DM.

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Table 1: Background and Demographic Data (n=522)		
Age Distribution		
Age Group	*Total*	*Percent (%)*
< 65 years	110	21.0%
65-74 years	285	54.5%
≥ 75 years	128	24.5%
Race & Ethnicity		
Race	*Total*	*Percent (%)*
White	469	89.8%
Black/AA	40	7.7%
Native Hawaiian/other pacific islander	3	0.6%
American Indian/Alaska native	3	0.6%
Asian	2	0.4%
Declined/Unknown	5	1.0%
Ethnicity		
Not Hispanic/Latino	516	98.9%
Hispanic/Latino	4	0.8%
Unknown/declined	2	0.4%
Rurality		
Zip code determination	*Total*	*Percent (%)*
Rural zip code	400	76.6%
Urban zip code	122	23.4%
Distance Traveled to VA Facility Prior to Telehelath Implementation		
Round-trip distance traveled (miles)	*Total*	*Percent (%)*
≤ 10	39	7.5%
≤ 20	93	17.8%
≤ 50	249	47.7%
> 50	273	52.3%

Table 2: Primary and Secondary Outcomes (n=522)		
Change in Average HbA1c 6 Months Before and Average HbA1c 6 Months After the Impelementation of Telehealth (Primary Outcome)		
Change in Average HbA1c	*Total*	*Percent (%)*
0-1% change in HbA1c (maintained)	376	72.0%
>1% increase in HbA1c (worsened)	82	15.7%
>1% decrease in HbA1c (improved)	64	12.3%

Average Number of CPP Visits Before and After the Implementation of Telehealth		
Clinic Visit Modality	*Date(s)*	*Average number of visits*
Face-to-face	6/1/2019-12/1/2019	2.34
Telehealth total (telephone and video visits)	6/1/2020-12/1/2020	2.12
Telephone		1.91
Video		0.22

Patients Impacted by Metformin SA Drug Recalls and Facility-Wide Discontinuation		
Status of metformin prescribing:	*Total*	*Percent (%)*
Receiving metformin SA *(6/1/2019-12/1/2019)*	82	15.7%
Switched to metformin IR *(6/1/2020-12/1/2020)*	25	4.8%
Stopped metformin *(6/1/2020-12/1/2020)*	57	10.9%