Medication Dispensing System to Support Medication Adherence for Individuals Living at Home with Chronic Conditions: A Randomized Controlled Trial

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Background

Age-related innovations provide an enormous opportunity to enhance the quality of life for Alberta seniors. It is estimated by 2045, one in five Albertans will be 65 or older.[1] Research areas related to independent living and enhanced care in communities and homes should set the strategic approach toward care and support of older adults as a priority.[1] Firstly, Community Care enhances seniors' comfort, convenience, and overall experience while increasing their independence and quality of life.[2] Secondly, Community Care eases demand on hospitals and promotes the financial sustainability of Alberta's healthcare system as the cost of care lowers in healthcare facilities.[1,3] Thirdly, improved care in the community allows for acute care services to be more accessible for Albertans who truly need the right care at the right place by the right care provider. [1] The Provinces of Ontario and British Columbia have taken the initiative to introduce this approach with its 'Home First' and 'Better at Home' programs, respectively.[4,5] Similarly, the Government of Alberta has invested $200 million in community healthcare, allowing more Albertans to remain independent and receive care in their homes.[6]

Medication compliance in the senior population is a significant challenge for optimizing patient outcomes.[7,8] Therapeutic management of multiple chronic diseases can only be realized when the individual is adherent to their prescribed pharmacological regimen.[9] When left untreated, many chronic conditions can lead to complications including heart attacks, stroke, kidney failure, and diabetic reaction, among others that decrease patients' quality of life and increase their risk of death.[10] For example, complications due to the lack of adherence to hypertensive, hyperlipidemia, and diabetes medication regimens result in substantial morbidity, mortality, and disability. [9]

This has significant implications when nearly 69% of medication-related hospitalizations are attributed to non-adherence and the estimated cost to the Canadian healthcare system is $7-$9 billion.[11] The ability for current hospital infrastructures to accommodate these preventable acute care admissions – both from the financial perspective and, more importantly, quality-of-care perspective – is unsustainable in the long run.[12] As such, a system-level change is occurring with more emphasis on care in the home setting. Despite the overwhelming awareness of the benefits associated with medication adherence, 50% of Canadians with chronic diseases are non-adherent to their medications.[13]

Adherence is defined as "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes"— corresponds with agreed recommendations from a healthcare provider.[14] The World Health Organization (WHO) defines adherent patients as those who take 80% of their medications prescribed for a period of time.[9] Multiple factors contribute to poor medication adherence. For example, taking several medications within a treatment regimen, increased frequency of medication intake, and a prolonged course of drug therapy contribute to decreased medication adherence.[9] Almost two-thirds of those aged 65 and older take five or more prescription drugs, thus increasing the risk of adherence issues.[15]

The spencer medication dispensing system is a new integrated technology that improves medication compliance. This innovative device offers independence to senior patients at home while providing real-time pharmacist and caregiver support.[16] The spencer system improves

patient medication compliance and experience. In addition, it allows for data collection of patient self-reported outcomes, enabling better understanding and solution for maintaining high quality care for seniors in the community setting.[16] Alberta Health Services (AHS) is committed to strengthening community care by adopting age-related innovations and implementing it at a larger scale.[1] Patients using spencer are connected to a spencer certified clinical pharmacist and family caregivers (as appropriate). The system allows us to track the number of interventions initiated by the pharmacist in response to clinical engagement questions and medication adherence reports.

Technology Partner Profile

Catalyst Healthcare is a technology company based in Kelowna, British Columbia (BC). It is dedicated to improving medication adherence and reducing the costs associated with non-adherence to health systems. Catalyst works diligently with its network pharmacy members on data-driven collaboration with the care team, who offers timely clinical interventions to improve patient outcomes and support independence in the home care setting. Catalyst provides a pharmacy model that greatly impacts healthcare delivery. Through its medication adherence ecosystem, a suite of connected technologies that gather, share, and correlate data in real-time, pharmacists can better serve their patients and play a key role in improving population health.

