

Evaluating the Usability of a Medication Organizing Tool on Home
Medication Management - A Proof-of-Concept Experiment

by
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Author's Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Background: Chronic disease and medication self-management is a life-long process in which patient self-efficacy plays an important role in determining success. Efforts to improve self-management have traditionally focused on enhancing self-efficacy through medication and disease education, development of problem solving skills and decision making. These approaches have been proven to have moderate short-term benefits on clinical outcomes while evidence on long-term, post-intervention benefits is less convincing. In this project, we were interested in evaluating if patients would find a newly developed medication organizing tool (a.k.a. the MedManager) helpful to their medication and disease self-management processes. *Methods:* We conducted a proof-of-concept experiment where participants were introduced to the MedManager. A follow-up session was then conducted during which utilization of the MedManager was observed. Also during the follow-up session and using a semi-structured interview format, we explored participant's perceived barriers in areas of medication therapy self-management as well as their perceived advantages of the MedManager in these areas. Quantitative and qualitative data obtained were analyzed using descriptive statistics, simple correlation and thematic analysis. *Results:* The MedManager was utilized by a number of our participants at follow-up, primarily for its storage function and portability. Interviews with participants revealed a number of perceived barriers with existing medication self-management strategies, perceived advantages of the MedManager and areas for product improvements. *Conclusion:* The MedManager were perceived as helpful by a number of participants; evidenced by their utilization of the tool at follow-up and the perceived advantages of the tool over existing medication self-management strategies expressed during interviews. A number of suggestions for product improvement offered by participants can be helpful to enhance the MedManager functionality in future versions.

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Operational Definitions

The following definitions are used within this paper:

Chronic Disease Management: Collaborative efforts from patient, family, healthcare team and society to reduce impacts of chronic illnesses.

Chronic Disease Self-Management: Patient's ability to manage symptoms, treatment, physical, psychological and social consequences, and lifestyle changes inherent in living with a chronic condition. (Barlow, et al. 2002)²¹

Medication Management: An integral component of chronic disease management that "aims to optimize therapeutic outcomes for individual patients". (APhA. 2008)²⁰

Usability study: Study that employs participants who are representative of the target population to evaluate the degree to which a product meets specific usability criteria (e.g. regarding its usefulness, ease of use, learnability or likeability). (Rubin, J. 1994)⁹⁷

Usefulness: The degree to which a product enables a user to achieve his or her goals, and is an assessment of the user's motivation for using a product. (Rubin, J. 1994)⁹⁷ In this project, usefulness is assessed by observing actual utilization as well as by exploring user's rationale/motivation for utilization.

Utilization: Usage of a product or tool by the user in order to achieve his or her goal.

Utilization Score: An attempt to quantify the degree of utilization by assigning scores based on each component's utilization status at follow-up.

Qualitative study: A study that employ qualitative frameworks or methods as *primary* means to address the research question. Examples of qualitative frameworks are Ethnography and Phenomenology; examples of qualitative methods are semi-structured interviews, focus groups and thematic analysis.

Grounded Theory Research: Qualitative research enquiry in which the researcher generates a general explanation (a theory) of a process, action, or interaction shaped by the views of participants. (Creswell, 2003)⁹⁰

SECTION 1: BACKGROUND ON RELEVANT TOPICS

As our project sought to evaluate the usefulness of a product on medication and chronic disease self-management processes, it was necessary for us to obtain an understanding on relevant topics in these areas. This section presents an overview of chronic diseases; followed by a review on common approaches to chronic disease management and medication therapy management with a focus on self-management processes; an overview of medication adherence research; and a discussion on health challenges faced by rural residents in Canada.

I. CHRONIC DISEASE OVERVIEW

1.1. Definition, Characteristics and Impacts

The World Health Organization defines chronic diseases as those “of long duration and generally slow progression”.¹ Examples of chronic diseases are cardiovascular diseases, chronic respiratory diseases, and diabetes. Chronic diseases typically become more common at older age, have a gradual onset and progress over time. They can negatively affect quality of life and often necessitate long term management.²

Chronic diseases are the most common and costly of all health problems. In fact, the majority of healthcare spending in developed countries is devoted to controlling of chronic diseases and their associated risk factors. According to the Center for Disease Control, chronic diseases are responsible for more than 75% of total healthcare spending in America.³ The economic impact of chronic illnesses in Canada appears to be relatively lower. Nonetheless, more than half (58%) of all annual healthcare spending in 2010 was for chronic diseases management and prevention.⁴ The economic impact of chronic diseases goes beyond the healthcare sector. Reported indirect costs associated with loss of income and productivity due to chronic illness in Canada was \$122 billions in 2010, doubling that of direct healthcare costs.⁴

1.2. Prevalence

Chronic diseases are common. Data from the 2005 Canadian Community Health Survey showed chronic conditions affecting at least one third of all Canadians.⁵ Chronic disease prevalence also increases with age with up to 71% of adults 60 to 79 years of age reportedly having at least one chronic condition.⁵ Co-

morbidity, which is the presence of one or more additional chronic conditions, is also common among people with chronic conditions, reportedly affecting nearly half of those 65-79 years of age.⁵

Globally, residents of low-income countries are more severely affected by chronic illnesses. Mortality rates attributable to chronic diseases were 65%-85% higher in low and middle income countries compared to those in high income countries.⁶ In low and middle income countries, chronic diseases also kill at a younger age where 29% of all deaths attributable to chronic diseases occurred among those under 60 years old, compared to 13% in high income countries.⁶

1.3. Risk Factors

The development of chronic diseases is influenced by a complex interaction of factors. Among these are the underlying socio-economic, political, cultural, and environmental aspects of countries. For instance, globalization, urbanization and the aging population contribute to the rising incidence of chronic diseases because they can lead to unhealthy diets, physical inactivity and tobacco use which increase the risks for development of chronic diseases.⁷

At the individual level, age and genetics are often implicated in the development of chronic diseases and these cannot be modified.⁷ Unhealthy behaviors, on the other hand, are modifiable and they are the main driving force behind the chronic disease epidemic. It has been estimated that up to 80% of cardiovascular diseases, strokes and type 2 diabetes as well as over a third of all cancers could be prevented by eliminating modifiable risk factors.⁸ The four most common modifiable risk factors for chronic diseases are lack of physical activity, unhealthy diet, tobacco use, and excessive alcohol consumption.^{7,8} The 2011 U.S National Health Interview Survey reported 52% and 76% of adult Americans did not meet recommendations for aerobic exercises and muscle-strengthening physical

activities respectively, 38% ate fruit less than once a day, and 23% ate vegetables less than once a day. Additionally, in 2012 close to one in five U.S adults said they smoked cigarettes and one in six reported binge drinking on average once weekly with 8 drinks per binge.³ These numbers suggest the high prevalence of unhealthy behaviors in the general population.

1.4. Impacts of Chronic Diseases on Individual, Family and Health Care System

1.4.1. Individual

Chronic diseases affect people's physical and mental health, as well as their social functioning. While some individuals with chronic diseases can live full and productive lives, others have to cope with isolation, depression, and physical pain as consequences of ongoing chronic illnesses.⁹ Certain chronic conditions such as arthritis can also lead to work disability and consequently reduction in work income.¹⁰ Individuals with co-morbidities are at even greater risks for disability, more likely to be hospitalized, and often utilize more health services compared to those with only one chronic condition.⁹ The psychological impact of chronic illness has also been documented. Surveyed Americans cited fear of inability to pay for care, loss of independence, and becoming a burden to family and friends as major concerns of having chronic illnesses. They also worried about not being able to receive adequate disease and treatment information, having trouble accessing needed services, and inadequate quality of care.⁹

1.4.2. Family and Caregivers

For people with disabling chronic conditions such as dementia or severe arthritis, family caregivers and friends are usually the first line of support to provide daily personal care and help navigating the often confusing health care system. Caring for an elderly individual can be burdensome and stressful to many

family members.¹¹ A typical caregiver reportedly spends 20.4 hours per week providing care, and 39.3 hours/week among those who live with their care recipients.¹²

The demand and supply trends in family care giving are pulling in opposite directions. The chances of becoming a caregiver to someone with a chronic condition are higher today than ever before due to the aging population and likely will continue to increase.⁹ On the other hand, the supply is decreasing due to decreasing birth rates, smaller family sizes and smaller family networks.⁹ People are also marrying and having children at later stages in their lives which increases the size of the “sandwich generation”, those simultaneously care for their children and their own parents or elderly relatives.⁹

1.4.3. The Health Care System

Nolte and McKee suggested chronic diseases affect the health care system in three main areas: Human Resources, Decision Support and Financing Structures.¹³ Managing chronic diseases requires the involvement of many healthcare professionals working with patient as team to achieve stated goals.¹⁴ Healthcare professionals would then require an efficient support system (e.g. clinical practice guidelines, computerized systems...) to help ensure effective delivery of treatment.¹⁴ Lastly, paying for chronic conditions management is important and often constitute a major government expenditure in most developed countries.^{9,13} The financing structure of health system has significant implications to the nature and quality of services provided.¹⁵ Traditional payment structures for institutions and individual providers have included fee-for-service, capitation and salary but from the patient point of view, none of these methods are seen as fully aligning financial incentives with the goal of providing optimal care.¹⁵ In contrast, pay-for-performance, which has been defined as “financial incentives that reward providers for the achievement of a range of payer objectives”, is an emerging approach to ensure quality and cost-effectiveness of delivered care.^{15, 16}

II. FRAMEWORKS FOR CHRONIC DISEASE MANAGEMENT AND MEDICATION THERAPY MANAGEMENT

2.1 The Chronic Care Model

The Chronic Care Model (Wagner, Austin, and Von Korff 1996) represents a common approach to chronic disease management within healthcare system by outlining six key components and their roles within the chronic disease management process.¹⁴ The Model has been refined and widely adopted as frameworks for chronic disease prevention and management in the U.S, U.K, Australia, New Zealand and Canada.^{17,18} There is evidence that the Chronic Care Model, when effectively implemented can improve outcomes and reduce healthcare costs.¹⁹ The roles of each individual component within the Chronic Care Model are summarized in Table 1.

Table 1: Six Essential Components of Chronic Disease Management

(Adapted from the Chronic Care Model and the Ontario’s Framework on Preventing and Managing Chronic Disease)^{14,17}

Self-Management Support	Self-management support empowers and prepares patients to manage their own health while acknowledging the patient’s central role in chronic disease management. Self-management support strategies include goal-setting, action-planning, problem-solving skills and allocating available resources to provide ongoing self-management support.
Provider Decision Support	Promotes clinical care that is in consistent with current scientific evidence and patient preferences. Examples include evidence-based practice guidelines embedded into daily clinical practice, ongoing provider continuing education, access to specialist expertise and routine evaluation of care delivered.
Delivery System Design	Assures the efficient and effective delivery of care. Improving chronic care requires transforming the delivery system from one that is essentially reactive (e.g. responding when a person is sick) to one that is proactive by focusing on helping people stay as healthy as possible. This requires on-going long-term care from an interdisciplinary healthcare team working collaboratively with clearly defined roles and responsibilities to achieve individualized goals.
Clinical Information Systems	Provides care providers with convenience access to clinical information about patients, their care plans and expected outcomes in order to facilitate delivery of the best care possible. Examples of innovations in clinical information systems include Client Registries (allows for patient classification and identification based on certain criteria or ICD code), Electronic Health Records, Provider Portals, Client Portals, Population Health Data.
The Health System	The Health System should create a culture, organization and mechanisms that promote safe, high quality care. Examples include offering population-based funding incentives to reward organizations or sectors if cholesterol rates fall in the target population or if smoking rates drops; implementing outcome-based reimbursement

	mechanisms; measuring clinician and organization productivity by outcomes instead of numbers of visits and technical procedures performed to encourage proactive outreach care and alternative follow-up structures such as telephone or email interactions with patients.
The Environment/Community	Supportive community recognizes that individuals are more likely to be healthy if they live in surroundings that allow them to make healthy choices. Supportive social and community environments include building social networks to minimize social isolation, foster positive family relationships, safe schools and workplaces, create an overall sense of security due to low crime rates, and offer programs that support people to be healthy.

2.2. The Medication Therapy Management (MTM) Service Model

Medication Therapy Management (MTM) is an integral part of chronic disease management and has been defined as “A distinct service or group of services that optimize therapeutic outcomes for individual patients”.²⁰ Following a patient-centered approach, a main focus of MTM services has been to empower patients to take an active role in managing their medications.²⁰ The American Pharmacist Association and National Association of Chain Drug Stores Foundation identified five core elements that form a framework for an MTM Service Model in pharmacy practice. These elements are described in *Table 2*.

Table 2: Five Core Elements of Medication Therapy Management (Adapted From the APhA MTM Service Model)²⁰

<p><i>Medication Therapy Review (MTR):</i> Patients should receive an annual comprehensive MTR and additional targeted MTRs to address new or ongoing medication-related problem(s). Significant events such as important changes in the patient’s medication therapy, changes in the patient’s needs or resources, changes in health status or condition, a hospital admission or discharge, an emergency department visit, or an admission or discharge from a long-term care or assisted-living facility could justify additional comprehensive MTRs.</p>
<p><i>Personal medication record (PMR):</i> The PMR is intended to assist patients with medication self-management. Patient should be encouraged to maintain and update this perpetual document. Additionally, patients should be educated to carry the PMR with them at all times and share it at all health care visits and admissions to or discharges from institutional settings to help ensure that all healthcare professionals are aware of their current medication regimen.</p>
<p><i>Medication-related action plan (MAP):</i> The MAP is a patient-centric document containing a list of actions for the patient to use in tracking progress for self-management. The patient MAP includes only items that the patient can act on that have been agreed to by relevant members of the health care team. The MAP helps reinforce a sense of patient empowerment and encourages the patient’s active participation in his or her adherence behavior and overall medication therapy management.</p>
<p><i>Intervention and referral:</i> These are consultative services to address medication-related problems. Interventions may include collaboration with physicians or other healthcare professionals to resolve existing or potential medication-related problems or working with the patient directly.</p>
<p><i>Documentation and follow-up:</i> Creating and maintaining an ongoing patient-specific record that document all provided care in an established standard format (E.g. the SOAP note). Services and interventions performed by pharmacists or other healthcare professionals should be documented in a manner appropriate for evaluating patient progress and sufficient for billing purposes.</p>

III. CHRONIC DISEASE SELF-MANAGEMENT

3.1 Definition, Tasks and Characteristics

Chronic Disease Self-Management is an important component of the overall chronic disease management process and has been defined as “the individual’s ability to manage symptoms, treatment, physical, psychological and social consequences and lifestyle changes inherent in living with a chronic condition.”²¹

Corbin and Strauss (1988) delineated 3 sets of tasks faced by people with chronic conditions: 1) Medical management such as taking medications, changing diet, or self-monitoring clinical parameters; 2) Creating and maintaining new meaningful life roles regarding jobs, family and friends; and 3) Coping with the anger, fear, frustration, and sadness of having a chronic condition.²² These self-management tasks reflect the reality that patients are ultimately responsible for their health, and that health care providers should view their relationships with patients that of a partnership where patients should be encouraged to contribute to the decision making process.²³

A key determinant of successful chronic disease self-management is self-efficacy, “one’s belief in their ability to influence events affecting their lives.”²⁴ High levels of self-efficacy often require sufficient knowledge of the chronic conditions and its treatments as without understanding the rationale and importance of treatments, patients often fail to implement them.²⁵ Additionally, personal values such as positive outlook, accepting responsibility and independently solving problems have been identified as helpful in maintaining high levels of self-efficacy and effective self-management of chronic diseases.²⁵

3.2 Subsequent Health Behavior Changes following Diagnosis of Chronic Illness

Performing chronic disease self-management tasks requires behavioral changes and maintenance of the established changes. The diagnosis of chronic conditions represents a “wake-up-call”, an opportunity for individuals to make lifestyle changes known as secondary prevention. Adopting healthy behaviors following the onset of diseases are important because they can lower the risk of recurrence, reduce severity of disease, increase functioning, and extend longevity.²⁶ Smoking cessation following acute myocardial infarction, for instance, has been shown to reduce risk of a subsequent heart attack by half.²⁷

The literature, nevertheless, suggested that behavioral changes following chronic disease diagnosis are difficult to make and that the majority of individuals newly diagnosed with a chronic conditions did not subsequently adopt healthier behaviors.^{26,28} Furthermore, behavioral changes that are temporary are unlikely to have substantial effects and long-term maintenance of established behavioral changes may be difficult for patients to achieve.^{26,29}

3.3. Perceived Barriers to Chronic Disease Self-Management

Only few studies have attempted to characterize patient’s perceived barriers to chronic disease self-management.³⁰ Commonly reported barriers were lack of knowledge about the condition and plan of care,^{9,25,30} physical limitations caused by chronic conditions,³⁰ feeling of helplessness and frustrations,^{9,25,31} poor physician communication and family support.³² Within the context of medication self-management, reported barriers have included complex medication regimens,³³ side effects of medications,³⁰ and medication adherence difficulty.³² A main limitation seen with the reviewed studies is the inconsistent results on identified barriers and their prevalence. Moreover, given the various data collection methods used, the subjective nature of the data collected (e.g. through questionnaires) and the differing patient baseline characteristics, generalization of any results is difficult.³² Nevertheless,

results obtained from these studies have formed the basis for development of new chronic disease self-management interventions.^{31,32}

3.4. Health Behavioral Theories

Health behavioral change theories are attempts to explain why people change (or do not change) their health behaviors by establishing determinants to behavioral change. Table 3 summarizes key characteristics of common health behavioral change theories and models that have served as theoretical basis for development of many health behavioral interventions.³⁴

Table 3: Characteristics of Common Health Behavioral Change Models and Theories

Name/Author(s)	Underlying principle(s)	Stages of Change	Determinants to Behavioral Change
Health Belief Model (Rosenstock, et al. 1966)	Health behavior change are based on a rational appraisal of the balance between the barriers to and benefits of action. ³⁴	N/a	<ul style="list-style-type: none"> • Perceived Severity • Perceived Susceptibility • Perceived Benefits • Perceived Barriers³⁵
Theory of Reasoned Action (TRA) (Fishbein & Ajzen, 1975)	Behavior is a function of the intention to perform that behavior. ³⁵ Intention is in turn influenced by personal positive or negative beliefs (attitude) and perceived expectations of others (subjective norms) ³⁴	N/a	<ul style="list-style-type: none"> • Attitudes • Subjective norms³⁵
Theory of Planned	An extension of TRA. Intention is determined	N/a	<ul style="list-style-type: none"> • Attitudes

