

AHRQ Grant Final Progress Report

Title of Project:

A demonstration project: Assessing the significance and impact of utilizing a novel telemedicine application in the delivery of community based palliative care in a rural seriously ill population.

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Inclusive Dates of Project: 09/30/2019 – 09/29/2021

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Award Number: 5R21HS026565-02

Acknowledgment of Agency Support: This project was supported by grant number 5R21HS026565-02 from the Agency for Healthcare Research and Quality.

Structured Abstract

Purpose: The goal of this project was to evaluate the impact on patients and providers of integrating a virtual pharmacist into a telehealth model. The objective of the study was to test the feasibility, acceptability, and usability of a novel telemedicine application which incorporates a virtual pharmacist in the delivery of patient-centered palliative care in a rural population in Western North Carolina.

Scope: While community-based palliative care (CBPC) has been shown to improve patient outcomes in those with serious illnesses, access is limited for patients in rural areas. Polypharmacy and adverse effects of medications continue to be an issue for this seriously ill population. Telehealth is a potential solution to provide access to palliative care and pharmacy services.

Methods: A telemedicine application incorporating virtual pharmacy consultation was implemented for 31 CBPC patients. Pharmacists identified drug-drug interactions (DDIs) and made recommendations to clinicians. Questionnaires were used to assess participant perceptions and explore patient-reported outcomes (PROs). DDIs and recommendations were evaluated by overall characteristics and clinician response.

Results: Pharmacists identified 79 DDIs and made 80 clinical recommendations for 31 patients. 112 discrete drugs were involved in DDIs, and 51 drugs appeared in more than one interaction. Questionnaires demonstrated usability and acceptability of program components and modest improvements in exploratory PROs. Limitations included lack of comparison group, relatively small sample size, and susceptibility to self-report bias. This pilot demonstrates the capability of using a telehealth platform incorporating a virtual pharmacist to enhance care.

Key Words: telehealth, telemedicine, polypharmacy, palliative care, virtual pharmacist

Purpose

This project evaluates the impact on patients and providers of integrating a virtual pharmacist into a telehealth model. The purpose of this study was to test the feasibility, acceptability, and usability of a novel telemedicine application which incorporates a virtual pharmacist in the delivery of patient-centered palliative care in a rural population in Western North Carolina. This telemedicine application, Adapt, is powered by the TapCloud platform and is offered by DeltaCareRx, a well-known pharmacy service provider in the hospice industry. The Adapt/TapCloud platform includes the following components: 1) a virtual pharmacist; 2) remote patient monitoring (systems, medications, vital signs, photo uploads); 3) messaging between patients/caregivers and providers/pharmacists; 4) videoconferencing with patients, caregivers, family members, and/or providers/pharmacists; and 5) provider clinical dashboard monitoring.

The project has the following specific aims:

Specific Aim 1: Evaluate the feasibility, usability, and acceptability of a virtual pharmacist for providers and patients in a palliative care telemedicine model.

Specific Aim 2: Identify the common drug-drug interactions (DDIs) by a virtual pharmacist in a palliative care population.

Specific Aim 3: Evaluate recommendations by a virtual pharmacist for medication management in a palliative care population.

Specific Aim 4: Examine the effects of virtual pharmacy consultations on patient-reported outcomes.

Scope

Background

The rising prevalence of serious illness has significantly increased the need for palliative care. Community-based palliative care (CBPC) offers a specialized approach to meeting the physical, psychosocial, and spiritual needs of patients with serious illnesses by integrating interdisciplinary care across inpatient and outpatient care settings^{1,2}. Geographic barriers and the shortage of CBPC providers result in patients lacking access to CBPC, and providers struggle to deliver services to at-home patients, especially in rural areas^{3,4}. As a result, this leads to lower utilization of hospice care, slower response time from providers, inferior clinical outcomes, and reduced patient/family satisfaction compared to more urban service areas⁵. In addition to these challenges, patients suffering from serious illnesses are likely to be receiving multi-drug therapy (polypharmacy)^{6,7} that is associated with drug-drug interactions (DDIs) and adverse events⁸, adding to the patient's symptom burden and decreased quality of life (QOL)^{9,10}. The reported frequency of DDIs increases with the number