Catalyst initially started as a pharmacy services provider to seniors in BC. [17] For over 10 years, Catalyst's patented AdhereNet platform has been linking real-time pharmacy data from pharmacy management software and packaging automation to support safe administration with its oneMAR electronic medication administration record in long-term care. Today, that same technology platform is being used to connect pharmacy and care teams with patients and their loved ones to improve care for seniors at home. [17] The platform helps to improve medication adherence and allows pharmacies to monitor, intervene and track outcomes. [17] Catalyst works with leading healthcare companies and pharmacies which can be a valuable resource for successful implementation and completion of the study.

Description of spencer System

Catalyst has launched an integrated at-home medication dispenser called spencer. [16] Spencer is a natural extension that plugs into Catalyst's AdhereNet platform, connecting high-risk patients in home care setting to a multi-disciplinary care team in real-time. It allows the team to monitor medication adherence and ask active engagement questions to obtain patient-reported outcomes. As well, the system is able to link readings from Bluetooth enabled devices and offer telehealth capabilities with an embedded camera. [17, 18]

AdhereNet manages medications to the pill-level, informing automation to package patient-specific multi-dose strip pouches that are bar-coded for tracking and monitoring.[18] Fully automated central fills provide patient-ready spencer refills to pharmacies; or, pharmacies use their own automated medication packagers to produce spencer refills which are then delivered to the patient at home on short cycles of one to two weeks.[16, 18] The spencer solution aims to optimize medication adherence by dispensing medications on time with reminder alerts while

tracking medications and changes to symptoms experienced by patients.[16] Additionally, the device captures clinically relevant outcomes data crucial for the care team's insight into the patients' well-being. Utilization of spencer involves three steps: (a) placing the device at home in the desired location (b) loading a medication refill prepared by spencer-certified pharmacists and delivered to the patient at home, and (c) engaging with the care team through embedded interactive features. [16, 17]

AHS Priorities

AHS is committed to investing and enhancing care in the community. The aim is to shift from providing care in hospitals to more community-based care that is closer to home. The collaboration of the healthcare system, communities and healthcare technology partners is required to provide linkage and ensure patients are retaining independence as they age.

AHS is constantly searching for innovative ways to better quality of life and improve patient outcomes or experience. [1] The 2015 – 2020 AHS Strategy for Clinical Health Research, Innovation and Analytics attempts to identify gaps in healthcare; by building strong partnerships with technology leaders, research and innovation will offer significant benefits to patients and the health system. [19, 20] Age-related innovations for seniors are critical components of enhancing care in the community.

The department of Health Systems Evaluation & Evidence (HSEE) at AHS is working in collaboration with Catalyst Healthcare to evaluate the benefits of spencer. The study is funded by the Centre for Aging and Brian Health Innovation (CABHI) through their Industry Innovation Partnership Program (I^2P^2). CABHI is a government-funded program focused on improving senior's health through innovation themes of Aging in Place, Caregiver Support, Care Coordination and Navigation, and Cognitive Health. Catalyst Healthcare was awarded the grant as the spencer system addresses CABHI innovation themes and AHS priority areas.

Primary Research Question

1. *Does the spencer system improve medication adherence in individuals 50 years or older living in the community, taking five plus medications?*

Secondary Qualitative Research Questions

2. *Do healthcare providers require less need for medication management home visits with the use of the spencer system?*

3. *Does the spencer system reduce family caregiver burden related to medication management?*

Aims and Objectives of this Study

The objective of the proposed study is to evaluate how the use of medication dispensing system improves medication compliance in the senior population. In particular, the study will focus on the following objectives:

- Identify changes in adherence to medication regimens and self-reported outcomes for seniors using spencer versus other medication management methods
- Describe the patients' experience with spencer and collect informative data
- Evaluate the perceived benefits of spencer system on patient independence and support self-management of multiple comorbidities
- Assess caregiver burden, attitude, and experience with spencer

Methodological Approach

Study Design

This Randomized Controlled Trial (RCT) with the spencer system will be conducted in Calgary, Alberta. The data will be collected over a six-month period, beginning in May 2019 and will continue until October 2019. This is a proof of concept study for which no formal sample size calculation is required. [21] A total of 100 study participants will be recruited in the study (50 in the intervention group and 50 in the control group). Participants will be randomly assigned to either the intervention group or the control group. The intervention group participants will be using spencer and the control group will continue to use their medication management method such as blister packs, pill organizers, and plastic prescription vials.