<p>Behavior (Fishbein & Ajzen, 1975)</p>	<p>by attitude, subjective norm and perception of the degree to which they are capable of, or have control over, performing a given behavior (perceived behavioral control).³⁴</p>		<ul style="list-style-type: none"> • Subjective Norm • Perceived Behavioral Control³⁴
<p>Social Cognitive Theory (Bandura 1950's)</p>	<p>Behavior can be explained in terms of triadic reciprocity between three key concepts which operate as determinants of each other: The individual, the environment and behavior.³⁶</p>	<p>N/a</p>	<ul style="list-style-type: none"> • Knowledge of health risks • Benefits of change • Self-Efficacy • Outcome expectations³⁴
<p>Transtheoretical/ Stages of Change Model (Prochaska & DiClemente, 1983)</p>	<p>Behavioral change process consists of a number of qualitatively different stages. People move through these stages, typically relapsing and revisiting earlier stages before success.³⁴</p>	<p>Five Stages of Change:</p> <ul style="list-style-type: none"> • Precontemplation • Contemplation • Preparation • Action • Maintenance³⁶ 	<p>Ten Processes of Change: Consciousness raising, dramatic relief, self-liberation, social liberation, counter conditioning, stimulus control, self-reevaluation, environmental reevaluation, reinforcement management, helping relationship.³⁶</p>
<p>Health Action Process Approach (Schwarzer and Fuchs, 1996)</p>	<p>The process of health behavior change is conceived as a structured process that include intention formation, planning and action.³⁷</p>	<ul style="list-style-type: none"> • Motivational phase (Intention-forming stage) • Volitional phase (Planning, action and maintenance stages)³⁷ 	<ul style="list-style-type: none"> • Self-Efficacy • Outcome Expectancies • Risk perception³⁷

The Health Belief Model, Theory of Reasoned Action, Theory of Planned Behaviour and Social Cognitive Theory are designed to predict behaviors at a single point in time.³⁷ They have been called motivational models because of their focus on motivational factors that influences the individual's decision to perform (or not perform) the health behavior in question such as self-efficacy.³⁷ The multi-stage models (Transtheoretical Model and Health Action Process Approach) on the other hand viewed the process of change as consisting of distinct stages with distinct determinants at each stage.³⁷

Theories are often utilized as underlying principles to guide program development and implementation³⁸ and there is evidence that theoretically-informed programs are more effective in changing health behaviors than those that are not theoretically informed.³⁹ Nevertheless, application of theories in health behavioral interventions remains challenging due to the number of theories available and that they need to be properly interpreted and faithfully implemented within the intervention.⁴⁰

IV. CHARACTERISTICS OF CURRENT CHRONIC DISEASE SELF-MANAGEMENT PROGRAMS - A LITERATURE REVIEW

4.1. Objectives

We were interested in examining current interventions to enhance chronic disease self-management and therefore conducted a literature review on published chronic disease self-management programs. The objectives of the literature review were: 1) To understand existing approaches to enhance chronic disease self-management and 2) To learn about their effectiveness on clinical outcomes.

Within the context of this project, we were particularly interested in examining the medication-related component of existing self-management programs and therefore only considered programs that had included a medication self-management component.

4.2. Methodology

4.2.1. Identification of Literature

After reviewing library resources on steps to conducting a literature review, we searched PubMed, SCOPUS and PsyNet from inception to September 1, 2014 for published chronic disease self-management programs using the following key words: “Self-Management”, “Program”, “Intervention”, “Chronic disease” and “Randomized controlled trial” in title and abstract.

We input our search queries as followed:

PubMed: (chronic disease[Title/Abstract] AND self management[Title/Abstract]) AND program[Title/Abstract] AND (Clinical Trial[ptyp] AND ("1000/01/01"[PDAT] : "2014/09/01"[PDAT]))

SCOPUS: (TITLE (program) AND TITLE (self-management) AND TITLE-ABS-KEY (chronic disease)) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (EXACTKEYWORD , "Randomized controlled trial"))

PsyINFO: Title: Self Management AND Title: Program AND Abstract: Chronic Disease AND Methodology: Treatment Outcome/Clinical Trial

Each article identified by the search queries was reviewed to determine if it has met our pre-defined inclusion criteria. The inclusion criteria were as followed: 1) Be available in fulltext in English at time of review, 2) Be a Randomized Control Trial that has a “Usual Care” or “Control” group, 3) Primary outcome(s) must be patient-related clinical outcome(s) (e.g. cost analysis and health utility studies were excluded), 4) The intervention was specific for chronic disease self-management (e.g. post-hoc analyses were excluded), 5) Were conducted in community settings and 6) Must include pharmacologic intervention.

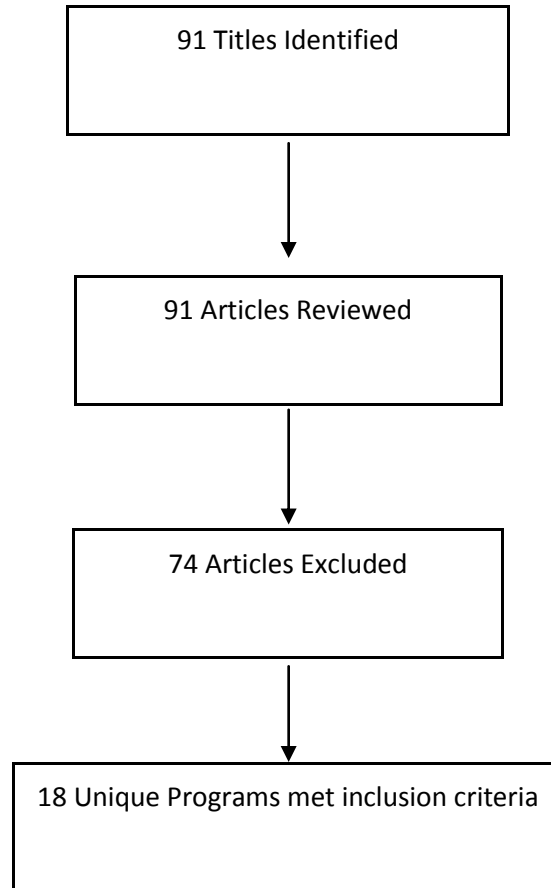
Prior to this review, my knowledge on chronic disease self-management interventions was limited with regards to current approaches and their effectiveness. The literature review was intended to address this knowledge gap. With regards to our inclusion criteria, we only included randomized controlled trials due to concerns about the inherent methodological limitations with other study designs that could prevent us from inferring on the validity of reported results. We also thought the inclusion of a placebo or usual care group within randomized controlled trials would allow us to examine the absolute effectiveness of the interventions. Furthermore, as findings from the literature review was intended to help form the basis for formulating our project methodological approaches, we further limited our review to interventions designed exclusively to enhance chronic disease self-management, included a medication self-management component and were implemented within community settings (e.g. not institutional) because these were also characteristics of the MedManager and our project. Finally, we were only interested in reviewing program effectiveness on patient-related outcomes and therefore excluded those not stating a patient-related clinical outcome as primary objective (e.g. health utility and proof-of-concept studies)

4.2.2. Data Abstraction and Analysis

Full-text version of each eligible study was reviewed to collect data on a) Study underlying theoretical framework (if any), b) Mode of Delivery, c) Intervention details (duration, pharmacologic components, non-pharmacologic components) and d) Reported effectiveness on patient-related outcomes. These study characteristics were intended to help us understand each study's approach and effectiveness. Collected data was then reviewed to look for common themes regarding underlying theoretical frameworks, study designs, and documented effectiveness.

4.3. Results

Figure 1: Summary of review process



The search queries identified a total of 91 titles, 18 of which met the eligibility criteria. Key characteristics of these studies are summarized in Table 4, followed by an analysis on review findings.

Table 4: Key characteristics of reviewed chronic disease self-management programs

		Theoretical Framework and Mode of Delivery	Intervention Details	Pharmacologic-related intervention	Clinical Measures and Effectiveness
1	Preparing Adolescents With Chronic Disease for Transition to Adult Care: A Technology Program Huang, et al.	-Social Cognitive Theory -2-month intensive Web-based and text-delivered disease management and skill-based intervention.	-Target self-management constructs of Monitoring disease symptoms, Responding to treatment effectiveness, Actively working with healthcare providers.	-Education on Self-assess and respond to appropriateness of treatment	-Validated Clinical Scales -Intervention group demonstrated significant short-term (<6 months) improvements on performance of disease management tasks, health related self-efficacy, and patient-initiated communication compared with controls. -No change in other measures such as disease status, functional status, or quality of life in treatment group over study period.
2	Effectiveness of Moving On- An Australian designed generic self-management program for people with a chronic illness Williams et al.	-Theory of Self-Efficacy and Trans-Theoretical Behavior Change Model -Seven 3-hour-per-week group education sessions, delivered by two trained facilitators (a health professional and a lay leader.	-Group education on Managing fatigue, Physical activity, Healthy eating, Coping with chronic illness, Stress management, Relaxation, Working with healthcare team, Developing and evaluating personal action plan and getting the most out of medications	-Group education on “getting the most out of medications”.	-Validated Clinical Scales -At 16-week follow-up, there was no significant difference between groups in self-efficacy scores, self-rated health or health distress scores. -No significant difference between or within groups in self-management knowledge and stage of change of behaviors. -Intervention group has higher but nonsignificant adjusted physical activity and nutrition scores.
3	Chronic Disease Self-Management Program (Original) Lorig, KR, et al.	-Self-Efficacy -7 weekly group education sessions of 2.5 hours duration by peer leaders	-Group Education on: adoption of exercise programs; use of cognitive symptom management techniques, such as guided relaxation and distraction; nutritional change; fatigue and sleep management;	-Education on Medication use.	-Validated Clinical Scales (on Health Status, Health Services Utilization and Perceived Self-Efficacy) -Improvements in health distress and self-efficacy vs. control. Reductions in ambulatory health care

			use of medications and community resources; managing the emotions of fear, anger and depression; training in communication with health professionals and others; health-related problem-solving; and decision making.		utilization during 2-year period.
4	<p>Living well: An Intervention to Improve Self-Management of Medical Illness for Individuals With Serious Mental Illness</p> <p>Goldberg RW, et al.</p>	<p>-Adaptation of the Original CDSMP to better fit mentally ill patients.</p> <p>-13-session peer-facilitated group education sessions. 60-75 minutes each over 13 weeks.</p>	<p>-Group Education on action planning, peer feedback and support, modeling, problem solving.</p> <p>-Application of techniques and skills to nutrition, exercise, sleep, addictive behaviors, coordination of general medical and psychiatric services.</p>	-Education on Medication management	<p>-Validated Clinical Scales</p> <p>- Participants were evaluated on attitudinal, behavioral, and functional outcomes. Intervention group showed significant post-intervention improvements across attitudinal (self-efficacy and patient activation), behavioral (illness self-management techniques), and functional (physical and emotional well-being and general health functioning) outcomes. Attenuation of effect was observed for most outcomes at 2 months post-intervention.</p>
5	<p>The Health and Recovery Peer Program: a peer-led intervention to improve medical self-management for persons with serious mental illness</p> <p>Druss BG, et al.</p>	<p>-Adaptation of the Original CDSMP, with modifications to better suit mental patients.</p> <p>-Intervention group attended 6 group sessions led by a mental health peer specialist</p>	<p>-Group Education on: Overview of self-management, Exercise and physical activity, Pain and fatigue management, Healthy eating on a limited budget, Medication management, Finding and working with a regular doctor.</p> <p>-Development of Action Plan</p>	-Education on Medication management	<p>-Validated Scales and Questionnaires</p> <p>-Intervention group had significantly greater improvement in patient activation and likelihood of using primary provider services as well as non-significant greater improvements in physical HRQOL, physical activity and medication adherence at 6-month follow-up.</p>
6	<p>Perceived control moderated the self-efficacy-enhancing effects of a chronic illness self-management</p>	-Self-Efficacy. Home-based variant of the Chronic Disease Self-Management Program.	-Exercising safely, Coping with difficult emotions, Communicating effectively with family and healthcare	-Medication Use	<p>-Validated Scale</p> <p>-Only the home-based group showed enhanced self-efficacy from chronic illness self-management.</p>

	<p>intervention</p> <p>Jerant A, et al.</p>	<p>-3 groups: Weekly interventions provided in homes or by telephone vs. control over 6 weeks. Same content as CDSMP but differ in method of delivery: (individual vs. group setting, no professional involvement)</p>	<p>providers, Relaxation and cognitive symptoms management techniques.</p>		<p>The effect is not sustained at 6-month follow-up</p>
<p>7</p>	<p>A pilot study of telephone care management and structured disease self-management groups for chronic depression</p> <p>Ludman, EJ, et al.</p>	<p>-Developed partly based on experience with phone care management and the Original CDSMP</p> <p>-Four groups: 1) Usual care, 2) Usual care plus Telephone care management (monthly for 3 months, then as needed), 3) Usual care plus Telephone care management plus Peer-led chronic disease self-management group program (on-going bi-monthly group meetings), 4) Usual care plus Telephone care management plus Professionally led depression psychotherapy group program (Manualized intervention over 10 weeks, followed by 6 months of twice monthly “booster” sessions.</p>	<p>--Telephone care: Monitor treatment quality and adherence, decisions support, ensure appropriate follow-up care.</p> <p>-Group education on: Disease-related goal setting and problem solving, Cognitive symptom management, Communication skills, Use of community resources.</p> <p>-Cognitive-behavioral therapy delivered by a psychologist.</p>	<p>- Education on medication adherence, management of side effects, motivational enhancement strategies to address ambivalence about medication use in non-adherent patients.</p>	<p>-Validated Scales</p> <p>-Unable to detect any differences between groups in measured clinical outcomes.</p>

8	<p>Evaluation of the chronic disease self-management program (CDSMP) among chronically ill older people in the Netherlands</p> <p>Elzen, H., et al.</p>	<p>-Application of the Original CDSMP.</p> <p>-Intervention consists of 6 weekly group education sessions, each 2.5 hr long facilitated by a psychologist.</p>	<p>-Group education on: Exercise, Cognitive symptom management techniques, Information on nutrition, Fatigue management, Managing emotions, Communication, Decision-making</p>	<p>-Medication Use</p>	<p>-Validated Scales</p> <p>-No evidence of short-term or long-term program effectiveness on self-efficacy, self-management behavior, or health status.</p>
9	<p>Internet-based chronic disease self-management: a randomized trial.</p> <p>Loriq KR, et al.</p>	<p>-Web-Based version of the Original CDSMP.</p> <p>-Internet-based program consists of interactive web-based instruction facilitated by a trained peer moderator with discussion groups and book.</p>	<p>-Cognitive symptom management, Emotion management, Physician-patient communication, Healthy eating, Fatigue management, Action planning, Problem solving.</p>	<p>-Medications Overview</p>	<p>-Validated Scales</p> <p>-At 1 year, online participants had improvements in health distress, fatigue, pain and shortness of breath, and a trend toward improvement in illness intrusiveness compared to control. Few significant differences in health behaviors at 1 year. No changes in health utilization in intervention group.</p>
10	<p>Evaluation of the chronic disease self-management program in a Chinese population</p> <p>Siu, AM, et al.</p>	<p>-Application of the Original CDSMP in Chinese population</p> <p>-Six 2-hour weekly group education with one health professional and one lay person.</p>	<p>-Group education on Diet, Exercise, Medication, Fitness, Emotion management, Problem-solving skills, and Communication with health professionals</p>	<p>-Medication management</p>	<p>-Validated Scales</p> <p>-Intervention group demonstrated significantly higher self-efficacy, exercise behavior and application of cognitive coping strategies compared to control at 1 week post intervention.</p>
11	<p>A randomized controlled trial of a self-management program for people with a chronic illness from Vietnamese, Chinese, Italian and Greek backgrounds</p> <p>Swerissen H., et al.</p>	<p>-Application of the Original CDSMP in people with selected ethnic backgrounds in Australia</p> <p>-6 weekly group education sessions with instruments delivered in participant's</p>	<p>-Symptom management, Problem solving, Emotion management, Exercise and relaxation, Healthy eating, Communication skills.</p>	<p>-Medication use.</p>	<p>-Validated Scales</p> <p>-At 6 months, intervention group has significantly better outcomes on energy, exercise, symptom management, self-efficacy, general health, pain, fatigue and health distress. No significant improvement on health service utilization.</p>

		first language.			
1 2	Chronic disease self-management program for low back pain in the elderly Haas, M. et al.	-Application of the Original CDSMP to low back pain seniors. -109 seniors with chronic LBP were randomly allocated to the CDSMP or a wait-list control group. Program included weekly 2.5 hour sessions for 6 weeks.	-Group Education on: General principles of chronic conditions; overview of self-management principles; symptoms; care-seeking options; community resources; exercise; relaxation; nutrition; medication and side-effects; skills building; learning from others; sharing with others; goal setting; action plans; feedback; and problem-solving	-Medication Use	-Validated Scales -No advantage in intervention group in improving pain, general health, self-efficacy, and self-care attitudes vs. control. Suggested benefits for emotional well being, fatigue, functional disability.
1 3	Activities of daily living function and disability in older adults in a randomized trial of the health enhancement program Phelan, EA., et al.	-Buchner/Wagner model of disability -201 adults aged 70 years and older at a senior center were randomized to intervention or controlled. Multi-component approach: -Individual component: Participants meet individually with a NP who gathered health and risk factor information and developed a "health action plan" tailored to the participant's goals and preferences. Had 3 in-person meetings and 9	-Education on: Self-management of chronic conditions, physical inactivity, depression, and social isolation	-Addressed use of unnecessary psychoactive medications	-Mailed Questionnaires -At 12 months, intervention was more likely vs. control to improve Activities of Daily Living (ADL) function in those with mild to moderate ADL disability. No significant difference in development of new ADL disability or on worsening of ADL function.