of medications prescribed; 38% with four medications to 82% with eight or more concomitant drugs¹¹. Adverse drug effects are the fifth leading cause of death in the US and the number of medications is the single greatest risk for adverse drug reactions¹². In the last year of life, it has been shown that the number of medications increase by 50% and that a reduction in medication usage leads to increased functional capacity and improved QOL^{13,14}. Incorporating a pharmacist into the palliative care team is an effective method to address the issue of polypharmacy in the serious illness population. Pharmacists have a unique knowledge base for optimizing patient care by reducing polypharmacy using patient education, multidisciplinary rounds, medication reconciliation, and deprescribing¹⁵. Specifically, for patients with serious illness, the addition of a pharmacist to a CBPC team has demonstrated improved medical management, decreased medical errors, improved symptom management, and enhanced patient and clinician knowledge^{16,17}.

Context

Telemedicine has grown dramatically over the last decade, especially in delivery of chronic care management, and has shown great promise in improving access to care in rural areas⁵. A home-based palliative care program utilizing videoconferencing demonstrated that patients receiving telemedicine had reduced hospitalizations and increased hospice utilization compared to usual care¹⁸. In addition, a recent study demonstrated that integration of remote monitoring of symptoms in patients with metastatic cancer was associated with increased survival compared to usual care¹⁹. There are few studies on telemedicine in palliative care, and further research is needed. Moreover, existing studies have not addressed the role of the pharmacist in caring for seriously ill patients using telemedicine. In 2016, Four Seasons Compassion for Life in Western North Carolina (WNC) initiated a pilot telemedicine project as part of a Centers for Medicare & Medicaid Services Healthcare Innovation (CMMI) award, using a remote patient monitoring (RPM) software application called TapCloud. TapCloud connects patients and providers outside the clinic setting and is designed to meet the needs of each patient via individualized care plan/reminders, check-ins, and symptom review. This application significantly enhanced the services that the CBPC team was able to provide in these rural areas and showed positive initial results in terms of patient adaptation and provider buy-in²⁰.

This study built on the pilot project and tested an enhanced telehealth intervention incorporating input and recommendations from a virtual pharmacist, offered by DeltaCare Rx, a well-known pharmacy service provider in the hospice industry with a longstanding relationship with Four Seasons. In addition to utilization of TapCloud, in this intervention a pharmacist assessed each patient's medication list, identified drug-drug interactions (DDIs) using a standard classification system, made recommendations to clinicians, and if desired, provided tele-counsel to providers or patients.

Settings of Care

This project was conducted in the rural counties in WNC where Four Seasons provides CBPC services. Most of these counties are HRSA-designated rural and medically underserved areas and the poverty rate in these counties has exceeded state and national average for the past ten years. The mountainous geography and climate make delivery of palliative care services to at-home patients in these areas challenging. Because of these factors the number of palliative care patients a provider can see in a day is limited.

Recruitment

All recruitment and study procedures were approved by an Institutional Review Board and followed Good Clinical Practice guidelines and adhered to HIPPA regulations. Patients in a home setting who were eligible to receive CBPC services were evaluated for participation in this study. CBPC providers were recruited from Four Seasons and were primarily responsible for recruiting and referring patients for study participation. Inclusion criteria for patients included: 1) One or more life-limiting illnesses (excluding dementia); 2) ≥ 18 years of age; 3) palliative performance score (PPS) ≥ 30 ; 4) lives at home in Four Seasons service area; and 5) home has wireless or 3G/4G capabilities. Informed consents were obtained prior to any data collection. Participant recruitment began early in the study, targeting an average enrollment rate of three participants per month toward a goal of 150 total patients over the two-year project period. However, enrollment was limited by the impact of the COVID-19 pandemic from early 2020.

Participants

There were 31 patient participants and 11 provider participants. Table 1 describes these participants. The average age of patients was 60, and almost three quarters were female. Nearly all patient participants identified as White and Non-Hispanic. Of the clinicians, nine were nurse practitioners and two physicians, and all except one were female.

Table 1. Characteristics of patient participants.