We will be using block randomization and assign the participants into the intervention or control group as soon as they enroll in the study. Block randomization is the recommended method for sample sizes of 50 or less in each group. It is used to balance the groups in terms of the number of subjects they contain and in the distribution of potential confounding variables. The study is not blinded so the blocks will vary in sizes (10, 12, 14) to reduce the predictability of the intervention assignment. A project assistant (a contracted staff who will not be involved in data collection or analysis activities) will produce computer-generated sets of random allocations in advance of the study and seal them in consecutively numbered opaque envelopes. Once the patient has given consent to be included in the study, he/she will then be irreversibly randomized into the groups through opening the next sealed envelope containing his/her assignment.

This study design will enable us to capture patient, caregiver, and staff experiences and perceptions about spencer and allow us to evaluate the effectiveness, feasibility and sustainability of the medication dispensing system.

Prior to the recruitment of patients and deploying the spencer system, ethics approval will be sought from the Human Research Ethics Board at the University of Alberta.

Setting and Population

The Healthcare providers from d East Calgary Health Center (ECHC) will help with recruiting seniors living in the community, who are currently having medication adherence issues. These

individuals have one or more chronic conditions, depend heavily on home care services, but still live independently in the community. The research team believes aging is a subjective experience and depends on multiple factors, such as the onset of certain comorbidity and individuals' lifestyle. In order to increase our pool of potential participants and still include complex patients with higher needs, we will be including individuals aged 50 and older. Further, the spencer system is designed as a medication reminder and management support system for patients on multiple medication regimens. Most of the literature defines polypharmacy as a numeric definition of five or more medications daily.[22] The age 50 and older group with one or more chronic condition and regularly taking 5 plus medications will help determine observable benefits of utilizing the spencer system compared to other methods.

Participants will be deployed in the Calgary area. The ECHC has clientele of about 5500 patients and out of those, 725 are aged 50 years or older and taking 5 plus medications. For the 6-month duration of the study, recruiting a sample of 100 patients seems feasible. This will help to validate the technology and develop a sustainable model for improving medication adherence that will support patient self-management in a home care setting.

Inclusion Criteria:

- English speaking or have access to a translator for interpretation
- Age 50+
- Have been diagnosed with one or more chronic conditions
- Currently taking five or more prescription medications
- Be a resident of the city of Calgary

Exclusion Criteria:

- Individuals with moderate to severe cognitive impairment

The enrolled participants will provide the informed consent. As we are only including participants with no or mild cognitive impairment, the participants needed to be deemed fit to provide consent. We will be including patients with Cognitive Performance Scale (CPS) of zero, one and two with description of intact, borderline intact and mild impairment, respectively. The higher score indicates a greater degree of cognitive impairment. Hence, the research team anticipates to include patients with CPS score of 0-2 and equivalent average Mini Mental State Examination (MMSE) score of 19 or higher. This will correspond to cognitive skills for daily decision making of 0 and 1 for participants being independent or have modified independence status. A score of 2 for cognitive skills for daily decision making corresponds to minimally impaired function and these patients might require supervision and the spencer use might not be the right fit for them. Therefore, individuals with more moderate impairment would likely be unable to engage with spencer safely. The healthcare provider will determine if the participant is cognitively fit to provide consent and suitable for the spencer device.

Recruitment Strategy

The Family Care Clinic at ECHC will compile a list of potential patients and will be mailing invitation letters. The invitation letter will explicitly mention that the letters are send on behalf of the study team and no identifying information has been released. The interested participants will be required to directly contact the research team. Research staff will connect with potentially interested participants for study enrollment.