		calls over 12 months. -Group-setting component: exercise class, chronic disease self-management class, peer support.			
1 4	Implementation and quantitative evaluation of chronic disease self-management programme in Shanghai, China: randomized controlled trial Fu, D, et al.	-Adaptation of the Original CDSMP with content modification for cultural reasons. -Seven 2-2.5 hours group education sessions with lay-taught and professional-taught components	Group Education and Materials on: Exercise; Use of cognitive symptom management techniques; Nutrition; Fatigue and sleep management; Use of community resources; Use of medications; dealing with the emotions of fear, anger, and depression; Communication with others, including health professionals; Problem-solving; and Decision-making.	Education on Medication Use	-Validated Scales -The intervention improved health behavior, self-efficacy, and health status and reduced hospitalization at 6 months post intervention. Chinese lay-leaders was as successful as professionals.
1 5	The Hepatitis C Self-Management Program: Sustainability of Primary Outcomes at 1 Year Groess, E.J. et al.	Bandura's Social Cognitive Model. (increases in health-related knowledge and the acquisition of specific behavior change skills within a supportive group environment results in health behavior improvements and increased self-efficacy)- With adaptations from the Original CDSMP with added contents specific to HCV. -Six 2-hour weekly group education sessions led by	HCV-specific disease education, Problem solving, Treatment decision making, Psychological management and Communication with healthcare providers.	Antiviral treatment, substance use	-Validated Clinical Scales -Intervention group demonstrated advantage in disease knowledge, energy/vitality and Quality of Well-being at 12 months.

		health professionals and peer leaders and information booklets.			
16	<p>Twelve-month outcomes of an Internet-based diabetes self-management support program</p> <p>Glasgow, RE, et al.</p>	<p>-Social-Ecological Theory</p> <p>-Two web-based intervention groups + Usual care group.</p> <p>-First intervention group were given access to program website that allows for goal setting in medication adherence, physical activity and food choices. Participants create personalized “action plan” at week 6 for medication taking, healthy eating, and physical activity, identified barriers to achieving stated goals.</p> <p>-Second intervention group received follow-up phone calls and invitation to group sessions.</p>	<p>-Web-based goal setting, action planning and education on medication taking, healthy eating, and physical activity. Two follow-up phone calls and three group visit invitations were added for second intervention group.</p>	<p>-Education, Goal setting and action plan on Medication taking and adherence</p>	<p>-Validated Clinical Scales</p> <p>-Between-group differences were largely non-significant in most measures of psychological outcomes and biological outcomes. Health behavioral outcomes improved significantly in intervention groups vs. enhanced usual care at 12 months on eating habits, fat intake, physical activity but not medication adherence. No difference between intervention groups.</p>
17	<p>Randomized controlled trial of a Psychoeducation program for the Self-Management of Chronic Cardiac Pain</p> <p>McGillion, MH, et al.</p>	<p>-Self-Efficacy Theory- Adaptation of the Original CDSMP with added pain-related contents</p> <p>-Six 2hr weekly sessions by a registered nurse in group format.</p>	<p>-Group education to enhance self-efficacy, including making action plan, cognitive symptom management, problem solving, Managing Emotional Response, Communication.</p> <p>-Pain-related content includes: Relaxation and stress management, symptom</p>	<p>-Medication review (Angina and common heart medications)</p>	<p>-Validated Clinical Scales</p> <p>-Statistical improvement in HRQL (Physical functioning, General Health, Frequency, Stability of Angina pain symptoms) and self-efficacy at 3-month follow-up.</p>

			monitoring and management, medication review, diet, emotional management		
1 8	Effectiveness of an Educational self-Management program for outpatients with chronic heart failure Otsu, H, Moriyama, M.	-Based on clinical guidelines, previous programs, and surveys data from CHF patients -Six one-on-one monthly nurse-directed sessions in clinic setting.	-Education on: Adjust to CHF, How to quit smoking, Letter to family, Diet and alcohol, Self-management, Medication Administration and Monitoring, Activities and Exercises.	-Medicine administration and monitoring	-Clinical outcomes and Validated Clinical Scales. -Compliance (Diet, exercise, self-monitoring) and BNP levels significantly improved in the intervention group vs. control at 6 months. QOL significantly improved intervention group vs. control at 6, 9, 12 months though measured effects attenuated overtime.

4.3.1. Underlying Theoretical Frameworks and Modes of Delivery of Reviewed Programs

While many reviewed programs did not explicitly cite a guiding health behavioral theory, their stated objectives, common approaches, and measurement strategies often reflected a focus on enhancing patient's self-efficacy, that is, to provide patients with knowledge, skills and motivation needed to adopt healthy behaviors.^{42-52,54,55,57} Many programs^{43-52,54,55,57} were adaptations of the Stanford Chronic Disease Self-Management Program (CDSMP) (Lorig, et al.) which in itself was also based mainly on the principles of enhancing self-efficacy.⁴⁸

The most common Mode of Delivery was in-person group education.^{42-45,47,48,50-52,54,55} Web-based^{41,49,56}, Telephone-based^{46,47}, and one-on-one interventions^{6,13,18} as well as material hand-outs^{15,17} have also been utilized, either exclusively or in combination with group education.

4.3.2. Intervention Details, Outcome Measurement Strategies and Documented Effectiveness

Regardless of Mode of Delivery, efforts to improve chronic disease self-management have traditionally been focusing on enhancing patient's self-efficacy through education on disease knowledge, self-management skills and decision making techniques.^{42-52,54,55,57} Many were modified versions of the Stanford Chronic Disease Self Management Program (CDSMP) in order to better fit targeted patient populations which have included those with specific chronic condition (e.g. Diabetes or Chronic Depression)^{44,45,47,52,55-57} or ethnic background (e.g. Chinese population) by adding disease-specific or culturally-relevant education components.^{50,51,54} As a result, education topics were often seen as similar among programs and typically included: Diet and Exercise, Emotional Management, Disease Symptom Management, Communication with Healthcare Team, and Medication Management. Education on medication management seemed to have only played a small part in the overall interventions and seen to have addressed areas such as medication knowledge deficit, medication adherence, side effect

management, as well as monitoring and responding to medication effectiveness.^{47,53,56} Another feature seen with identified programs was the focus on enhancing goal-setting and decision making skills (e.g. through creation of an Action Plan).^{42,44,45,49,52,53,56,57}

Most in-person group education sessions have been delivered in weekly intervals for 6-7 weeks, typically lasted 2-2.5 hours each and taught by either health professionals or trained peer leaders.^{42,43,44,45,47,48,50,51,52,54,55} Web-based programs often included interactive components such as discussion forums with trained moderators,⁴⁹ or are complemented by interactive approaches such as text-based and telephone-based follow-ups or invitations to in-person meetings.^{41,56} Settings for in-person programs typically included clinics and community centers though we also came across one program that delivered home-based interventions.⁴⁶

Program effectiveness was commonly measured by administration of validated clinical scales⁴¹⁻⁵⁸ to capture a variety of outcomes such as perceived health status, quality of life and self-efficacy. The majority of reviewed programs were able to demonstrate short-term effectiveness in some outcomes while failed to show effectiveness on others. Furthermore, the observed effectiveness often subsided in subsequent post-intervention follow-ups.^{44,58}

4.4. Discussion

4.4.1. Literature Review Limitations

Our literature review used a very specific search strategy within a limited number of research databases. Consequently, the reviewed studies may not have represented all existing approaches to chronic disease self-management. Additionally, the review process was conducted primarily by the student researcher. The lack of additional researchers in the review process could have reduced the objectivity of data collection and interpretation. Nevertheless, the similarities seen in many reviewed programs regarding

their underlying theoretical framework, intervention design and relative effectiveness provided us with an understanding on common approaches and effectiveness of existing programs.

4.4.2. Limitations and Effectiveness of Existing Chronic Disease Self-Management Interventions

There were two limitations seen with existing self-management approaches: their short intervention period and the group-based format. The group-based format, while in itself can be an advantage (e.g. allows for peer-to-peer discussion, more cost-effective compared to one-on-one formats), prevents designing of more flexible programs that are customizable to individual self-management needs. Additionally, self-management needs can change from time to time and should ideally be addressed by an on-going, long-term program.

Nevertheless, improving patient's health status through enhancing self-efficacy has proven to be a promising approach. This is supported by the short-term improvements on clinical outcomes seen in the majority of reviewed programs as well as possible long term post-intervention effects as demonstrated in subsequent follow-ups of the Original CDSMP.⁴⁸ Additionally, innovative modes of delivery such as web-based or text-based programs have also been proven to be effective, are low cost alternatives to traditional programs, and have the potential to reach a much larger number of patients over a more extended period of time.

V. EXPANDED LITERATURE REVIEW ON USABILITY AND QUALITATIVE STUDIES ON CHRONIC DISEASE SELF-MANAGEMENT

5.1. Objectives

In order to include relevant usability studies and qualitative studies on Chronic Disease Self-management, an expanded literature review on published articles was conducted using the following inclusion criteria:

1) Be original research available in full-text in English at time of review. 2) The primary objective is to evaluate an innovative product or tool specifically designed to improve self-management processes -OR- Employed qualitative methods as primary mean to address the research question and 3) Conducted in community settings (e.g. not institutional settings)

Study abstracts and full-texts were reviewed to determine if they meet the inclusion criteria. Full-text of each eligible study was subsequently reviewed more closely to collect information on a) Tool/program description and/or study objectives, b) Methodological approaches (e.g. testing procedures, data collection and analysis strategies) and c) Findings.

5.2. Identification of Literature

Published articles on PubMed, SCOPUS and Psynet from inception to December 31, 2014 were searched using key words: "Self-management", "Chronic disease" in study title.

Search queries were input as followed:

SCOPUS: (TITLE (chronic disease) AND TITLE (self-management))

301 studies identified

→ 50 Reviews excluded

→ Conference paper, Note, Editorial, Book chapter, Short Survey, Article
in Press, Letter, Book: 3 eligible studies included out of 42

→ Clinical trials: 27 eligible studies included out of 209

PubMed: (chronic disease[Title]) AND self-management[Title]

Filters Activated: Filters activated: Clinical Trial, Comparative Study, Evaluation Studies, Journal
Article, Multicenter Study.

144 studies identified → 3 additional eligible studies included

PSYInfo: Title: chronic disease AND Title: self-management

101 studies identified → 1 additional eligible study included

Table 5 summaries key characteristics of eligible studies

Table 5: Characteristics of Reviewed Usability and Qualitative Studies on Chronic Disease Self-Management

A. Usability Studies					
		<i>System description</i>	<i>Evaluation Procedures</i>	<i>Data Collection and Analysis</i>	<i>Findings</i>
1	<p>Usability Study of a Computer-Based Self-Management System for Older Adults with Chronic Diseases</p> <p><i>(Or, C., Tao, D. 2012)</i></p>	<p>A paper prototype version of a computer-based, interactive, touch screen self-management system designed for patient use in their homes. The system allows patients to assess, record, and track their vital signs, including weight, blood pressure, blood glucose level, temperature, and oxygen saturation. It can also remind patients to take their prescribed medications at predetermined times.</p>	<p>Two parts:</p> <ul style="list-style-type: none"> -Heuristics Evaluation (3 expert evaluators): Evaluated system interfaces for their conformity to a set of 26 human factors design heuristics by asking expert evaluators to determine conformity by responding “yes” or “no” to each heuristic. -End-User Testing (57 participants): 3 stages: <ul style="list-style-type: none"> • Preparation stage (Participant Selection, Task Design, and planned Data Collection methods). • Testing stage: At a community center. Procedures pilot tested on first 7 participants. Participants asked to perform a set of pre-determined experimental tasks with the think-aloud method. Video recorded. Field notes from RAs, participant feedback on 	<ul style="list-style-type: none"> -Post-test questionnaires using Likert Scale: <ul style="list-style-type: none"> • Satisfaction with the interface design • Perceived usefulness • Perceived ease of use • Intention to use -Post-test interview on participants’ opinions about the interface design. -Performance measures: task completion time, task incompleteness time, frequency of error, frequency of help. -Obtain recommendations for System Design Modifications -Descriptive Statistics and Content Analysis of collected data. 	<ul style="list-style-type: none"> -Participants were able to perform assigned tasks and expressed mostly positive responses about the perceived usability measures regarding system interface. -Revealed a number of usability problems related to system navigation, information search and interpretation, information presentation and readability. -Areas for future modifications were discussed.

			<p>difficulties after test completion.</p> <ul style="list-style-type: none"> • Follow-up stage: Data analyzed using descriptive Statistics and simple content analysis. 		
2	<p>Self-Management support using an Internet-linked tablet computer (The EDGE platform)-based intervention in chronic obstructive pulmonary disease: Protocol for the EDGE-COPD RCT</p> <p><i>(Farmer, A. et al. 2014)</i></p>	<p>An Internet-linked tablet-based intervention developed to support patients with COPD in monitoring their health and to provide information and education about their condition. Components included:</p> <ul style="list-style-type: none"> • A daily symptom diary consisting of a series of standard questions about symptoms. • Bluetooth-enabled pulse oximeter with finger probe. • Questionnaires presented every 4 weeks • Software modules to provide Personalized plans, Education information <p>Data is transmitted in real time to a server and</p>	<p>-Intervention group: Participants provided with a tablet computer, given instructions on the use of the EDGE Platform and an information booklet.</p> <p>-Participants input clinical data daily. Data is reviewed by a clinician periodically and follow-up phone calls are made to participants and HCPs if data crosses thresholds.</p> <p>-Usual care group: No tablet computers.</p>	<p>-Primary outcome is quality of life, measured by St George's Respiratory Questionnaire for COPD patients (SGRQ-C) at baseline, 6 months and 12 months.</p>	<p>In progress-Results due in Sept. 2015.</p>

		reviewed by a clinician periodically.			
3	A Feasibility Study of Low Income Homebound Older Adults' Participation in an Online Chronic Disease Self-Management Program <i>(Choi NG, An S, Garcia A., 2014)</i>	A 6-week long "Better Choices, Better Health" consists of a password-protected, dedicated website that contains Learning Center, Discussion Center, Tools, Post-Office, Help and Class Profile.	Each week for 6 weeks, older participants who are low-income are asked to log on at least three times and participate in that week's activities.	Data on feasibility collected by: <ul style="list-style-type: none"> •Observational field notes during each in-person visit or telephone call •Short Evaluation Form that participants fill out weekly •Open-ended questionnaires post intervention covering the participant's experience, perceptions, and suggestions. 	-Post intervention follow-ups show improvement in health and self-management outcomes per self-reported scales. -Participant qualitative feedbacks show high satisfactions.
4	Adaptation of the health literacy universal precautions toolkits for rheumatology and cardiology – Applications for pharmacy professionals to improve self-management and outcomes in patients with chronic disease.	Two health literacy toolkits focuses on issues related to rheumatology and cardiology, including components such as a video using teach back method, a rheumatology specific guide, medication aids and handouts, patient education materials for HCPs.	-Testing plan for healthcare staff at participating sites consisting of 3 milestones: 1) Form and Train your health Literacy Team, 2) Conduct Health Literacy Assessment of Your Practice, 3) Implementation of Tools. -Pre and post questionnaire/feedback. Recorded conference calls guided by a structured interview at completion of each milestone.	-Questionnaire/feedback from post-test forms and conference calls. -Qualitative and quantitative data was reviewed by team members to determine tools with the most relevance to pharmacists.	-Participating pharmacists and staff had positive experiences overall with the toolkits, offered suggestions for revisions. -Identified 5 specific tools (out of 22) that might be of particular interests to pharmacists

	<i>(Callahan LF., et al, 2013)</i>				
5	Application of the content expert process to develop a clinically useful low-literacy Chronic Kidney Disease Self-Management Knowledge Tool <i>(Devraj, R. Wallace LS. 2013)</i>	An instrument that helps clinicians assess patients' knowledge of self-management behaviors in CKD patients.	Instrument development and evaluation by expert panel consisting of 16 content experts. 7 steps from initial item generation and drafting, qualitative reviews by content experts, cycles of revisions, review, revisions, etc.	-Qualitative Review: Electronic mail asking identified experts to evaluate individual items, general perceptions and formatting features. -Quantitative Review: 3-point scale for each item: 1) Essential, 2) Useful but not essential, 3) Not necessary. Calculation of Content Validity Ratio	-Final version contains the 11 items rated as "Essential" by content experts.
6	The South Australia Health Chronic Disease Self-Management Internet Trial <i>(Lorig, K., et al. 2013)</i>	An online CDSMP that is similar in content to that of the Stanford CDSMP but delivered electronically using threaded bulletin board.	Participants complete baseline, 6-month and 12-month data on eight health status measures, seven behaviors, four utilization measures, self-efficacy, and health care satisfaction.	-Conveniently sampled participants completed self-administered questionnaires at baseline, 6-month and 12-month utilizing validated clinical scales.	-The online program was found to be acceptable and useful by participants. Appeared to decrease symptoms, improve health behaviors, self-efficacy, and reduce healthcare utilization up to 1 year.
7	Usability Evaluation of an Online, tailored Self-Management Intervention for Chronic Obstructive	A Web program that incorporates eight Behavioral Change Techniques and allows patient to choose between different modules: Health Risk Appraisal, Smoking Cessation, Medication	-Evaluation sessions took place in a lab setting. Participants log on, follow presented instructions to complete the program. -Pre-test on one individual. -Each participant was asked to complete 2 pre-determined	-Task completion rate, completion time, program rating. -Think-aloud data, keystrokes, mouse clicks were reviewed. -Analysis of markers on video recordings, field	-Areas for improvement in all three areas: Layout, Navigation and Content. -Participants found program was easy to use. -Some behavioral change techniques were

	<p>Pulmonary Disease Patients Incorporating Behavioral Change Techniques</p> <p><i>(Voncken-Brewster, V. et al. 2013)</i></p>	Adherence and Physical Activity.	<p>tasks (2 modules) and to verbalize their thoughts while performing the tasks. (think-aloud method)</p> <p>-Screen shots and mouse clicks were captured, together with verbal and non-verbal reactions using a webcam.</p> <p>-Participants were interviewed about their experiences with the tasks after testing.</p>	<p>notes, semi-structured interviews to identify problems.</p> <p>-Problems were grouped into three categories: content, layout, navigation and classified as major problems or minor problems.</p> <p>-Repeating between testing rounds, program refinement, and subsequent testing until no new problems were discovered.</p>	perceived as helpful and easy to use, while others evoked frustration.
8	<p>Integrating a tailored e-health self-management application for chronic obstructive pulmonary disease patients into primary care: A pilot study.</p> <p><i>(Voncken-Brewster, V. , et al., 2014)</i></p>	<p>An e-Health application with:</p> <ul style="list-style-type: none"> • A Health Risk Appraisal Questionnaire • Behavior Change Modules • Feedback messages provided to patients and quarterly reports to nurses. 	<p>Participants receive a password to log in to the application from home using a computer with internet access. They also receive phone calls from the researcher who explains the study, gives user instructions, and answers questions.</p> <p>Follow-up after 1 year.</p>	<p>-Mixed method approach.</p> <p>-Quantitative data: Self-reported health risk appraisal questionnaire, medical records and validated clinical scales pre and post intervention. Frequency of use during the intervention period.</p> <p>-Qualitative data: Semi-structured interviews with patients and practice nurses during second half of intervention period. Questions on influence of application on outcomes, application use and satisfactions, impacts on</p>	<p>-Patient's initial interests diminished after multiple uses. Revealed opportunities for application improvements.</p> <p>-Showed that it is possible to integrate a web-based COPD self-management application into current disease management process.</p>

				the organization of care.	
B. Qualitative Studies					
		<i>Goals/Objectives</i>	<i>Program Descriptions</i>	<i>Qualitative Methods used</i>	<i>Findings (from qualitative methods)</i>
9	Breaking barriers to self-management of chronic diseases – The MaXi project <i>(Nohr, C., Bertelsen, P., Kanstrup, AM., 2009)</i>	To understand barriers to patient’s ability to master chronic diseases by means of information technology	-Based on principles of Participatory Design and User Driven Innovation. “Living lab” concept with 3 phases: <ul style="list-style-type: none"> • Cooperation: Selecting innovators, evoking innovative potential • Contextualization: Understanding situations, staging situations (interviews, workshops, experiments) • Conceptualization: Conceptualizing ideas, Modeling): Sorting, Sketching, Visualizing 	-Qualitative data collection through family interviews (structured), post-cards and PDAs for additional data collection following interviews. -Prototype development and testing by participants in a “living lab”(utilizing participatory design and user-driven innovation)	-The “living lab” and participatory design provided a safe zone in which interactions between designers, enterprises and users can experiment with real life situations and yielded a richness of data adequate for design cycles.
10	Implementation and Evaluation of the Chronic Disease Self-Management Program among Chinese Immigrant Older Adults in the U.S <i>(Wang X., et al. 2014)</i>	To evaluate the experience Chinese older adults who participated in a CDSMP in a U.S metro area	Adaptation of the standard Stanford CDSMP (delivered in Chinese Mandarin by students).	One focus group session at the last workshop. (No details mentioned)	-Participants reported increasing in knowledge, skills, and confidence in the program. -Program capability in addressing culture differences may need improvements.