Characteristic	Patients (%), N=31 patients
<i>Age</i>	
18-39	4 (12.9)
40-61	14 (45.2)
62-83	10 (32.3)
≥84	3 (9.7)
<i>Gender</i>	
Female	22 (71.0)
Male	9 (29.0)
<i>Race/ethnicity</i>	
Non-Hispanic White	29 (93.5)
Non-Hispanic Black	1 (3.2)
Hispanic	0 (0.0)
Other	0 (0.0)
Unknown or not provided	1 (3.2)

Methods

Study Design

The design of this study is an implementation and quality project assessing the significance and impact of an enhanced telemedicine application incorporating a virtual pharmacist to enhance delivery of care in rural Western North Carolina and improve polypharmacy issues in this seriously ill population. The standard of care provided in our service area at the beginning of the study incorporated a basic level of telemedicine to include messaging and a comprehensive word cloud allowing for patients and caregivers to communicate messages and symptom burden to their provider/team. This model further enhances that service with a virtual pharmacist.

Data Sources/collection

Data sources included phone interviews, clinical records using structured forms, and Likert-type surveys.

The Telehealth Usability Questionnaire (TUQ)²¹ was completed via phone interview with patients who utilized the telehealth application. The TUQ is a comprehensive questionnaire that measures usability, acceptance, and satisfaction of a telehealth system including factors such as usefulness, ease of use and learnability, interface quality, interaction quality, reliability, and satisfaction and future use. Patients who had utilized the telehealth system completed this survey via telephone interview approximately four weeks after enrollment. Clinicians also completed an adapted version of the TUQ. If patients had consulted directly with the pharmacist, they were also asked to complete The Functional Assessment of Chronic

Illness Therapy – Satisfaction with Pharmacist (FACIT-SWiP) at four weeks after enrollment. This is a 7-question survey measuring patient satisfaction of collaboration and communication with the pharmacist, with total scores from 0-28. Higher scores indicate greater satisfaction. (Appendix). The Adapt Pharmacy Form was completed by the pharmacist after initial consultation and with subsequent drug recommendations. This form was reviewed by the clinicians with acceptance of changes documented as well as reasons for not accepting the recommendations. Patient anxiety and depression were measured using the PROMIS® - Emotional Distress – Anxiety and the PROMIS® - Emotional Distress – Depression short form 8a scales, completed via telephone or web-based platform upon enrollment in the study, again at four weeks after enrollment, and a third time at no more than 12 weeks or after two additional encounters with the palliative care team, excluding the pharmacist consult. Each of these scales measures its respective symptoms through 8 Likert-type questions, which are aggregated and converted into a T-score through a standardized process. The T-score is then used to grade the severity of the symptom. Scores of at least 70 indicate severe symptoms, while scores within 60.0 and 69.9 indicate moderate symptoms.

Interventions

The intervention utilized the Adapt platform, powered by the TapCloud application and offered by DeltaCareRx. During an initial comprehensive visit by a CBPC team member, enrolled patients were set up on TapCloud/Adapt and were instructed in its use. Patient personal devices were used for this project; no devices were provided by Four Seasons due to COVID safety concerns. The study team notified DeltaCareRx via the Adapt interface that a patient was enrolled in the study. The pharmacist at DeltaCareRx reviewed the patient's medications and provided recommendations to the provider via secure forms and messaging within the application. The provider was able to discuss recommendations with the pharmacist prior to implementing or recommending medication adjustment or changes with the patient. The provider then met with the patient either in-person or via telehealth within 2-4 weeks and offered the patient an initial consult with the pharmacist (via phone or videoconference) where the pharmacist could provide education, review DDIs, and provide medication recommendations. All interactions were tracked on the Adapt Pharmacy Form. Throughout the project both CBPC providers and patients had the ability to consult with the virtual pharmacist via the teleconferencing platform regarding symptom- and medication-management. Providers were able to log in to the application via smartphone, tablet, or laptop to view and monitor the clinical dashboard. If medication issues or symptoms were identified, the provider could send secure messages via the application to the patient/caregiver to remedy the situation. If unsuccessful, telephone calls or videoconferencing were used to further resolve the issue, and, if needed, a home visit occurred. The pharmacist was also able to follow the patient symptom profiles in the EMR

and clinical dashboard as well, which was especially important after medication changes to look for any adverse effects.