For patients with scheduled appointments and visiting their healthcare on regular basis (both ECHC and Home), the healthcare provider will inform the patient about the study using the script. The healthcare providers will determine the eligibility of each patient, based on the inclusion criteria. The provider will refer potential participants to the research staff. A member of the research team will explain the study and provide relevant information, and address any questions. If the participant is interested, the research staff will obtain written consent. If the participant needs more time to decide, research staff will hand-over the study information letter and obtain contact information for the follow-up, if permitted by the patient. Research staff will contact potential participants to determine if they are still interested.

Pharmacy Site

Sandstone Pharmacies operating under APEX pharmacies Ltd. has multiple locations in Calgary. Their Enhanced Care Solutions site has spencer certified pharmacists using the Catalyst AdhereNet platform. Sandstone is committed to supporting the study. Sandstone Pharmacies will deliver the spencer unit and medications refills to patient's home within the Calgary Area. Through study recruitment and randomization, the Sandstone Pharmacies will have a total of 50 participants in the intervention group who will receive a spencer system. For the duration of the study, the intervention group participants will be asked to change their current pharmacy to Sandstone. The 50 participants in the control group will continue using their current method of medication management and will not be required to change their current pharmacy. However, the research team will monitor the control group for medication management over a 6-month period.

Technology Intervention

The spencer system comprises interactive tools to optimize medication adherence and clinical outcomes. The device dispenses the patient's medications on time with reminders by sending visual and audio alerts. The sound of the audio alerts gets louder if the medication pouch is not removed from the device by the patient. Patients have a two-hour window to remove the medication pouch. If not removed, patients are considered non-adherent for that particular time frame. Spencer allows individuals to dispense their medication early if away from home. Medication adherence is tracked through spencer care platform. The medication adherence is based on an assumption that medication was administered by a patient once the pouch was removed from the device.

Also, spencer uses a multi-disciplinary approach of care team members including pharmacists, caregivers, and a spencer medication adherence platform to provide healthcare in the homes of the high-risk, chronically-ill population. The device supports a personalized plan that tracks medication adherence and response to therapy. Spencer displays personalized and condition-specific questions to meet the individual goals of patients. Patients can respond to disease-specific questions in spencer. Clinicians and spencer certified pharmacists have the ability to review patient responses remotely and determine the need for reassessment, medication reconciliation, and clinical intervention as appropriate. Spencer permits intervention remotely through telehealth capabilities and consultation. Patients receive an appointment time directly from spencer that rings at a designated time and a call is initiated when the patient answers with the touch of a screen. Daily tracking of both medication adherence and response to relevant clinical engagement questions will be conducted via the spencer platform. There will be no routine video interactions required for data collection purposes. Pharmacists will be monitoring patient adherence and determine a need to intervene based on the responses to personalized questions through spencer.

Through the connected devices, spencer ensures that everyone in the circle of care can participate in the well-being of the patient. Spencer Assist is a mobile app that allows caregivers and family members to support patients at home. Medication adherence data is also accessible to the healthcare team. The pharmacist, healthcare provider and caregiver are now electronically connected to patients and can access data regarding deviations in adherence in real time. This connectivity allows for earlier intervention to provide the support needed for improved healthcare outcomes.

The spencer system empowers patients to manage their treatment regimen and schedule from the comfort of their own home. The spencer system addresses key priority areas related to aging in place, independence, caregiver support, and care coordination with the care team and caregivers.

Spencer systems are non-inclusive and approved by Health Canada. We will be aggregating the data for research purposes and will not release participant-specific data. Also, since this research falls under the auspices of AHS, all data collection, management, and storage processes will fully comply with the Health Information Act and the Freedom of Information and Protection of Privacy Act.