11	<p>Exploring telemonitoring and self-management by patients with chronic obstructive pulmonary disease: A qualitative study embedded in a randomized controlled trial</p> <p><i>(Fairbrother, P. et al., 2013)</i></p>	<p>To explore patient and professional views on self-management within the context of telemonitoring in chronic obstructive pulmonary disease</p>	<p>No intervention</p>	<p>-Purposive sampling of COPD patients and HC professionals to maximize baseline variation. -Semi-structured one-on-one interviews using an interview guide, audio recorded and transcribed verbatim. Interviews were conducted until data saturation had been reached. -Data analysis using the Framework approach consisting of 1) data management, 2) descriptive accounts, 3) explanatory accounts and involved multiple reviews of transcripts by the researcher, coding, identifying emergent categories and themes which then reviewed by the research team to refine categories and themes. Constant comparison (e.g. checking experiences between participants) to help ensure the analysis represented all perspectives.</p>	<p>-Patients considered telemonitoring empowered self-management by enhancing their understanding of COPD and providing justification to adjust treatment or seek professional advice. -Professionals discussed telemonitoring as promoting self-management but concerns about creating dependence on HCPs.</p>
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12	<p>Spanning Boundaries into Remote Communities: An Exploration of Experiences with Telehealth Chronic Disease Self-Management Programs in Rural Northern Ontario</p> <p><i>(Guilcher, SJ. Et al. 2013)</i></p>	To explore the experience of participants in a chronic disease self-management program via telehealth to inform future tele-CDSMP delivery models.	The Stanford CDSMP delivered via telehealth to rural communities in Northern Ontario.	<p>-Focus group post-intervention (minimum of 6 participants each) to explore the overall experiences of participants and to gain understanding of the facilitators and barriers of telehealth delivery.</p> <p>-Researcher triangulation (several research team members coded transcripts independently, and analyses are compared).</p> <p>-Thematic analysis consisting of transcript coding (dividing texts of transcripts into segments and attaching descriptive codes to these segments), grouping codes into topic-oriented categories, and refining topic-oriented categories into analytical categories (themes).</p> <p>-Concurrent data collection and data analysis to allow for confirmation or modification of emerging themes as new transcripts are analyzed.</p>	-Four final themes identified, together with key barriers and facilitators reported by focus group participants.
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13	<p>Recruitment for a clinical trial of chronic disease self-management for older adults with multimorbidity: A successful approach within general practice</p> <p><i>(Reed, R., et al. 2013)</i></p>	To explore reasons for participation in a CDSM support program.	Recruitment procedure for original study: Eligible participants received an invitation letter from general practices. Letters were signed by general practitioners endorsing the study, stressing the importance of their contribution, Prepaid return envelopes. Interested participants were further contacted for recruitment after receiving the return envelopes.	<ul style="list-style-type: none"> -Purposeful sampling of past participants between and within different strata for maximal baseline variations. -Sampling continued until no new information was found to emerge from the interviews (30 total). Interviews were tape recorded and transcribed. -Thematic analysis of transcribed data with researcher triangulation through team reviews of final coding, selection of quotes, and emerging interpretations. 	Primary reasons for participation identified were: Altruism, Hope of health gains, and Recommendation of doctors.
14	<p>Programmes to support chronic disease self-management: should we be concerned about the impact on spouses</p> <p><i>(Master, S. et al. 2013)</i></p>	To explore the impacts of Chronic Disease Self-Management Support (CDSMS) on Spouses.	The CDSMS Program is a clinician-led intervention including 3 home visits and 4 telephone calls over a 6-month period.	<ul style="list-style-type: none"> -Part of a mixed method approach. -Semi-structured interview with spouses using a pilot-tested interview guide. Voice recorded and transcribed. -Copies of transcripts were mailed to interviewees with a reply paid envelope to confirm accuracy, clarify meaning or expand on topics discussed. - Spouses were assigned 	-CDSM programs have little impact (either positive or negative) on spousal strains. -Increase in spousal strain may occur if there is deterioration in the health status of the CDSM participant.

				to low, moderate or high carer risk groups. Data analysis included open coding of transcripts; identifying themes which were discussed at weekly meetings there they are refined.	
15	<p>Mental health and Relational Self-Management Experiences of Patients with Type 2 Diabetes and Stage 3 Chronic Kidney Disease</p> <p><i>(Sakraida, TJ., Robinson MV., 2012)</i></p>	To characterize the transition experience to self-management in patients with T2DM and CKD.	No intervention. Participants recruited from endocrine and kidney specialty outpatient clinics at a medical center in the Rocky Mountain region who met pre-defined criteria.	<ul style="list-style-type: none"> -Convenient sampling, ethnography approach. -Two focus group sessions of the same group, 1 month apart to allow time for preliminary analysis of major themes and to refine interview guide questions to seek more thorough data. Utilize semi-structured interview guide with a moderator and two note takers. Audio recorded and transcribed. -Thematic analysis of transcripts and field notes. -Researcher triangulation during coding, developing and refining themes. 	-Two major themes regarding Mental Health Self-Management (Coping) and Relational Self-Management (Social support)
16	<p>Exploring Participation and Engagement in a Study of Self-</p>	To investigate why some participants engaged more fully than others in a CDSM program (the Pathways Home Program)	The PHP is a CDSM program for patients with COPD aimed to assist patients with developing skills in self-management in the	<p>Qualitative, interpretative study consist of:</p> <ul style="list-style-type: none"> -Purposive sampling to ensure diversity in age, gender, geographical 	-Motivation to participation is based on dominant voluntaristic or altruistic values, which can be

	<p>Management for People with Chronic Obstructive Pulmonary Disease</p> <p><i>(Willis, KF. et al. 2011)</i></p>		<p>community by facilitating the development of self-efficacy and provide participants with a self-management mentor.</p>	<p>location and illness severity. Semi-structured interviews, digitally recorded and transcribed verbatim.</p> <p>-Thematic analysis consisting of coding of transcripts, categorizing, and refining emerging themes. Alternating data collection and data analysis (data analyses between interviews) to allow for comments on areas for additional investigation or clarification.</p>	<p>problematic for researchers attempting to demonstrate the benefits of CDSM strategies.</p>
17	<p>Chronic disease self-management for individuals with stroke, multiple sclerosis and spinal cord injury</p> <p><i>(Sakraida, TJ., Robinson, MV., 2012)</i></p>	<p>To explore the experience of people with neurological conditions who take the CDSM programme.</p>	<p>Standard Stanford CDSMP</p>	<p>-Semi-structured interviews within 1 week of completion of CDSM workshop using an interview guide, tape-recorded and transcribing verbatim.</p> <p>-Content analysis consisting of identifying and refining categories and definitions with researcher triangulation by separate transcript coding and subsequent team review to reach</p>	<p>-5 categories emerged from interviews that might provide insights regarding optimal ways to present the CDSM program to people with neurological conditions.</p>

				<p>consensus on units of information.</p> <p>-Summary of findings mailed to participants with subsequent follow-up phone calls for confirmation of data accuracy.</p>	
18	<p>Seeking the views of health professionals on translating chronic disease self-management models into practice</p> <p><i>(Lake, AJ., Staiger, PK. 2010)</i></p>	<p>To examine health professional's formal self-management training and their views and experiences on the use of self-management techniques when working with people with a chronic illness</p>	<p>No intervention</p>	<p>-Purposive sample included a wide range of stakeholders involved in the care of individuals with a CD across professional disciplines.</p> <p>-Semi-structured interviews in both individual and group format, audio-taped and transcribed.</p> <p>-Thematic analysis consisting of coding, defining emerged categories and themes and researcher triangulation through consensus on emerging themes.</p> <p>-Ensure credibility, for example, by leaving an audit trail.</p>	<p>Professional preference for a "comprehensive" approach to self-management, relying primarily on 5 identified elements.</p> <p>-Revealed some central problems associated with CDSM regarding medication management or limited efficacy with some patient groups.</p>
19	<p>Chronic Disease Self-Management:</p>	<p>To understand how Chinese culture influences chronic disease self-</p>	<p>No intervention</p>	<p>-Qualitative descriptive study using focus group methodology</p>	<p>6 themes identified. Findings suggested older Chinese tend to make</p>

	<p>Views Among Older Adults of Chinese Descent</p> <p><i>(Wang, J., Matthews, JT. 2010)</i></p>	management		<p>-Recruitment by flyers in monthly newsletter and reception area of a senior center.</p> <p>-Two unique focus groups, 1 week apart using semi-structured schedule of questions, audio-taped. Transcribed in Chinese, then translated in English. Transcripts were reviewed by more than one facilitator.</p> <p>-Data analysis consisting of coding of responses, creating categories and identifying recurring themes.</p>	<p>healthy lifestyle decisions and view self-management of chronic disease as integral to everyday life. They also show strong influence of Chinese culture throughout all aspect of daily life. And difficulties communicating with HCPs may hamper efforts to optimize health.</p>
20	<p>Evaluation of a rural chronic disease self-management program</p> <p><i>(Stone, GR., Packer, TI. 2010)</i></p>	To evaluate the implementation process of the Stanford CDSMP into existing practice in an Australian rural setting.	Standard Stanford CDSMP	<p>-Participants were recruited by letters of invitation.</p> <p>-Semi-structured interviews with managers, course leaders and participants, subsequently audio-recorded and transcribed.</p> <p>-Thematic analysis to identify emergent themes as well as positive and negative perceptions of the program.</p>	<p>-Positives and negatives of providing the program were represented by two identified key themes: a) Program content and quality and b) Logistics of delivery</p> <p>-Recommendations by participants were grouped into 3 categories: (enhancing quality, improving logistics, and providing resources.)</p>
21	The experience	To examine the perceived	Standard Stanford CDSMP	-Qualitative study nested	-3 themes identified at

	<p>of attending a lay-led, chronic disease self-management programme from the perspective of participants with multiple sclerosis</p> <p><i>(Barlow, J., Edward, R., Turner, A. 2009)</i></p>	value and experience of the CDSMP for people with MS		<p>in a RCT. Study participants were purposively selected to ensure a range of ages and disease duration.</p> <p>-Telephone interviews of enrolled participants by two researchers at enrolment of CDSMP and 4 month follow-up on pre-determined subjects related to the program. Interviews were tape-recorded and transcribed verbatim.</p> <p>-Framework analysis (with pre-identified themes but allows for new themes to emerge from the data).</p>	<p>baseline, and 4 themes identified at follow-up.</p> <p>-The CDSMC was viewed as a valuable source of new skills and a reminder of previously learned self-management skills.</p>
22	<p>Understanding metaphor to facilitate emotional expression during a chronic disease self-management course</p> <p><i>(McFarland, L., Barlow, J., Turner, A., 2009).</i></p>	To investigate the role of emotional expression by identifying , from the perspective of the tutors, the emotions observed in people attending a CDSMC.	Standard Stanford CDSMP	<p>-Recruitment through emails to tutors who recently completed delivery of the CDSMC.</p> <p>-Semi-structured interviews with tutors, digitally recorded and transcribed verbatim. Interpretive phenomenological analysis (Offers insights into how a given person, in a given context, makes sense of a given</p>	Two main themes: Metaphor and Off-loading. Results could be applied to training of CDSMP tutors.

				phenomenon) including data familiarization, identifying relevant themes and refining themes. -Researcher triangulation through transcript cross-examination and verification of each other's findings.	
23	Health Literacy Self-Management by Patients with Type 2 Diabetes and Stage 3 Chronic Kidney Disease <i>(Sakraida, TJ., Robinson, MV. 2009)</i>	To describe self-management experience of patients diagnosed with type 2 diabetes and stage 3 CKD	No intervention	-Ethnography approach (to understand the illness experiences of select populations). -Purposive sampling to establish a focus group with different subsets of potentially contrasting and common viewpoints. - -Semi-structured focus group interviews and observation field notes. Two focus group sessions of the same group, scheduled 4 weeks apart to allow time for initial analysis and modification of questions. -Focus group meetings were transcribed and audited. Coding of clustered sentences, identifying and label	Two major threads of self-management experience identified: a) transition experience to self-advocacy and b) partnering with the health care provider.

				<p>patterns and themes.</p> <ul style="list-style-type: none"> -Multiple rounds of transcript review led to pattern redundancy and no new discernible themes supported conclusion of data analysis. -Information letter with identified patterns and themes sent to focus group participants to elicit whether the interpretation was congruent. 	
24	<p>Self-management behaviors for patients with chronic obstructive pulmonary disease: a qualitative study</p> <p><i>(Chen, KH., et al. 2008)</i></p>	<p>To explore the self-management behaviors of patients with COPD to understand how COPD patients manage their disease</p>	<p>No intervention</p>	<ul style="list-style-type: none"> -Convenience sampling. Sample size was determined by theme saturation (data collect continued until theme saturation was achieved during the last two interviews) with prolonged engagement of resourceful participants. -Semi-structured, face-to-face interviews, tape-recorded, transcribed and reviewed. -Concurrent data collection and data analysis. Data analyzed using three-step method: 	<p>Participants demonstrated the ability to choose disease management behaviors to prevent symptoms and complications. Identified 5 themes of disease management behaviors.</p>

				<p>data reduction (e.g. coding), data display (e.g. sorting of codes) and conclusion drawing (identifying and defining themes).</p> <p>-Researcher triangulation during analysis steps (e.g. transcript review, interpretation of findings).</p>	
25	<p>The Self-Management Experience of People with Mild to Moderate Chronic Kidney Disease</p> <p><i>(Constantini, L. et al. 2008)</i></p>	<p>To explore, describe and stimulate interest in the self-management experiences of patients with mild to moderate CKD</p>	<p>No intervention</p>	<p>-Purposeful sampling to ensure representation of men and women of varying ages.</p> <p>-Face to face semi-structured interviews to elicit participant's perceptions on pre-determined topics. Interviews are taped and transcribed verbatim. Memos were used to document non-verbal observations.</p> <p>-Content analysis consisting of line-by-line coding of text, repeated reviewing of transcripts to develop emerging themes.</p> <p>-Researcher triangulation to confirm findings and refine themes. Data analysis continued until</p>	<p>-A number of themes were identified.</p> <p>-Participants with early CKD want to self-manage their illness in collaboration with HCPs.</p>

				themes seen as accurately reflected experiences.	
26	<p>Factors contributing to intervention fidelity in a multi-site chronic disease self-management program</p> <p><i>(Perrin, KM., et al. 2006)</i></p>	To assess the fidelity of a CDSM program implementation	The Diabetes Mellitus and Hypertension Disease Self-Management Program based on health literacy principles in 14 community Health Centers in Florida	<p>-Review of documentation obtained from implementation of a larger study: Logs of technical assistance and field notes, class observations, patient narratives, exit interviews with health educators</p> <p>-Qualitative data entered into qualitative analysis software, reviewed by project staff, who developed a coding scheme and agreed upon common themes.</p>	The program was implemented with high fidelity to the original design.
27	<p>Qualitative evaluation of Chronic Disease Self-Management Program in Shanghai</p> <p><i>(Dongbo, F., et al. 2006)</i></p>	To explore the impact of Chronic Disease Self-management Program on participants' perception of their behavior, health status and quality of life.	The Shanghai CDSMP is based on the original Stanford CDSMP with modifications to become more culturally acceptable to Chinese population	<p>-Purposeful sampling to ensure a broad demographic and chronic disease spectrum. Sampling stopped when new topics no longer emerged from the last three interviews.</p> <p>-Semi-structured one-on-one interviews with an interview guide. Audio-taped and transcribed. Content analysis with researcher triangulation through individual coding</p>	6 themes emerged. The CDSMP was perceived to be effective to participants, though it has a few deficiencies on content and delivery that need to be modified.