Measures

To evaluate feasibility and usability of the telemedicine application incorporating a virtual pharmacist, this study measured the number of DDIs identified in the patient sample and quantified the most commonly involved drugs. Recommendations to clinicians from pharmacists were summarized using descriptive analysis and clinician actions in response to recommendations were tabulated in several discrete categories. Recommendations and clinical actions were also described qualitatively to contextualize the quantitative data and evaluate project outcomes. In addition, usability and acceptability of the program were measured using the overall composite score of the TUQ and the total score of the FACIT-SWiP instrument. The TUQ was administered to both clinicians and patients after interaction with the telehealth application and the FACIT-SWiP was completed by patients who had a personal interaction with the pharmacist via video or phone. Patient-reported outcomes (PROs) included the symptoms of anxiety and depression, measured by comparison of T-Scores of the PROMIS® surveys upon study enrollment with scores after 12 weeks.

Data were tabulated in Microsoft Excel®. Inspection of questionnaires repeated at 4 weeks and 12 weeks after enrollment revealed minimal change over time. Therefore, the questionnaires performed nearest the end of the study period were used in analysis.

Limitations

- Lack of comparison group, relatively small sample, susceptibility to self-report bias. Possibly variations in clinical process/COVID-19 restrictions and limitations

Small sample size. One limitation of this study is that the sample size was small. Enrollment began early in the project, targeting an average rate of three patients per month toward our goal of 150 total patients over the two-year project period. However, the study finished with fewer than a third the target number of patients, or a total of 31 patients. A major contributor to this is the significant impact of the COVID-19 pandemic on recruitment efforts since early 2020. Patients were fearful of staff entering their homes due to potential viral spread, and referrals decreased as primary care providers closed their offices and shifted to telehealth services. As an organization, much of Four Seasons' focus in the first months of the pandemic was in creating and implementing policies and systems of support for our patients, families, and staff, as well as in safely caring for COVID-positive patients. This meant staff moved to working from home and visits with community-based patients moved to telehealth throughout our service area. As a result, project staff relied on telephone and videoconferencing for recruiting patients, evaluating suitability for enrollment, completing consent forms electronically, setting up and troubleshooting technology (telehealth app),

following up on recommendations, and completing assessment tools. Initially, recruiting efforts were focused on the most rural and isolated counties of our service area. However, to increase enrollment and because Four Seasons moved to telehealth service provision throughout the entire WNC service region, the geographic footprint for this study was expanded beyond the most rural areas. While this did help somewhat to recruit more patients, we found that as the pandemic continued to worsen, patients were more reluctant to participate in clinical trials.

Results

Principal Findings and Outcomes

Specific Aim 1 – Evaluate the feasibility, usability, and acceptability of a virtual pharmacist for providers and patients in a palliative care telemedicine model.

Average total scores for the Telehealth Usability Questionnaire (TUQ) and the FACIT – Satisfaction With Pharmacist (FACIT-SWiP) are reported in Table 2. The majority of patients preferred limited utilization of the telehealth application and chose not to consult directly with the pharmacist, limiting the sample of patients who were able to complete acceptability questionnaires. However, completed questionnaires revealed high satisfaction among those who utilized these services extensively.

On the TUQ, patients reported an average composite score of 6.3 out of a possible 7 total points, with higher scores indicating higher overall satisfaction with the interface. Clinicians scored the application similarly. Those patients who completed the FACIT-SWiP reported an average score of 22.4 out of 28, indicating satisfaction with their consulting pharmacist.

Table 2. Acceptability Questionnaires.	
<i>TUQ</i>	<i>Average total score, n=10 patients and n=11clinicians</i>
Patient-reported	6.3
Clinician-reported	6.1
<i>FACIT-SWiP</i>	<i>Average total score, n=4 patients</i>
Patient-reported	22.4

Specific Aim 2 - Identify the common drug-drug interactions (DDIs) by a virtual pharmacist in a palliative care population.

Table 3 shows the ten drugs that appeared most often in DDIs. The most common was Gabapentin, appearing nine times. While 112 discrete drugs were involved in the 79 DDIs, 51 drugs (45.5%) appeared in more than one interaction. Including multiple appearances by the same drug, the total number of interacting drugs across all DDIs was 235. Several of the most common drugs were opioid analgesics.

Table 3. Top 10 most common drugs involved in DDIs.