Outcomes

Primary outcome: The study will look at patient-focused outcomes and seek to understand the influence of the medication dispensing system on medication adherence; specifically, increased patient medication adherence in the intervention group as a result of spencer utilization. In the intervention group, the medication adherence data will be retrieved from the Catalyst spencer medication adherence platform. In the control group, the medication adherence will be self-

reported and participants will be required to maintain monthly medication logs. We will complete a self-reported adherence questionnaire in both groups (intervention and control) at baseline assessment and every month for comparison purposes. This way, we can tackle the challenge of overestimation in self-reported medication adherence by comparing the difference between the two groups with the adherence data for spencer participants only.

Catalyst Healthcare defines adherence percentage as actual pill(s) dispensed from the spencer at the prescribed time, within a two hour time window. Average medication adherence will be calculated by an average of all "pill level" adherence numbers. For example, if all pills were taken within the window, the adherence number would only contain 100 values. Alternately, if no pills were taken within the window, the adherence number would contain only zero values. Adherence number for a patient within the time range divided by the total number of pills will provide the average medication adherence percentage.

Data Collection

The study will use a mixed methods evaluation approach, employing both quantitative and qualitative methods.

Quantitative Data Collection

Data sources and variables: We will obtain information from multiple sources. Participants health status and characteristics will be obtained through baseline assessment upon enrollment. The monthly follow-up will collect data relating to medication adherence and any changes in health status or healthcare needs. Adherence data for spencer-users will be collected from Catalyst technology platform. In the control group, adherence will be measured through pharmacy medication data and monthly medication logs completed by patients.

Qualitative Data Collection and Analysis

The quantitative outcomes data will be complemented by qualitative interviews to provide a holistic picture and evaluate the perceived benefits of the spencer system from the patient, healthcare provider, and caregiver perspective. This data will be essential to understanding the full potential of spencer. We will conduct qualitative interviews with 1) patients at the start and end of the study 2) health provider at the end of the study 3) caregiver at the start and end of the study. For each round of interviews, we aim to interview up to 20 patients (intervention group only), 10 healthcare providers (case managers, physicians, healthcare aide workers, and pharmacists) and 10 caregivers. Interviews with seniors using spencer are conducted to explore their sense of independence and level of engagement with the interdisciplinary healthcare team, as well as benefits and improved health outcomes. Interviews with healthcare providers will be conducted to determine whether the use of spencer helped in reducing workload for medication management. Interviews with caregivers will be conducted to explore potential decrease in caregiver burden.

***Baseline*:** Interview question with patients will obtain their current health status and probe for perceptions of current care processes and challenges for medication management and quality of care from home care services; these interviews will be conducted with members of the intervention group. Moreover, the intervention group will be asked about readiness for technology adoption and how they perceive care may be affected by spencer. The self-reported perceived benefits before and after the study could provide detailed insight for implementation of spencer.

Follow-up: We will interview members from the intervention group again at the end of the 6-month study period to probe for whether the integrated spencer system has improved patient adherence, independence, and self-management of medication for enhanced quality and safety of care. For the caregiver, we are interested to see if they report some level of decreased worry/stress/responsibility with regards to managing family member's medication with the use of spencer. For the healthcare providers, we want to know if spencer helps with a decreased need for human resources related to medication assistance program. We will also explore any increase in capacity of healthcare providers resulted in the reassignment of healthcare aides to other care support activities.

Interview Data Analysis: A thematic analysis is typical for qualitative data for which common topics are generated while also recognizing the uniqueness of the data. Themes emerging from the data will be explored and recurring patterns will be identified through coding, categorizing, and conceptualizing.[23] A final round of analysis, comparing themes from all data sources, will be completed once all data have been collected. All interview transcripts will be imported into NVivo12 software program to facilitate qualitative data management and analysis, enabling full exploration of elements and linkage between components.

Deliverables

1. A final report describing the potential benefits of the spencer system when utilized by seniors taking multiple prescription medications. The report will assess and evaluate the difference in medication compliance and self-reported outcomes among two groups (intervention and controlled group) in the urban setting for the Calgary zone. The patient experience will help to formulate recommended processes for spencer effectiveness and up-scaling of the intervention.

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