				of transcript, identifying and categorizing themes which then subsequently discussed and refined as team. -Final interpretation was sent to participants for validation.	
28	A qualitative study of GPs' attitudes to self-management of chronic disease <i>(Blakeman, T. et al. 2006)</i>	To explore General Practitioner's perspectives on their involvement in the facilitation of CDSM	No intervention	-Purposive sampling to acquire a wide range of characteristics such as sex, practice size and contractual status. -Semi-structured face-to-face interviews on pre-determined areas using an interview guide. Audio-taped and professionally transcribed. -Open coding. Categories are identified by comparison of codes. Categories found to relate to an existing theoretical model on the topic (Howie's theoretical model).	Three main themes related to three areas of the existing theoretical model: content of the consultation, GP values and context in which care is provided.
29	Self-management Training for People with Chronic Disease: A	To understand participant's experience of the CDSMC and subsequent use of self-management techniques	The Standard Stanford CDSMC comprises six, weekly sessions, lasting 2 hours each, and is delivered by pairs of trained lay leaders.	-Purposeful sampling of program participants representing a mix of diagnoses, age and gender using multiple recruitment methods.	-Participants appreciated the opportunity to share experience in a reassuring environment by attending the program. Goal setting

	<p>Shared Learning Experience</p> <p><i>(Barlow, JH., Bancroft, GV., Turner, AP. 2005)</i></p>			<p>-Semi-structured phone interviews at 4 month and 12 month post intervention on pre-defined topics. Audiotaped and transcribed.</p> <p>-Content analysis through multiple reviewing rounds of transcripts, identifying emerging themes.</p> <p>Researcher triangulation through independent data analysis and subsequent consensus over categorization of data.</p>	<p>was critical in making changes.</p>
30	<p>Volunteer, lay tutors' experiences of the Chronic Disease Self-management Course: being valued and adding value.</p> <p><i>(Barlow, JH., Bancroft, GV., Turner, AP. 2005)</i></p>	<p>To examine tutor's experience of course delivery and their perceived impact on their own use of self-management techniques.</p>	<p>Standard Stanford CDSMC</p>	<p>-Purposive sampling to give a range of chronic disease, age and gender. Telephone interviews using a guide. Audiotape and subsequently transcribed.</p> <p>-Thematic analysis including coding, multiple reviews of transcripts and identifying and refining themes.</p> <p>-Researcher triangulation by independent data analysis by two researchers and subsequently reaching</p>	<p>-Being a lay tutor was perceived to be enjoyable and valuable experience despite a number of challenges associated with course delivery.</p> <p>-Course delivery prompted the initiation and maintenance of tutors' own self-management behaviors.</p>

				consensus over categorization of data.	
31	<p>Qualitative Exploration of Rural Focus Group Members' Participation in the Chronic Disease Self-Management Program, USA</p> <p><i>(Harvey, IS, Janke, M. 2014)</i></p>	To explore the benefits perceived by rural residents due to their participation in the CDSMP	The Standard Stanford CDSMP	<p>-Qualitative exploratory study with phenomenological approach.</p> <p>-Six focus groups (34 participants total). Audio-taped, transcribed verbatim by a research assistant and verified by another.</p> <p>-Thematic analysis involving data familiarization, coding, categorization, developing and refining themes. Inter-rater using external auditor for validation of raw data and final themes. (Researcher triangulation)</p>	2 prominent themes suggesting that CDSMPs can initiate positive changes which can in turn influence the health of rural populations.
32	<p>Building the Evidence Base for Chronic Disease Self-management Support Interventions Across Canada</p> <p><i>(Johnston, S., et al. 2012)</i></p>	To determine how to improve evaluation of self-management support in Canada	No intervention	<p>-Multi-method approach:</p> <ul style="list-style-type: none"> • Literature Review • Internet Scan • Stakeholder semi-structured Interviews and subsequent thematic analysis • Theoretical framework review • Expert review meeting 	-Four common themes identified. -Stakeholders need better evidence on how to support self-management in their communities. -Outcome evaluation must be an explicit part of program implementation.
33	A 12-month	To describe participants'	Adopted versions of the	As part of a larger study,	CDSMP participants

	<p>follow-up study of self-management training for people with chronic disease: Are changes maintained over time?</p> <p><i>(Barlow, JH. et al. 2005)</i></p>	<p>use of self-management techniques 12 months after commencing the CDSMP course</p>	<p>Stanford CDSMP in the U.K</p>	<p>phone interviews were conducted with a subset of participant, followed by content analysis to identify themes.</p>	<p>compared themselves with others and were motivated to change the way they manage their conditions.</p>
34	<p>Chronic disease self-management and health literacy in four ethnic groups</p> <p><i>(Shaw, SJ., et al. 2012)</i></p>	<p>To gain insight into day-to-day chronic disease self-management practices.</p>	<p>No intervention</p>	<p>-Participants recruited from a community health center in a medically underserved, refugee resettlement area. -Combination of focus groups and in-depth interviews conducted, audio-taped, transcribed and translated to English together with chronic disease diaries and home visits. -Individual coding of transcripts, theme development and refining by three individual coders during regular meeting.</p>	<p>Culturally variable health beliefs identified among participants interviewed that may play important roles in their chronic disease self-management practices.</p>

5.3. Results

5.3.1. Usability Studies

The majority of known innovative products and tools that assist with chronic disease self-management have been computer-based applications designed to deliver self-management education^{2,3,6-8}, enhance self-efficacy⁶ or assist with tracking and monitoring of chronic conditions¹⁻². Reviewed usability studies uses two common approaches to evaluation of innovative products or tools:

Those conducted prior to completion of final prototype^{1,4,5,7} often utilized the user-centered approach by asking participants to perform a number of pre-determined tasks, either in their natural setting (e.g. home) or within a “testing environment” with the *primary goal of refining the developing prototype*. Collected data has commonly included participant’s perceived usefulness, perceived ease of use, satisfaction and areas of improvement using both quantitative and qualitative methods such as post-test questionnaires and interviews. Performance measures such as task completion time, frequency of error, frequency of help together with non-verbal reactions were also often collected during the testing period.

Other usability studies were conducted at later stages of the product development cycle (e.g. after a final functional prototype has been developed) and sought to evaluate clinical effectiveness of the newly developed product on outcomes of interest.^{2,3,6,8} These studies often administered validated clinical scales at baseline and periodically to participants during the testing period to measure clinical outcomes such as quality of life^{2,6}, self-efficacy⁶ and satisfaction⁸.

5.3.2. Qualitative Studies

The majority of reviewed qualitative studies on chronic disease self-management have focused on evaluating aspects of an existing CDSMP from the participant's perspective, most notably participant's experience as the result of participating in CDSMP^{10,12,15,19,21,27,29} or their motivation for program participation^{13,16}. Other studies have explored program experience and impacts on other stakeholders such as spouses¹⁴, professionals^{11,18,28} and program leaders^{9,22,30}. Common qualitative approaches to address the research questions have included semi-structured one-on-one interviews^{11-18, 20-22, 24-25, 27, 28-30,34} and focus groups^{10,19,23,31,34} as data collection methods; data analysis typically involved familiarization with interview transcripts, coding, searching for themes, revising and defining themes^{11-13, 15-18, 20, 22-25, 27, 29-31} in consistent with steps to conduct thematic analysis proposed by Braun and Clarke (2006).⁹⁴ Use of qualitative data analysis software (such as NVivo7) is also common to assist with the coding and subsequent analysis steps. Strategies to ensure rigors are also commonly employed and have included researcher triangulation (e.g. by having each researcher perform data analysis independently and results are reviewed as team)^{12,13,15,17,22,24,25,27,29-31,34}, data saturation determination (e.g. analysis is performed during data collection process to allow for comments on areas requiring additional investigation or clarification and to determine when no new data is generated)^{11,13,24,27}, purposive sampling (in order to maximize baseline variations)^{11,13,16,18,21,23,25,27-30}, and participant validation (the collected data is "played back" to the informant to check for perceived accuracy and reactions)^{14,17,18,23,27}.

VI. MEDICATION ADHERENCE

6.1. Definition and Prevalence

Medication adherence is an important aspect of chronic disease and medication self-management and has been defined as “the extent to which patients take their medications as directed by healthcare providers over the prescribed period”.⁵⁹

The threshold by which medication adherence is determined is debatable and depends on the condition for which the medication is being taken.⁶⁰ For example; therapies for conditions such as HIV or oral contraception generally require a very high level of adherence in order to maintain effectiveness. For common chronic conditions such as hypertension, diabetes and hyperlipidemia, patients are usually considered adherent if they take more than 80% of the prescribed medications.⁶⁰ Despite being used in many medication adherence studies for categorical purposes, this cut-off point is somewhat arbitrary and there is evidence suggesting that there may be additional clinical benefits when going beyond the 80% cut-off point.⁶¹

Clinical trials have reported adherence rates varying between 43-78% among patients receiving treatments for chronic conditions.⁵⁹ Types of chronic conditions^{62,63} and duration of treatment therapy⁶⁴ also appeared to have an influence on medication adherence.

6.2. Impacts of Medication Adherence on Outcomes and Costs

Many observational studies have associated better medication adherence with improved outcomes and decreased costs of care.^{65,66,67} However, Ho et al. noted the observed association between adherence and outcomes might be in part due to medication adherence being a surrogate marker for the overall healthier behaviors such as eating healthy and regular exercising which were the real underlying reasons

for improved outcomes.⁶⁸ This is supported by post-hoc analyses of randomized controlled trials in which even adherence to placebo was associated with better outcomes. For instance, in the Beta-Blocker Heart Attack trial, patients who were non-adherent (defined as taking less than 75% of the prescribed medication) had an increased risk of death regardless of whether they were on propranolol (OR = 3.1) or placebo (OR=2.5).⁶⁹ Similar findings were reported in the Canadian Amiodarone Myocardial Infarction Arrhythmia Trial (CAMIAT) (increased RR of 2.11 and 3.15 for sudden cardiac death in non-adherent placebo and treatment groups respectively compared to adherent groups)⁷⁰ and the Candesartan in Heart Failure: Assessment of Reduction in Mortality and Morbidity (CHARM) program (reduced HR of 0.64 and 0.65 in mortality for adherent placebo and treatment groups respectively).⁷¹ These results suggested that good adherence behavior can be independently associated with improved clinical outcome and while not meant to undermine the importance of appropriate medication therapy in disease management, they prompted the broadening of adherence definition to include not only compliance to medication regimens but also patient ability to carry out other healthy behaviors that may affect clinical outcomes.⁶⁹

Estimated costs of medication non-adherence in the U.S range from \$100 to \$300 billion depending on reporting sources.^{59,66,72} Additionally, between 33 to 69 percent of all medication-related hospital admissions in the U.S are reportedly due to poor medication adherence.⁷¹

6.3. Causes

The causes of medication non-adherence are usually multi-factorial. Patient-associated factors include depression, physical limitations, cognitive impairments, younger age and lower health literacy. Medical conditions that are asymptomatic such as osteoporosis or hyperlipidemia have also been associated with higher non-adherence rates.⁶⁸

External factors can also impact medication taking behaviors. For example, institutional processes such as medication reconciliation and discharge counseling could play a role in improving patient's understanding of their medication regimen and promote adherence.^{73,74} Additionally, effective patient-physician communication could also be important to adherence maintenance.^{75,76}

The medication regimen itself can also affect adherence. Complex regimens with multiple medications, complicated directions of use, high dosing frequency and high costs have all been associated with lower adherence levels.^{77,78,79}

6.4. Medication Adherence Measurement Strategies

Osterberg categorizes methods to measure adherence as either direct or indirect.⁵⁹ Direct methods include observing patients taking medications and measuring serum levels of drugs, metabolites or biologic markers. Observing patient taking medications is probably among the most accurate and objective methods but is time consuming and often is impractical in clinical settings.⁶⁸ Measuring serum levels is also time consuming, requires expensive equipments and the results can sometime be distorted by patients who intentionally take their medications more frequently during the period just before testing, a phenomenon known as "white coat adherence".⁶⁸

Indirect methods have included patient self-report, assessing clinical response, performing pill counts, reviewing medication refill rates and electronic monitoring devices.

Obtaining adherence self-report by ways of interviews or validated clinical scales such as the MORISKY Scale (*Appendix 7*) is relatively simple to perform, but is susceptible to patient's recall bias as well as intentional lying which can lead to either under- or over-estimation of actual adherence.⁶⁸ Assessing clinical responses such as blood pressure, blood sugar levels or INR to determine medication adherence

can also be confounded by factors other than adherence itself such as diet, disease progression and drug interactions.⁵⁹

Pill count is one of the most commonly used adherence measurement strategies in clinical trials.⁶⁸ In this method, the actual number of pills in the drug container is counted and compared with the number of pills that is *supposed to be* in the container if the patient was taking the medication as directed. While the simplicity and objective nature of this method can be attractive to investigators, it cannot confirm whether the missing pills were actually taken by the patient, nor does it reveal the timing of doses taken which is important for some medications to be effective.

Refill records in computerized pharmacy systems have been increasingly utilized as a source for adherence information.⁶¹ While less time-consuming than pill count, refill record shares the same limitations mentioned previously. Nevertheless, a review conducted by Steiner, et al.(1997) found significant associations between refill records and other compliance measures and serum drug levels.⁸⁰ Moreover; adherence data obtained from refill records has been correlated with a broad range of clinical outcomes.⁸¹

Medication Event Monitoring Devices (MEMDs) have been used in clinical trials over the past 30 years to obtain adherence data.⁵⁹ These devices are capable of recording the time the medication bottle was opened and thus can provide a more detailed picture on patient's medication taking behavior such as exact date and time the medication was supposedly taken in addition to the overall adherence rate. Nevertheless, they still measure medication adherence indirectly and therefore incapable of confirming whether the patient actually takes the pill every time the container is opened. Additionally, the high costs of these devices prevent them from being widely used outside of clinical trials.⁵⁹

6.5. Overview of Adherence Interventions

Interventions to improve adherence have been classified into four general categories: patient education, improved dosing schedules, improved clinic availability and improved patients-physician communication.⁵⁹ Patient education can be delivered face-to-face , by mail or by phone to patients or caregivers and generally aimed at improving disease and medication knowledge as well as self-efficacy.⁸² Strategies to improve dosing schedules include use of pill boxes, blister packs, simplifying dosing regimen and refill synchronization. Improved clinic availability usually involved making follow-up visits more convenient for patients and reducing wait time.⁵⁹ Finally, improved patient-provider communication has included regular telephone follow-ups and mailed communications.⁸²

Not all interventions have been shown to effectively improve medication adherence.^{82,83} In fact, even the most successful interventions have only led to moderate increases in adherence and treatment outcomes.⁸² Additionally, effective interventions were often complex and included a combination of many different strategies which makes generalization problematic, especially on which strategy worked and which one did not.⁸²

VII. HEALTH CHALLENGES IN RURAL CANADA

As we expected the majority of project participants will have come from small towns and rural areas of Canada, it was necessary for me to obtain a background on unique challenges rural residents face that could prevent them from obtaining needed care. This section highlights some main health challenges of Rural Communities and their residents.

A major challenge to rural Canadians has been accessibility to health services.⁸⁴ People in rural, remote and northern communities often have to travel long distances to obtain medical services. Rural residents are on average about 10 kilometers away from a physician compared to less than 2 kilometers for

residents in larger urban areas.⁸⁵ In northern and remote regions of Canada, nearly two-thirds of the population lives more than 100 kilometers away from the nearest doctor.⁸⁶ Geographic isolation, coupled with poor road condition, not only compromise access to health services but also directly contribute to higher incidence of on-the-road injury.⁸⁴

Compared to their urban counterparts, it is harder for rural residents to obtain quality care due to the inherent shortage of healthcare providers and services in rural areas. Physicians, especially medical specialists and nurses are concentrated in urban locations. Additionally, in many small rural communities there are no hospitals, and while the larger rural centers may have hospitals with basic facilities, patients typically have to be transported to larger urban centers for specialized treatment.⁸⁷

Aside from access to care, the inherent social-cultural structure, economic difficulties and working condition also contributes to health vulnerability of residents in rural communities. Most rural communities have a high “dependency ratio”, that is, large populations of children and seniors and relatively small populations of people of working age. This age distribution is a result of a combination of the aging rural population, the tendency of retirees to move into rural areas, and the migration of rural youth to urban centers for further education and employment opportunities.⁸⁵ Rural residents also have personal incomes well below the national average, lower levels of formal education and fewer employment opportunities compared to their urban counterparts.⁸⁵ Moreover, rural working conditions can pose serious health and safety hazards to rural workers due to the growing use of complex machinery, exposure to chemicals, noise, long working hours and extreme temperatures.⁸⁵ The rates of smoking, obesity and physical inactivity in most rural communities have also been reported above the national averages^{84,85} and they are major risk factors for chronic conditions such as diabetes, arthritis and high blood pressure and can lead to disabilities.

SECTION 2: EVALUATING THE USABILITY OF A MEDICATION ORGANIZING TOOL ON MEDICATION SELF-MANAGEMENT AT HOME: A PROOF-OF-CONCEPT EXPERIMENT

This section describes our methodological approaches to examine the perceived usefulness of a medication organizing tool (the MedManager) to one's medication self-management tasks, and reports on our findings and conclusions.

I. OVERVIEW ON THE MEDMANAGER CONCEPTUAL DESIGN, NEED ANALYSIS AND PROTOTYPE DEVELOPMENT

1.1. Conceptual Design

The “MedManager” design (*Appendix 1*) was developed by an emergency physician due to his experience that many patients arrived at the emergency room without their medications and medical information while others had an unorganized way to carry medications with them. This consequently reduced staff efficiency and quality of care. The designer believed a tool allows patients to organize home medications and medical information that could also be conveniently carried to emergency rooms or office visits would be helpful to both patients and health professionals.

1.2. Pre-production Need Analysis

In order to examine public opinion on this conceptual design, the designer conducted two surveys, one with potential end-users, the other with practicing community pharmacists.

i. End-user Survey (n=10) (Appendix 2)

Ten potential end-users (unknown baseline characteristics) were shown the MedManager design and asked about their medication management habits. Responses from the survey showed that: a) The majority of surveyed patients (6 out of 10) reported not having an organized system to manage home medications and b) Most (7 out of 10) were also interested in, and would purchase a product as designed if the price was less than \$30.

ii. Community Pharmacists Survey (n=5) (Appendix 3)

Five community pharmacists were asked if their pharmacies were selling any systems to assist with medication organization and their thoughts on the design. Pillboxes and compliance packaging were the only organization tools reportedly available in pharmacies. Additionally, all five pharmacists thought the toolkit would be useful for people with multiple medications and is something they would promote to their patients. Cost and the large size of the design were mentioned as potential barriers to its use.