<i>Drug</i>	<i>Number times drug appeared in a DDI (%), N=235 interacting drugs.</i>
Gabapentin	9 (3.8)
Clonidine	8 (3.4)
Oxycodone	8 (3.4)
Nortriptyline	6 (2.6)
Sertraline	6 (2.6)
Tramadol	6 (2.6)
Clonazepam	5 (2.1)
Prochlorperazine	5 (2.1)
Morphine	5 (2.1)
Methadone	5 (2.1)
Cyclobenzaprine	4 (1.7)

There were 112 discrete drugs involved in 79 interactions across 31 patients. Counting multiple appearances by the same drug, there were a total of 235 interacting drugs

Specific Aim 3 – Evaluate recommendations by a virtual pharmacist for medication management in a palliative care population.

A total of 79 DDIs were identified from 31 patients. The median number of DDIs per patient was three. While some patients had as few as zero or as many as eight DDIs identified, almost all patients had 5 or fewer. 33% of interactions were classified as “Major” (equivalent to Severe) in the Lexicomp Grading System. Table 4 describes the distribution of DDIs per patient identified by pharmacists in the study and the Lexicomp gradings associated with each interaction. DDIs most often involved 2-3 drugs, but occasionally involved as many as 8 or 9.

Table 4. Summary of DDIs identified by pharmacists.	
Total	79 DDIs
<i>Per patient, N=31 patients</i>	
Mean	2.6
Median	3
Range	(0,8)
Interquartile Range	3
<i>DDIs Identified</i>	<i>Patients (%), N=31 patients</i>
0-1	9 (29.0)
2-3	12 (38.7)
4-5	9 (29.0)
6-8	1 (3.2)
<i>Lexicomp Risk Rating</i>	<i>DDIs (%), N=79 DDIs</i>
C – Monitor Therapy	34 (43.0)
X – Avoid Combination	12 (15.2)
D – Consider Therapy Modification	33 (41.8)
<i>Lexicomp Severity</i>	
Major (Severe)	26 (32.9)
Moderate	46 (58.2)
Minor	47 (8.9)
<i>Lexicomp Onset</i>	
Delayed	27 (34.2)
Immediate	40 (50.6)
Rapid	11 (13.9)
Unavailable	1 (1.3)

Each clinical recommendation from the pharmacist was based on an identified DDI. Therefore, the distribution of recommendations per patient was almost the same as that of DDIs per patient, although one patient had an extra recommendation resulting from consultation between the clinician and pharmacist. Table 5 summarizes the distribution of recommendations.

Table 5. Summary of clinical recommendations.

Total	80 Recommendations
<i>Per patient, N = 31 patients</i>	
Mean	2.6
Median	3
Range	(0,8)
Interquartile Range	3
<i>Recommendations Made</i>	<i>Patients (%), N=31 patients</i>
0-1	9 (29.0)
2-3	11 (35.5)
4-5	10 (32.3)
6-8	1 (3.2)

Recommendations were provided in narrative form, incorporating the associated medication interactions identified along with the pharmacist’s suggestions and observations of potential adverse effects. Because interactions were often complex with multiple involved drugs, recommendations tended to be detailed and highly individualized. In general, most recommendations alerted the provider to the risk of certain adverse effects and suggested monitoring and evaluation for potential regimen changes if applicable. Occasionally, stronger recommendations were offered to discontinue or alter dosage when warranted. An example of a recommendation is given in Figure 1.

Figure 1. Example Recommendation.

Monitor for additive CNS depressant effects whenever two or more CNS depressants are concomitantly used. Consider reassessing the need for Zaleplon with Belsomra, and Amitriptyline all dosed at bedtime. Reassess the root cause of patient's insomnia and confirm correct type of sleep aid is being utilized based on patient's type of insomnia.

Clinician actions in response to recommendations were grouped into three categories: 1) *Implemented or planning to implement*; 2) *Monitoring or evaluating with patient*; 3) *No plan to implement or monitor*. Table 6 summarizes clinician actions. Monitoring or evaluating with the patient and implementing the recommendation accounted for a majority of clinician responses. About 20 percent of recommendations were not implemented during the study period, usually due to additional clinical considerations, such as other healthcare providers prescribing the medications of interest. For most patients (about 64 percent), clinicians planned to implement at least one recommendation.

Table 6. Clinician actions in response to recommendations.