In summary, data from the two simple surveys together with the designer's personal experience as a physician suggested that there may be a) Unmet needs in the area of home medication management (as reported by surveyed patients and current lacking of a product designed to help with medication organization) and b) Interests from both patients and healthcare professionals in the MedManager design.

1.3. Prototype Development

The design had undergone several modifications during prototype development. The final prototype which was mass-produced has the following features and components: *(Appendix 4)*

- Storage space for medication vials and medical documents

- A 7-day pillbox

- A Medication List Template *(Appendix 5)*

-A Calendar that also serves as appointment reminder and allows for daily recording of Blood Pressure, Blood Sugar and Weight

-A Pill Cutter / Magnifying Glass / USB Drive / Notepad

II. PROJECT RATIONALES AND OBJECTIVES

Ability to manage home medications is important to maintain safety and effectiveness of medication regimen and is a significant component of chronic disease self-management process. Efforts to improve medication and disease self-management have traditionally been focusing on enhancing self-efficacy through education on disease knowledge, problem-solving skills and decision making skills. While this approach has improved certain outcomes in the short-term, the effects were often seen to have diminished over time after the intervention has stopped. Moreover, the complexity of existing interventions coupled with unclear cost-effectiveness can be barriers to their widespread implementation outside of clinical trials. These shortcomings justify development and evaluation of innovative approaches to further assist patients with self-management tasks.

We were presented with evidence that many patients may not have an organized way to store their medications and medical information at home, and that patients and healthcare providers were interested in a design (the MedManager design) intended to assist with home medication organization. The usefulness of such tool in the real world however is unknown because to our knowledge, there were no similar products available publicly. We therefore would like to see if patients would find the MedManager helpful and if they would utilize it in performing medication self-management tasks as well as their rationales for utilizing (or not utilizing) the tool.

We realized that efforts to understand the rationales for utilizing (or not utilizing) the MedManager needs to be based on an understanding of patient's existing medication management strategies. To our knowledge, this area was not well-characterized in existing literature.^{88,89} We therefore also would like to learn how people are currently managing their medications at home including rationales for adopting such management strategies and any barriers they currently have.

Project Objectives:

a. *Primary objective:*

To determine if introducing the MedManager to participants would lead to its utilization.

b. *Secondary objectives:*

- i. *To examine the underlying reasons for utilizing (or not utilizing) the MedManager by participants.*
- ii. *To evaluate the effect (if any) of the MedManager on the following clinical outcomes:
Blood Pressure, Blood Sugar and Weight.*

III. METHODOLOGICAL APPROACHES

3.1. Study Design

In order to answer the main research question (whether participants would find the MedManager useful), we planned to conduct a proof-of-concept experiment where eligible participants would be introduced to the MedManager which is made available free-of-charge. An in-person follow-up session would then be conducted at participant's house during which observations are made in each of four areas: Medication list, Medication Storage, Adherence Aids, and Clinical Parameter/Symptom Tracking in order to understand participant's existing medication management strategy and to determine

whether the MedManager was utilized in each of these areas. This approach reflected the post-positivist form of enquiry where the researcher attempts to make a knowledge claim using quantitative strategies and methods while ensuring the validity of research claims by remaining objective throughout the research process.⁹⁰

Our observations would then be followed by a one-on-one semi-structured interview to explore participant's rationales for utilizing existing management strategies and the MedManager if applicable, and to obtain any suggestions participants may have for product improvements.

3.2. Inclusion and Exclusion Criteria

Participants were invited to enroll in the project if they either:

- a) Have expressed interests in using the MedManager toolkit

-Or-

- b) Have met one of the following criteria:

- Take 5 or more chronic medications

- Take 12 or more doses per day

- Have 3 or more chronic conditions

- Have difficulty with remembering to take medications (e.g. medication non-adherence)

- Take one of the following medications (Warfarin, Anti-seizures medications, Mood stabilizers, Digoxin)

-Have vision problem, dexterity problem (arthritis, etc.), mild cognitive impairment or language difficulties

We were interested in recruiting patients who we believed would be most likely to find the toolkit useful. And while it was unclear to us during project planning who, if any at all, would find the MedManager useful, since the MedManager was intended primarily as an organizing and adherence-assisting tool, we thought those who having difficulties with medication organization and adherence may find the tool beneficial. Among these are those with complex medication regimens, multiple chronic conditions, non-adherent, or have certain conditions that could interfere with performing medication management tasks such as vision problems or dexterity problems. Furthermore, we didn't want to limit our recruitment to a rigid set of criteria and therefore also enrolled those who had expressed an interest in using the MedManager even though they may not have met our other inclusion criteria.

There were no explicit exclusion criteria.

3.3. Recruitment

We set recruitment goal at 25 participants based on the number of MedManager we had and estimations on other resources made available for the project. Recruitment was done primarily in Seaforth, Ontario. We approached potential participants in two main ways: we either invited patients at a local pharmacy clinic to complete a screening survey (*Appendix 6*) following their regular clinic appointments or introduced them to the MedManager in-person by way of an information desk set up at the Huron Community Care Access Center lobby. Those who met at least one of our inclusion criteria were further contacted for enrollment. A number of other recruitment strategies such as newspaper

and online advertisements were also tried over the course of the project. *Table 6* in the Results section listed recruitment strategies attempted and the number of participants we recruited from each strategy.

3.4. The Orientation and Follow-up Sessions

All enrolled participants received a one-on-one Orientation session where they were introduced to project objectives, provided an overview of the MedManager components, and information about the follow-up session regarding setting, duration, planned activities and expectations. The MedManager was typically delivered to participants at the end of the Orientation session.

During orientation, we administered the Morisky Scale to enrolled participants in order to assess their self-reported medication adherence level. The Morisky Scale (*Appendix 7*) is a validated four-item scale that has been used to assess adherence in many studies including chronic disease self-management studies.^{91,92} The scale classifies patients as having high, intermediate or low adherence based on their responses to the four Yes/No questions. Also during the Orientation, we asked participants a series of eight Yes/No questions (*Appendix 6*). These questions were adapted from the Medication Use and Self-Efficacy (MUSE) Scale which is a brief 8-item scale that has been shown to be reliable to assess self-efficacy in understanding and using prescription medications.⁹³

A one-on-one follow-up session was then scheduled to occur within a month of the MedManager delivery and was conducted at participant's home or at an alternate location (e.g. pharmacy clinic) if preferred by participants. 11 out of 12 follow-ups were conducted in participant homes.

During the follow-up session, we examined four areas within the participant medication self-management process: Medication List, Medication Storage, Adherence Aids and Clinical Tracking

System. In each area, using a guide, the study staff recorded a description on existing management strategy and whether there were any changes after the MedManager was introduced.

Also during the follow-up session, using a semi-structured interview format, (Appendix 8) the study staff interviewed the participant on his/her perceived advantages and disadvantages of existing management strategy and of the MedManager in each of the four areas, together with any suggestions for product improvement.

Table 6 summarizes the two main steps that make up the project intervention

Table 6: Two main steps in implementation of project intervention

<p><u>Step 1: Orientation</u></p> <p>Recruited participants are introduced to MedManager and study objectives.</p>
--

<p><u>Step 2: Follow-up session (preferably at participant's house)</u></p> <ul style="list-style-type: none">● Observations on existing medication management strategies and MedManager utilization in each of four pre-determined areas● Interviews on perceived advantages and disadvantages of existing medication management strategies, benefits of the MedManager and suggestions for product improvement

3.5. Data Collection and Analysis

We collected data on a) Participants' Baseline Characteristics (*Table 8*), b) Descriptions on existing medication management strategies (*Tables 9 and 11*), c) Utilization of MedManager components (*Table 10*) and d) Suggestions for improvement (*Table 12*). Data was collected primarily from the screening surveys and during follow-up sessions.

In an attempt to quantify participant's overall utilization of the MedManager, we assigned points to each component based on their utilization status at follow-up as followed:

-Currently Using: 2 points

-Not Using/Plan to Use: 1 point

-Not using/Do not plan to use: 0 point

We then calculated the total points earned by each participant to come up with their overall MedManager "Utilization scores" and plotted the scores against selected baseline characteristics to determine if there would be a correlation. We also examined for correlation between utilization of the MedManager's storage function exclusively against selected baseline characteristics as this is the most important function of the tool.

In order to analyze qualitative data collected during observations and interviews, we performed thematic analysis on notes obtained from follow-up sessions. Written notes were digitized, typically on the day obtained, in order to improve clarity and give the investigator a chance to review for accuracy and completeness as well as to become more familiar with collected data. We then identified codes from the processed data and sorted them under pre-defined categories together with associated observations, participant responses or quotes from which the codes were generated. Codes identified within each category were then examined to identify common themes. These themes were then reported together with associated quotes and observations as illustrations. Our thematic analysis steps were similar to those proposed by Braun and Clarke (2006), which consisted of data familiarization, generating initial codes, looking for themes, revising developed themes and defining themes.^{94,95}

IV. RESULTS

4.1. Recruitment and Retention

Figure 2 summarizes our recruitment process and retention

Figure 2: Overview of Project Recruitment and Retention at Follow-up

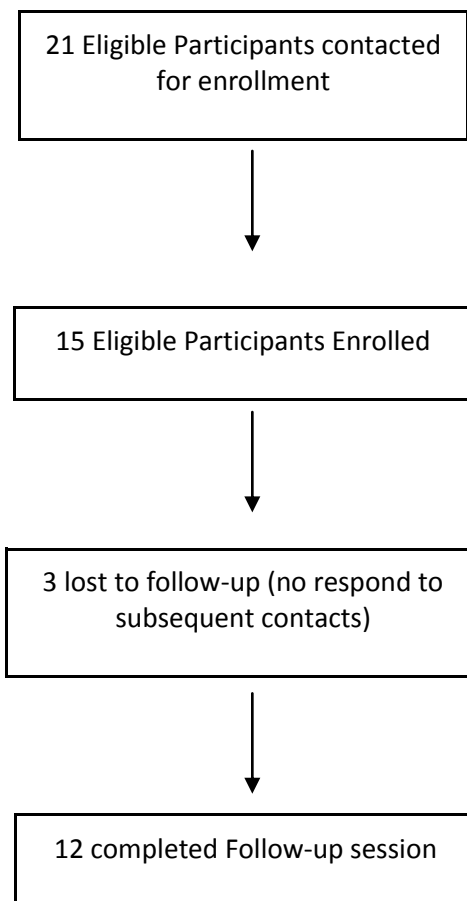


Table 7: Attempted recruitment strategies and number of participants recruited from each strategy

<i>Recruitment Source</i>	<i>Number recruited</i>	<i>Number completed follow-up interview</i>
Pharmacy clinic at local FHT	9	8
Information table at FHT lobby	3	3
Local research organization	2	0
Referrals from local physicians	1	1
Advertisement on local newspaper and hospital website	0	0
Direct emailing to potential participants	0	0
Total	15	12

We found direct, face-to-face recruitment strategies were more effective than indirect strategies (e.g. advertisement or emailing). Furthermore, an established trusting relationship with participants and physicians played an important role in recruitment successes as we observed hesitancy from both potential patients and physicians due to perceived project commitments and the unknown variables associated with the MedManager use.

4.2. Baseline Characteristics

Key baseline characteristics of participants are summarized in *Table 8* below. Our sample consisted mostly of participants 50 years of age or older and had a somewhat balanced gender mix. Many had relatively complex medication regimens with 9 out of 12 participants take seven or more regular medications up to 5 times daily. Most participants also demonstrated high levels of medication adherence as evidenced by the MORISKY Scores and self-reported number of times forgets to take medications per week (mean = 0.7/week). Additionally, most participants also reported a strong belief in their ability to learn about and use medications per their responses to screening survey questions.

Table 8: Participant's Baseline Characteristics (n=12)

	<i>Mean</i>	<i>(Range, SD)</i>
Age	60-69*	(<40 - >69, n/a)
Gender	7F/5M	
Regular medications	7.8	(2 - 13, 3.22)
Times to take scheduled medications per day	2.7	(1 - 5, 1.07)
Times forget to take medications per week	0.7	(0 - 2, 0.78)
Number of pharmacy(s)	1.2	(1 - 3, 0.58)
Primary physician visits over last 12 months	4.6	(1 - 14, 3.86)
MORISKY Score (0-4)	3.6	(3 - 4, 0.52)
Time to follow-up (days)	26.8	(18-33, 3.93)

*Most commonly reported age group

4.3. Summary of Existing Medication Self-Management Strategies and Utilization of MedManager at Follow-up

Tables 9 and 10 summarize our observations on characteristics of participant's existing medication self-management strategies and utilization of the MedManager at follow-up in the four pre-determined areas.

Table 9: Characterizations of Participant's Existing Medication Self-management Strategies (n=12)

	YES	NO
<i>Medication list</i>	8	4
<ul style="list-style-type: none"> ● Self-made <ul style="list-style-type: none"> ○ Hand-written ○ Electronic ● Prepared <ul style="list-style-type: none"> ○ By Hospital ○ By Pharmacy ○ Spouse/Relative 	<p>4</p> <p>2</p> <p>2</p> <p>4</p> <p>1</p> <p>2</p> <p>1</p>	
<i>Medication storage location</i>	12	0
<ul style="list-style-type: none"> ● Kitchen ● Livingroom ● Bedroom ● Bathroom ● Other 	<p>5</p> <p>3</p> <p>2</p> <p>2</p> <p>0</p>	
<i>Medication storage container</i>	12	0
<ul style="list-style-type: none"> ● Cabinet 	6	

<ul style="list-style-type: none"> ● Plastic container ● Open surface/Not reported 	<p>4</p> <p>2</p>	
<p><i>Medication Adherence Aids</i></p> <ul style="list-style-type: none"> ● Pillbox ● Blisterpacks 	<p>7</p> <p>6</p> <p>1</p>	<p>5</p>
<p><i>Clinical parameter or symptom tracking system at home</i></p> <ul style="list-style-type: none"> ● Notebooks ● Blood glucose meter 	<p>3</p> <p>2</p> <p>1</p>	<p>9</p>

**Section 4.5 provides a more detailed discussion on existing medication self-management strategies.*

Table 10: Utilization of MedManager Components at Follow-up (n=12)

Component	<i>Using</i>	<i>Not Using/Plan to use</i>	<i>Not Using/Do not plan to use</i>
<i>Medication List Template</i>	0	6	6
<i>Storage function</i>	7	0	5
<i>Provided Pillbox</i>	4	3	5
<i>Calendar</i>	2	1	9
<i>Pill cutter, Magnifying glass or USB drive</i>	1	1	10

Our participants also had a mean Utility Score of 3.1 (Range=0-7, SD=2.43). (The Methods section explains the purpose of Utility Scores and how they are calculated.)

4.4. Correlation between MedManager Utilization and selected Baseline Characteristics

We were interested in examining if certain baseline characteristics could have an influence on MedManager utilization. The following Charts present sub-group comparisons on the MedManager utilization in selected baseline characteristics using the calculated Utilization Scores (*Charts 1-3*). Additionally, we also looked specifically at utilization of the MedManager's storage function (*Charts 4 and 5*).

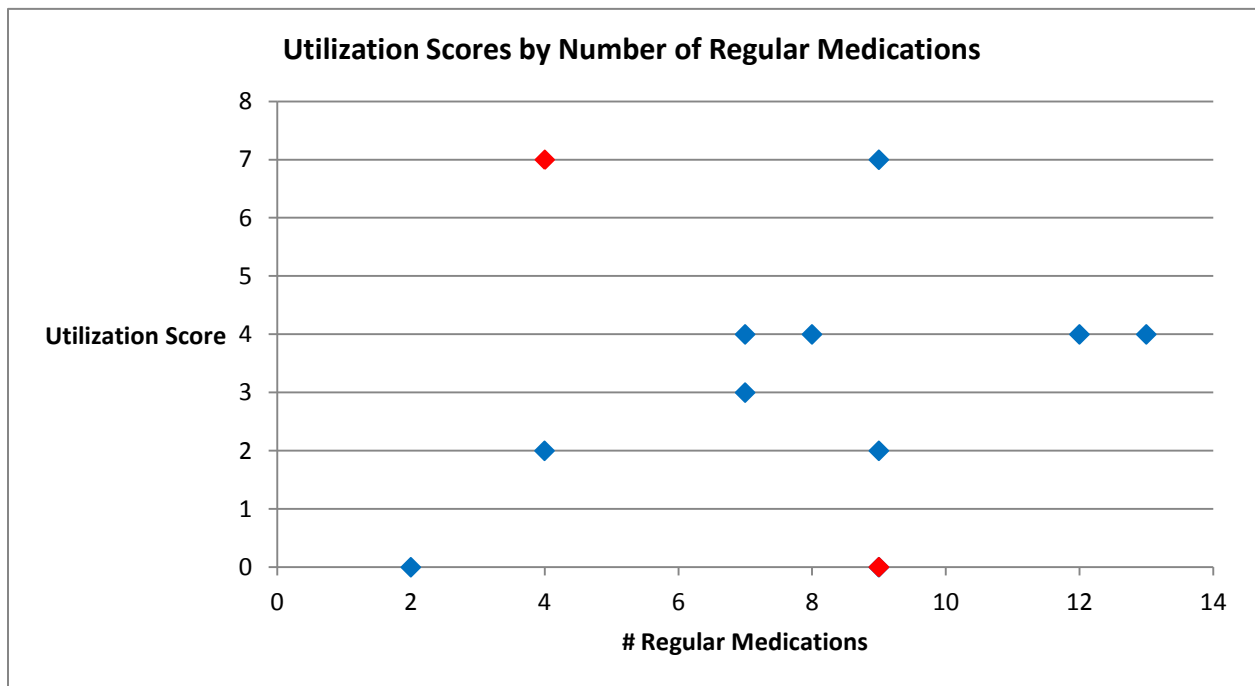


Chart 1: Scatter Diagram of Participant's Utilization Score by Number of Medications

*Higher Utility Scores represent higher overall utilization

In general, we do observe a correlation between participants' number of medications and their Utilization Scores with the exception of a few outliers (as shown in red) in *Chart 1*. Additionally, participants using plastic containers as storage system and those had a *self-made* medication list had higher mean Utilization Scores compared to alternatives as shown in *Charts 2 and 3* below.

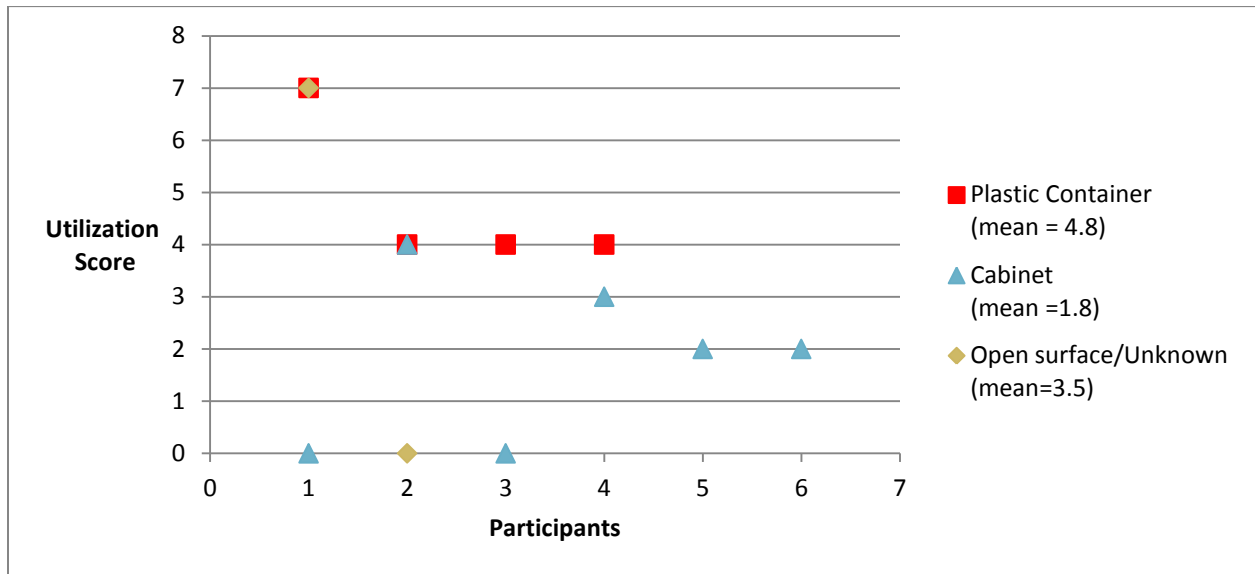


Chart 2: Participant's Utilization Score by Type of Storage Container

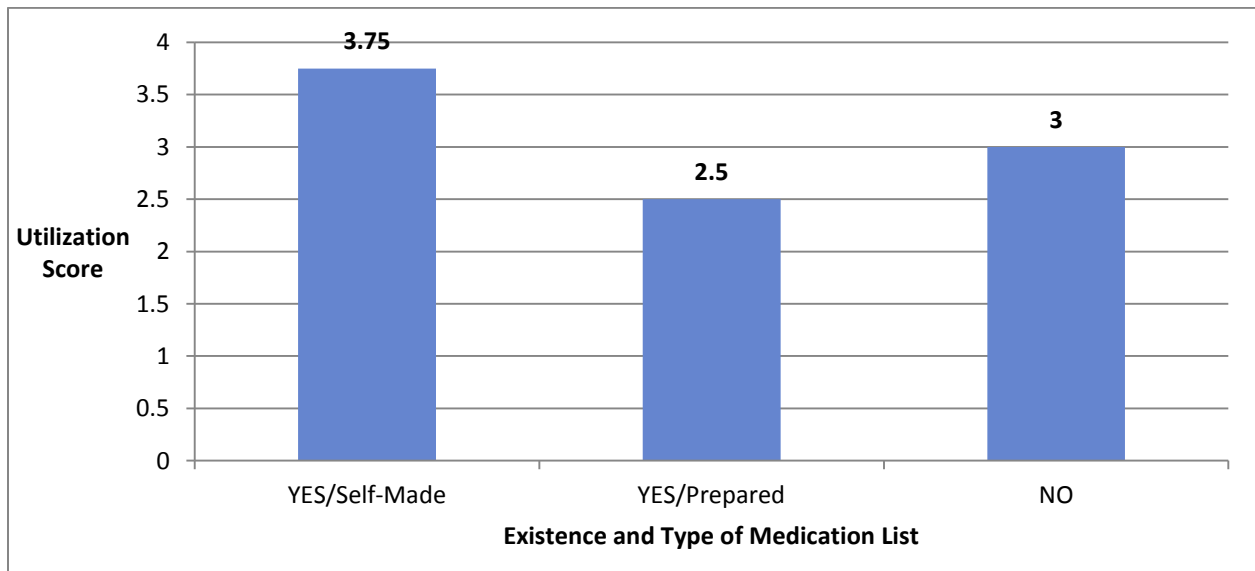


Chart 3: Participant's Utilization Score by Existence and Type of Medication List

Looking specifically at utilization of the MedManager storage function, those recruited from lobby and those previously utilized plastic containers were seen more likely than others to have later utilized the MedManager as storage space (at 67% and 100% utilization respectively). This is shown in *Charts 4 and 5*.

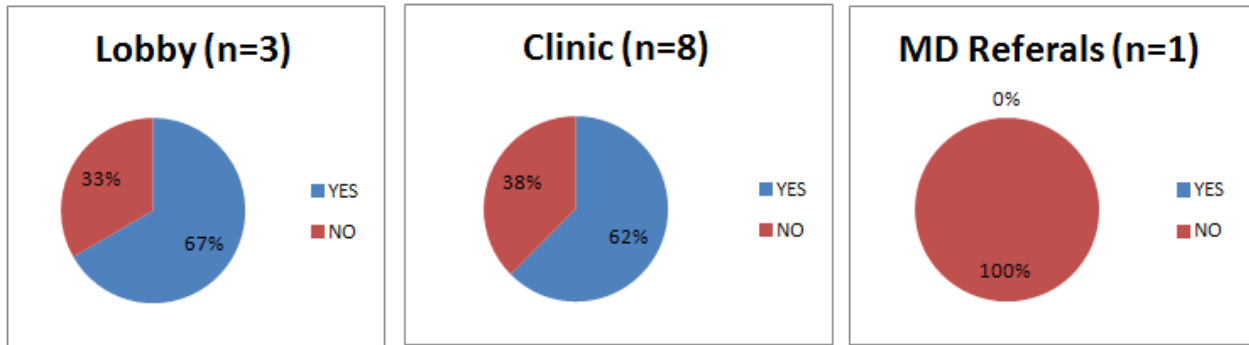


Chart 4: Participant’s Utilization of the MedManager’s Storage Function by Recruitment Source

**YES: Utilizers - NO: Non-Utilizers*

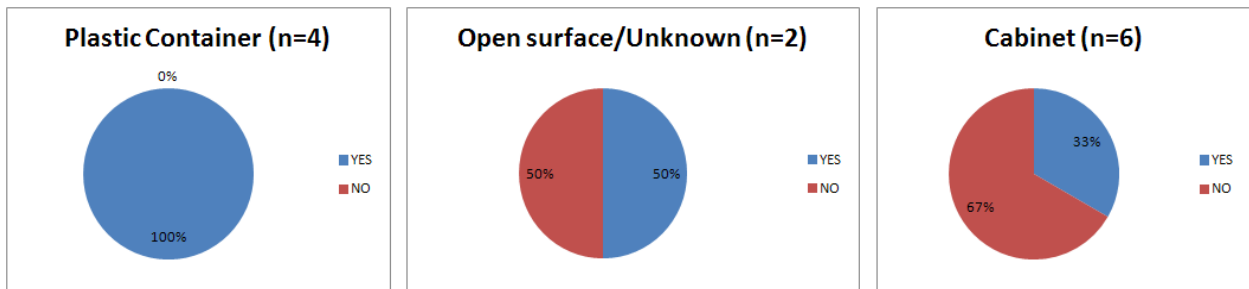


Chart 5: Participant’s Utilization of the MedManager’s Storage Function by Existing Storage System

**YES: Utilizers - NO: Non-Utilizers*

4.5. A Closer Look at Participant's Existing Medication Management Strategies and MedManager Utilization

4.5.1. Medication List

Participants adapted a wide variety of medication lists. Observed lists ranged from simple hand-written lists containing only names and dosages of medications to more detailed computer-generated lists created by hospitals and pharmacies containing information such as number of repeats, on-hold prescriptions and personalized notes written by pharmacists. Allergies and emergency contact information were commonly seen missing from observed lists. Hand written medication lists were typically small in size and usually allowed for convenient storage in a wallet or purse while those printed by hospitals and pharmacy were often on multiple A4 pages and would necessitate use of some sort of folder to store and carry around. Electronic medication lists were typically typed into smart phones using a note-written application and were relatively simple.

Participants utilized medication lists mainly as tool to effectively inform healthcare providers of current medications regimen at time of visits. Mentioned health care providers include family physicians, non-regular physicians, hospital staff, ER and EMS staff.

“The [new] eye doctor asked me for the [medication] list...”

“[A medication list] could be handy in case [I have a] medical emergency at home or at the ER.”

Conversely, participants without a medication list commonly cited a lack of need for one, most commonly on the ground that physicians already have their medication profiles in computers or that they can remember their medication regimen.

“It’s one of the things I always wanted to do, but I just don’t feel the need for it... The doctor office has my medication list on file.”

"I used to write down what I had been taking, but since [the number of] my medications was cut down, I didn't feel the need [for keeping a medication list] anymore."

"My wife knows what I'm taking and she's usually with me at hospital and doctor office"

"I have them in my head."

"I can look at the pill bottles"

The provided medication list template (Appendix 5) was not well utilized by participants. Half of participants however indicated at follow-up visit that they would fill it out at a later time. Participants reconsidered the template after being informed by the interviewer of its advantages; for instance the list allows for recording of information such as allergies and emergency contacts; is easier to carry than some existing larger lists and it could be more easily accessible by EMS staff in case of emergency compared to those inside smart phones.

4.5.2. Medication Storage Location and Container

Medications were often stored at locations fit into the participant's daily habit so that it is convenient for medication taking and also to serve as adherence reminder.

"[I store my medications in the kitchen because] I can take them with water and some food which are always available [in the kitchen]."

"As someone with brain injury, things have to be consistent [to me]. I wake up every morning, go to the bathroom, see the pills, take the pills out to go to the kitchen and take it with milk."

"[The kitchen] is the first place I walk to when I wake up."

"[I keep them in the living room because] this is where I live."

Participants mentioned convenient access to medications, be secured, and allow for organization of medications as desirable qualities of a storage system. Cabinets and simple plastic containers are the two commonly seen storage systems and neither met all of these qualities. Cabinets are commonly available in houses especially in kitchens and participants often cited their ability to allow for secured storage and easy organization of medications (e.g. on shelves).

"[I] put them up in the cabinet so they are safe from our grandkids"

"[The cabinet] helps keep medications organized."

On the other hand, those using simple plastic containers often cited reachability and togetherness:

"[The plastic container] helps keeping [my medications] together."

"It's [the plastic container] handy, it keeps everything together and makes you feel secured."

Participants using plastic containers nevertheless mentioned lack of organizability, risks of missing medications and unauthorized access to medications as disadvantages of their storage system:

"My medications [in the plastic container] were all over the places."

"It [sometimes] takes me like an hour-and-a-half to find my medication"

"Sometimes it's hard for me to find things [inside the plastic container] ... like the Spiriva pills"

"I fear of them getting lost. I used to lose my pill bottle and [later] found it under the couch"

"I have a cat that comes dig in my medications."

The MedManager was utilized by a number of participants as new storage system for its improved organizability, visibility and security that helped improve participants' sense of control over the

medication regimen. This was frequently expressed by four participants who previously used plastic containers to store medications, all of whom subsequently utilized the MedManager.

“[The toolkit] makes it so much easier for me to visualize [information on medication bottles] [compared to the plastic container] for example, when I need refills.”

“I have a cat that comes dig in my medications [in a plastic container].”

“Before [using the MedManager] my medications were all over the places [due to the open nature of the plastic container].”

“It keeps everything in one place.”

We also observed that some participants kept their pillboxes and emergency medications (e.g. inhalers) outside the MedManager at accessible locations while utilizing the tool to store medication vials and medical documents. The MedManager could then be put away at a separate location where it is accessed only periodically for pillbox refills.

Another perceived advantage of the MedManager as storage system is its portability that allowed for convenient carrying of medications outside the house. A couple of our participants reported to have utilized the MedManager as carrying tool during the study period, while others have expressed their intention for such use.

“It’s handy to carry around. Last time [I] went fishing for a week, I took the case with me and I had everything I needed.”

“I had to go to the hospital [last week]... I took the whole case to the hospital [and showed it to medical staff]... and they thought it was a great idea.”

“I have all my home medications [in the case]...When I have to go to the hospital, I can just take the case with me and hand them [the case].”

“This will become handy in case of emergency. We have tornado weather here in Seaforth. If there is a tornado warning, we can go to the laundry room with the case... and [also] to keep it [my medications] dry.”

Those who didn't utilize the MedManager as a storage and carrying tool, while praises its organizability, commonly cited the tool's large size as barrier. This view was commonly expressed by participants taking a relatively small number of medications (less than 5). Additionally, one participant on wheel chair thought carrying the case with him while traveling is inconvenient.

“... It could be half the size.”

“It's inconvenient [for me] to carry around [because I'm on a wheelchair].”

4.5.3. Adherence Aids

Many study participants have already been using pillboxes to help simplify the medication taking process. Observed pillboxes come in different designs and served somewhat different purposes. For instance, some participants put all regular medications in a multi-compartment-per-day pillbox, others put only selected doses (e.g. morning doses) or selected short-term medications (e.g. prednisone) in single compartmental pillboxes while keeping other regular medications inside bottles. Commonly cited benefits of pillboxes were convenience, adherence reminders and adherence tracking. Specifically, utilizing a pillbox can reduce the number of times participants have to open medication vials and make it easy to track whether the pills was taken. Additionally, pillboxes can be put at a more visible location (e.g. on kitchen table) to serve as adherence reminder.

“It's convenient so I don't have to open the vials every day.”

“I remember to take the Vimovo in the morning with my blood pressure pills, but sometimes forget to take it [by itself] at night, [so the pillbox helps with that].”

“This way I can tell whether I missed a pill or not.”

“It helps keep things organized.”

Conversely, those without pillboxes cited forgetfulness, impracticability and lack of need for one as reasons:

“[If I was to use a pillbox], I would need to fill the pillbox up every week, and I might forget [as someone with brain injury].”

“It doesn’t work for me. All my pills don’t fit in the compartment. ... [Plus] I don’t find the time to do it.”

“I [only] take two medications in the morning”

One participant who is on wheelchair chose blister pack as adherence aid to further simplify the medication taking and carrying process:

“When we go to London to see our kids, I can cut out the blister packs and carry them in [the] backpack.”

4.5.4. Clinical Parameter and Symptoms Tracking Systems

Most participants had not been keeping track of clinical parameters or symptoms. Three observed tracking strategies were automatic storing of blood glucose values by the glucometer; hand-writing daily blood pressure and blood sugar numbers inside a small booklet and one participant has been documenting her symptoms and possible precipitating factors in a small notebook as they occur. These tracking tools were reportedly often brought to physician office to assist with symptom monitoring.

“[I write down] when my breathing was hard... or when my sinus is logging”. “I think it really helps the doctors monitoring my case.”

Those who did not utilize a tracking system often cited lack of (or no longer have) needs for such system:

“It [my blood pressure] fluctuates a lot nowadays [so the numbers doesn’t mean much], and I have enough common sense to go to the ER when I don’t feel good.”

“I check my blood pressure when I’m at the pharmacy, [and] I have blood work done at the hospital.”

“[I] used to weigh [myself] every morning and had a piece of paper in the bathroom to write the numbers down but don’t do that anymore... because I’m feeling good.”

Table 11: Summary of perceived benefits and barriers of existing medication self-management strategies in the four main areas as reported by participants:

	<i>Perceived benefits</i>	<i>Perceived barriers</i>
<i>Medication list</i>	<ul style="list-style-type: none"> ● Inform new or non-regular HCPs of medication regimen ● Inform EMS staff in cases of emergency or if can't communicate verbally. 	<ul style="list-style-type: none"> ● Some are too large to carry around ● Providers can't access to phone in cases of emergency
<i>Medication storage location</i>	<ul style="list-style-type: none"> ● Convenient to daily habits ● Adherence reminder 	<ul style="list-style-type: none"> ● None reported
<i>Medication container</i>	<p><i>Cabinet</i></p> <ul style="list-style-type: none"> ● Organizability ● Security <p><i>Plastic Container</i></p> <ul style="list-style-type: none"> ● Convenience ● Togetherness ● Reachability 	<p><i>Cabinet</i></p> <ul style="list-style-type: none"> ● Relatively inconvenient access <p><i>Plastic Container</i></p> <ul style="list-style-type: none"> ● Lack of organizability ● Unauthorized access ● Risks of missing medications
<i>Adherence Aids (Pillboxes and Blisterpacks)</i>	<ul style="list-style-type: none"> ● More convenient to medication taking vs. vials ● Medication taking reminder ● Adherence tracking 	<ul style="list-style-type: none"> ● Needs to be refilled up at least one per week ● Commercially available pillboxes may not meet patient specific needs (e.g. take medications more than 4 times/day or large pills don't all fit into compartment) ● Lack of perceived need if simple medication regimen
<i>Clinical parameter and symptom tracking system</i>	<ul style="list-style-type: none"> ● Assist physicians with disease monitoring 	<ul style="list-style-type: none"> ● None reported

Also during the interviews, we asked participants about their perceived disadvantages of the MedManager (if any). Table 12 lists these perceived disadvantages and suggested solutions offered by participants.