<i>Action</i>	<i>Number of Recommendations (%), N = 81</i>
Implemented or planning to implement	28 (34.6)
Monitoring or evaluating with patient	37 (45.7)
No plan to implement or monitor	16 (19.8)
<i>Implemented or planning to implement</i>	<i>Patients (%), N=31 patients</i>
0	9 (36.0)
≥1	16 (64.0)
1	6 (24.0)
2	8 (32.0)
3	2 (8.0)
<i>Monitoring or evaluating with patient</i>	
0	8 (32.0)
≥1	17 (68.0)
1	4 (16.0)
2	7 (28.0)
3	5 (20.0)
4	1 (4.0)
<i>No plan to implement or monitor</i>	
0	15 (60.0)
≥1	10 (40.0)
1	4 (16.0)
2	6 (24.0)

Depending upon the characteristics of each recommendation, providers implemented suggestions in multiple different ways. Some of these included increasing or decreasing medication dosages, separating timing of administration, or in cases of supplements or medications prescribed by other healthcare providers, recommending alternatives or informing patients of potential risks. Occasionally clinicians relayed results of the program to other providers. In some cases of monitoring, the clinician did not make a change during the study period but planned to reassess with the patient or family during future care.

Specific Aim 4 – Examine the effects of virtual pharmacy consultations on patient-reported outcomes.

Table 7 summarizes the average scores on patient reported outcomes at baseline and end-of-study (12 weeks). For both the PROMIS® Anxiety and PROMIS® Depression scales, T-scores in the range of 60.0–69.9 indicate moderate symptoms. Although patients remained in this range over the course of the study, there were slight average decreases in both symptom scales.

Table 7. Patient Reported Outcomes.

	<i>Average T-score, N=31 patients</i>
<i>PROMIS Anxiety</i>	
Baseline	63.7
End-of-Study	61.2
Change	-2.5
<i>PROMIS Depression</i>	<i>Average T-score, N=31 patients</i>
Baseline	66.4
End-of-Study	63.8
Change	-2.6

Discussion

This study demonstrates the impact of including a pharmacist as a part of the palliative care team. In general, clinicians may not be aware of adverse drug reactions or DDIs. Pharmacists are skilled in evidence-based pharmacotherapy and by using the Lexicomp Drug Interactions database can aid clinicians by alerting them to potential adverse drug effects. Palliative care patients frequently have multiple comorbidities and are prescribed numerous medications, adding to issues of polypharmacy. Polypharmacy increases the risk of drug interactions leading to an increase in morbidity and mortality. In addition, deprescribing rarely occurs as patients are often told they need medications for their lifetime. Patients with serious illnesses often experience cachexia, with loss of both adipose tissue and muscle mass. As a result, intake, absorption, and bioavailability of drugs may change due to altered protein binding, fat storage, and volumes of distribution. Hepatic and renal dysfunction may impact the metabolism and excretion of drugs, leading to higher number of DDIs. Delirium has been reported to be a common DDI in palliative care patients²². Reducing DDIs can lead to enhanced quality of life by reducing side effects of drug interactions.

While the enrollment was less than anticipated due to factors related to the COVID pandemic, in those patients who enrolled, DDIs were a common finding, with 91.1% considered either moderate or severe. Approximately 2/3rds of the time, clinicians implemented the recommendations; these usually involved dosing changes, timing of medication changes, adding or deprescribing a medication. One of our main objectives was to determine the feasibility, usability, and acceptability of using a clinical pharmacist via a telehealth platform to help improve care related to medications and adverse effects. This study demonstrated that both patients and clinicians highly rated the use of the telehealth platform and those patients who used the opportunity of speaking to a pharmacist highly rated their satisfaction. In terms of measuring outcomes related to anxiety and depression, the results signal a slight improvement of these symptoms from the start to the end of the study. This is the first study we are aware of that uses a telehealth application including a remote pharmacist to review medications for palliative care patients and make recommendations to clinicians to avoid DDIs and adverse drug reactions.

Conclusion

While most community based palliative care programs do not employ or have access to a pharmacist, this small pilot demonstrates the ability to remotely use a pharmacist via a telehealth platform to enhance care and potentially decrease adverse effects from DDIs and medication recommendations.

Significance

DDIs account for a major cause of increased morbidity and mortality in the seriously ill population. The involvement of a pharmacist via a telehealth application could potentially lead to better health outcomes for these individuals.

Limitations

A larger sample size including a more diverse population will be needed to validate the findings of our pilot study. Enrollment was significantly impacted by the COVID-19 pandemic as patients were reluctant to have study personnel in their home setting as their focus was primarily around maintaining a safe home environment and limiting viral spread.

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