Table 12: Perceived Barriers of the MedManager as a Medication Organizing Tool and Suggested Solutions from Participants

<i>Perceived Barriers</i>	<i>Suggested Solutions</i>
Unnecessarily large	<ul style="list-style-type: none"> • Smaller version for people with less number of medications (e.g. only one row of vial holders)
Rubber bands are hard to fit medication vials in Rubber bands could lose their elasticity after some time	<ul style="list-style-type: none"> • Adjustable rubber bands • Using vicryl as medication bottle holder
Dates on Calendar doesn't print correctly	<ul style="list-style-type: none"> • Verify dates on calendar
Pillbox material breaks off after multiple open/close	<ul style="list-style-type: none"> • Consider more durable material for pillboxes
Pillbox only has two compartments for each day	<ul style="list-style-type: none"> • Consider three compartments/day pillbox design for those taking meds more than twice daily

V. DISCUSSION AND RECOMMENDATIONS

5.1. Barriers seen in Existing Medication Management Strategies

Absence of an effective medication organizing and carrying tool was seen in many project participants with multiple medications, who typically used a plastic container or cabinet to store home medications. As reported by participants, lack of organization can lead to the feeling of “not in control” of the medication regimen and interfere with medication adherence and communication with healthcare providers. This observation strengthened our prior assumption that there is a perceived need for better organizing and carrying of home medications. Efforts to characterize and address this need nevertheless should be done with caution and should take into account that what is perceived as difficulty or barrier to one might not be similarly perceived by others. Consequently, interventions designed based on generalization of perceived needs may not be very effective to the population as a whole. Moreover, daily habits often play an important role in determining medication management strategies as seen in our participants and in the literature⁸⁹ and they are often not easily changed. These observations led us to believe that efforts to improve home medication self-management should best be individualized, starting with examining patient-specific needs and preferences and taking into account patient’s daily habits.

We also observed that the act of maintaining a medication list as well as the nature of the medication list (e.g. self-made vs. prepared) often correlated with participant’s understanding of their medications and chronic conditions. For example, during interviews, participants with self-made medication lists were seen as being more knowledgeable about their medication regimen compared to those without a list and on average also reported higher Morisky Scores (4 compared to 3.3). Again, generalization of this correlation should be done with caution, taking into account considerations such as the complexity of patient’s medication regimen as well as the patient’s perceived needs for such list. As mentioned

previously, most observed lists did not include allergies or emergency contact information. Moreover, many participants did not keep a medication list (4 out of 12) either due to lack of perceived needs for one or the perceived “hassles” of maintaining one, for example, due to frequent medication changes and complex regimens. Maintaining a detailed medication list is an important aspect of chronic disease self-management²⁰ and can be beneficial to patients and healthcare providers especially in case of emergencies.

Pillboxes were the most commonly seen adherence aid, used by 50% of participants (6 out of 12). For reference purposes, a cross-sectional study has reported a pillbox prevalence of 80% in their diabetic participants.⁸⁹ Pillboxes simplify the medication taking process by sparing patients from having to open medication vials multiple times a day and can help patients track whether a pill had been taken or not. Pillboxes also can be more convenient to carry while away compared to medication vials, especially for those with multiple medications. They however typically need to be refilled once per week, which in itself can be a time-consuming process and barrier to those with cognitive impairment or functional disability. Additionally, pillboxes are not suitable for certain types of medications such as “as-needed” or inhaled medications therefore do not help with adherence to these medications. Moreover, patients with unusually large number of medications may find it impossible to fit all pills inside a typical compartment, while those who take medications more than four times daily may have problems finding a pillbox design that fit their medication taking schedule since the majority of available pillboxes have four compartments per day or less.

5.2. Perceived Usefulness of the MedManager as a Medication Management System

While the MedManager contains a number of components, the key value that is also unique to the tool was its storage function and portability. More than half of our participants (7 out of 12) utilized the

MedManager as a medication storage tool at follow-up; two of whom also had carried the tool with them while away or to the hospital while others had expressed intention for such use. We believed the observed utilization coupled with perceived advantages of the MedManager over existing storage systems as reported by participants demonstrated its feasibility to act as a medication organization and carrying tool in the real world. Other components of the MedManager, namely the medication list, pillbox and reminding calendar were not innovative in nature, nevertheless their inclusion within a single “toolkit” can promote their utilization in patients otherwise may not have been aware of the potential benefits of these components. For example, many patients may not be aware of the benefits of maintaining a current medication list, especially in cases of medical emergencies where access to medical records may not be immediately available. Like all products, however, utilization of the MedManager in this project was not universal which made it important to determine which patient demographics would be more likely to find the toolkit beneficial and this is discussed in the next section.

Our project has also revealed some potential disadvantages of the MedManager. First, there were a number of suggestions for product improvements offered by participants as mentioned in *Table 11*. Second, while we wasn’t informed of any risks or potential risks associated with the MedManager use, the short study period might have been inadequate to uncover unforeseen risks associated with its use. For instance, the risks of losing or misplacing the MedManager during transportation together with its contents cannot be excluded though one may argue that this risk might be comparable to the participant’s traditional methods of medication carrying. Lastly, the durability of the toolkit and acceptable price range were not known to us as they were not examined in this project.

5.3. Likely Utilizers of the MedManager

Determining which patient population would be most likely to utilize the tool is of key importance if the tool is to be promoted. In our project, all four participants who previously stored their medications in plastic containers subsequently utilized the MedManager as new storage system, two of whom also had carried the tool with them outside their homes (one while on a fishing trip and the other to hospital). Furthermore, these four participants also had relatively complex medication regimens (taking 8 regular medications or more). This suggests that those without an effective storage system or those with complex medication regimen may be more likely to find the tool useful. Nevertheless, it does not necessarily mean that the tool doesn't have a role in patients with less complex medication regimens. While these individuals might not have much difficulty with medication organization and adherence, the tool still can serve as a "portable storage cabinet" for home medications and medical files that can be kept at a more convenient or secured locations. This could become relevant in patients who also utilize weekly pillboxes and only need to access their medication vials periodically for pillbox refills as seen in a couple of our participants.

Participant's initial level of interest in the MedManager could be another potential predictor for the tool's utilization. While all participants in our project have expressed some level of interests in the tool prior to enrollment, those who actively communicated their interests to us were better utilizers. Specifically, those recruited from information desks were seen as more likely to utilize the tool compared to those recruited through screening surveys at clinic (*Chart 4*). These observations then suggests that "non-invasive" promotion strategies that aimed solely at raising patient's awareness of the tool such as newspaper advertisement or visual display at retail locations may be effective in reaching likely utilizers.

We couldn't find any correlation between other baseline characteristics such as Age or Adherence Measure (e.g. the Morisky Scale) and the MedManager utilization.

5.4. Project Strengths and Limitations

5.4.1. Strengths

Compared to other possible methodological approaches to address the research question, ours had a number of advantages.

With regards to recruitment, the flexibility in our inclusion criteria allowed for examination of the tool on a wider range of potential users instead of self-limiting our enrollment to only those with pre-determined characteristics. The approach was justifiable given the “uniqueness” of the tool during project planning which made defining target-user characteristics seemingly speculative. Additionally, we tried a variety of recruitment methods which allowed for examination on which recruitment strategy worked and which one did not. Specifically, those recruited through “non-invasive” recruitment strategies (e.g. information desk) which encouraged participant’s initiation of the conversation had better utilization rates compared to those recruited through more “invasive” strategies such as asking patients to fill out the screening survey.

Secondly, we collected descriptive data (e.g. on existing self-management strategies or MedManager utilization) mostly through direct observation in participant homes. Compared to other possible data collection methods such as surveys or interviews, direct observation reduces risks for reporting biases because the participants did not have to describe their management strategies themselves and the investigator did not have to interpret their responses. Moreover, during our interviews with

participants, direct observation often allowed us to better visualize participant talk points and in many cases, helped confirm the validity of their responses.

Lastly, the explanatory mixed methods approach by which the initial quantitative results are further explained with qualitative data⁹⁰ provided mechanism for deeper understanding of objective observations, something that would have been difficult to achieve with either quantitative or qualitative methods alone. For instance, the participant interviews helped us understand the rationales behind the observed utilization (or non-utilization) of the tool and helped strengthen our conclusion that the observed utilization is in fact due to the participant's perceived usefulness of the tool instead of confounding factors.

It is also worth noting that there are many ways to evaluate a product's usability.⁹⁷ Traditional usability testing typically involves asking targeted end-users to perform representative tasks (e.g. by providing them with a task list) within an artificial testing environment.⁹⁸ While this approach would have allowed us to examine the perceived advantages and disadvantages of each MedManager components more closely, it does not allow for observations on actual utilization and subsequently, characterization of likely utilizers which were our outcomes of interest. This project instead utilized the "what-if" approach often seen in proof-of-concept experiments that supposedly would allow us to examine these outcomes.

5.4.2. Limitations

We were not able to meet our recruitment target within the pre-defined recruitment period. This could be attributed to the inefficiency seen in many of our recruitment strategies. The implication of a reduced sample size is that it may have diminished the "richness" of quantitative and qualitative data collected. Additionally, the lack of a randomization process, sample size calculation and a well-defined

patient population prevented us from making inferences on how representative our observations (e.g. on prevalence of an existing self-management strategies) were compared to the actual prevalence in the general population or to any sub-population as well as what the actual effect size of our intervention (e.g. actual MedManager utilization rate) would be on such population.

We were also concerned with the possible influence of the observer effect (a.k.a Hawthorne effect) on the observed utilization of the MedManager. In other words, participants' actual utilization in their natural, unobserved setting might have been different from what was observed in this project. This is because people who know that they are being observed may temporarily change their behavior or performance.⁹⁹ While it was not possible to make our project truly unobtrusive (e.g. making participants unaware that they were being studied), we had taken several steps to reduce possible impacts of the observer effect during project implementation. Firstly, we maintained a neutral perspective on the effectiveness of the tool during our interactions with participants and emphasized that the toolkit is still in its prototype form and might not work as intended. Additionally, requests for project participation were made in the most non-committal way possible to reduce participant's "perceived obligations". Furthermore, during orientation we objectively introduced the functions of the MedManager and its components using scripted paragraphs without explicitly telling participants how or if they should use the tool. These steps were intended to reduce the possibility of participants performing project activities in ways perceived by them as beneficial to project objectives. Additionally, two participants informed us that they had utilized the MedManager as a carrying tool (one while on fishing trip and other to hospital), these were unlikely the results of the observer effect or perceived obligations but probably due to the perceived benefits of the tool. Moreover, we observed what we thought was genuine interests in the MedManager as an organizing tool from a number of participants during our interviews.

In short, we had reasons to believe that the observer effect was unlikely the deciding factor leading to the observed utilization of the MedManager.

Data analysis was performed primarily by the student investigator. The lack of researcher triangulation makes interpretations more prone to biases as “involvement of a number of researchers can be seen as an advantage as their different perspectives can enrich the research process”.⁹⁵

And lastly, we did not report on one of our secondary objectives that attempted to evaluate the effect of the MedManager on selected clinical outcomes (Blood Pressure, Blood Sugar and Weight). This is because only two of our participants tracked their clinical parameters on a scheduled basis and neither was utilizer of the MedManager at follow-up.

5.5. Project Implications and Future Directions

5.5.1. Considerations for Promotion of the MedManager as a Medication Organizing Tool

A common approach to new product development is Human Factor Engineering which is “the practice of designing products so that users can perform required tasks with a minimum of stress and maximum of efficiency.”⁹⁶ This philosophy places the user at the center of the product development process and that the product’s goals, objectives, context and environment are derived from the user’s point of view.⁹⁷ Within this context, a key step in promoting the MedManager would be to define its end-users: those who would be most likely find the tool beneficial. As mentioned earlier, we observed that those without an organized medication storage system and those who expressed interests in the displayed sample (e.g. at information desk) were more likely to later become utilizer. This then suggested that promotional approaches such as displaying the tool at retail locations including community pharmacies can be a good marketing strategy to reach potential users. Additionally, making the tool and its purposes

known to health professionals such as pharmacists and family physicians can also be an effective promotional strategy as these professionals have the tools to identify likely utilizers (e.g. those with complex medication regimens) and can recommend the MedManager where appropriate.

Given the early stage of this product, feedback from end-users and experts are also important and should be taken into considerations for future modifications. Moreover, there are many relevant questions that were not answered by this project; among them were the durability of the toolkit, its effectiveness on clinical outcomes if any, and possible risks associated with its use. Continuous quality assurance measures (e.g. through establishing and maintaining communication channels with end-users and health professionals) can help answer some of these questions, while others may require implementations of larger, well-designed clinical trials.

5.5.2. Future Considerations for Sample Size Determination

In a typical usability test, the number of participants depends on many factors such as the degree of confidence in the results that is required, the number of available resource to set up and conduct the test and the availability of the type of participants required.⁹⁷ Additionally, usability tests requiring statistically valid results will need to test enough participants to conduct the appropriate analyses and generalize to the specific target population, as well as to rigorously control for potentially biasing conditions and factors.⁹⁷ Neilson suggested the number of participants needed for a typical usability test is 5 participants, although quantitative studies (aiming at statistics, not insights) requires testing at least 20 participants, if not more, to get statistically significant numbers.¹⁰⁰ Therefore, if the testing goal is to try to expose as many usability problems as possible in the shortest amount of time, then testing four to five participants should expose the majority of usability problems.^{97, 101} However, Rubin mentioned that testing only four to five participants may overlook rare problems that could have severe ramifications

and that up to eight participants can be recruited if possible.⁹⁷ Another important consideration is whether more tests will be conducted during the product development cycle. If multiple tests are to be conducted, one may feel more confident testing fewer participants. If no other tests were expected to be conducted then more participants should be considered.⁹⁷ Our project differs from a typical usability test in that we approached the question as a neutral researcher who would like to observe usability, rather than as a designer who tries to enhance usability. Consequently, we decided to limit our sample size only on the estimated time and resources made available and the number of eligible participants recruited rather than on known recommendations at project planning. Nevertheless, we had seven participants who utilized the MedManager's storage function and therefore had reasons to believe that the usability problems suggested by these participants (*Table 12*) should probably represent the majority of usability problems in this particular area. Known usability tests of innovative self-management tools and products have included varied sample sizes ranging from 8 to 50 subjects without clear explanation of the basis for the size selected.^{1,4,7} Future studies that focus on exposing additional usability problems should utilize current recommendations for sample size determination as mentioned above, while those aiming at evaluating effects on clinical outcomes should consider performing the appropriate statistical analyses to ensure their sample size has the desired statistical power for the research question.

While not stated as a primary objective, our project included a qualitative component. In qualitative research, there is no rigidly set formula to determine sample size.⁹⁵ For most qualitative projects, the sampling process is flexible, and at the start of the research the number of participants to be recruited is not definitely known.⁹⁵ However, data saturation, a concept associated with grounded theory, is often used as a way of justifying the number of research participants and the sample size is considered adequate when "the emerging themes have been efficiently and effectively saturated with optimal

quality data”.⁹⁵ A common approach to achieve data saturation seen with qualitative studies in chronic disease self-management was to conduct semi-structured interviews or focus groups on purposively sampled participants and with concurrent data analysis where the analysis process allowed for identification of themes and guided subsequent data collection in order to further refine identified themes until few new data is generated.^{12,14,25,28} As mentioned earlier, our sample size was based primarily on logistics factor and data saturation was not a consideration during project planning. Furthermore, qualitative categories (e.g. advantages of current medication lists – see *Appendix 8*) were pre-determined during project planning and the large number of categories in this project implies it could be possible that not all of them have achieved data saturation at the conclusion of data collection.

5.5.3. Implications for the MedManager within context of the Chronic Disease Self-Management Process

In the research setting, incorporation of innovative tools as part of self-management interventions is not new.^{102,103} The MedManager’s feasibility to serve as a medication organizing tool, as demonstrated in this project, provided a rationale for its use in future chronic disease and medication self-management studies. In the clinical setting, recommendations for clinical use of the tool should be based on its demonstrated clinical safety and effectiveness, data on neither of which is not currently available. For example, policy makers may be interested in seeing if such tool would have any effect on medication adherence, something that we were not able to show in this project and therefore could merit further investigations. Additionally, within the medication therapy management (MTM) process, the MedManager could be utilized as an additional tool to help address medication-related problems discovered during their medication review process.

This project itself has also revealed a number of perceived barriers of existing medication self-

management process that is to our knowledge has not been well-documented in the literature (*Table 10*). These barriers should probably be taken into consideration in designing and implementation of future self-management interventions. It is also important to realize that chronic disease self-management is a life-long process in which patients may encounter barriers in many other self-management tasks besides medication taking and to recognize the importance of patient self-efficacy in performing these tasks. Interventions designed to improve self-management, whether through education or introduction of innovative tools, should continue to make enhancing self-efficacy a main objective.

VI. CONCLUSION

In conclusion, we believed the MedManager was perceived as helpful to a number of our participants. This was supported by the observed utilization of the MedManager components at follow-up and the perceived benefits of the MedManager over existing organizing systems as reported by enrolled participants. Those with relatively complex medication regimens but without an effective storage system were seen as likely utilizers of the tool. Future research or marketing activities that seeks to maximize the impact of the MedManager or similar tools should consider including these patient populations in their studies.

In addition to other existing medication management strategies such as pillboxes and blister packs, a medication organizing tool such as the MedManager represents another option to further assist patients with managing their medications and chronic conditions at home. Additionally, the tool's portability that allows patients to quickly and conveniently carry medications outside the home could be beneficial in cases of emergency, while on traveling trips or to the hospitals as seen in a number of our participants.

Moreover, the enthusiasm observed in a number of enrolled participants at follow-up suggested that the tool could provide additional motivation and encouragement needed for some patients to start taking steps to better manage their medication regimens and chronic conditions.

All of our participants lived in small towns or rural areas of Ontario. Compared to their urban counterparts, chronic disease self-management may be more important in rural communities for many reasons. Preventative care is less available in rural towns, and rural areas tend to have fewer primary care physicians and specialists. Additionally, rural residents may be less educated about their chronic conditions (e.g. due to lower levels of formal education).²³ Consequently, efforts to encourage and enhance self-management for rural residents including making self-management education programs and self-management aids such as the MedManager available to rural residents may help address these disparities.

Declaration of Interests

The MedManager toolkits were designed, manufactured, and are owned by Dr. Harry Wingate, MD. Those used in this project were made available free-of-charge by the owner. No other forms of assistance were provided by the owner in conducting of the project. The candidate and research team had no financial interests associated with the MedManager or its owner.

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Appendices

Appendix 1: MedManager Original Design

U.S. Patent

Jun. 5, 2012

Sheet 1 of 3

US D661,082 S

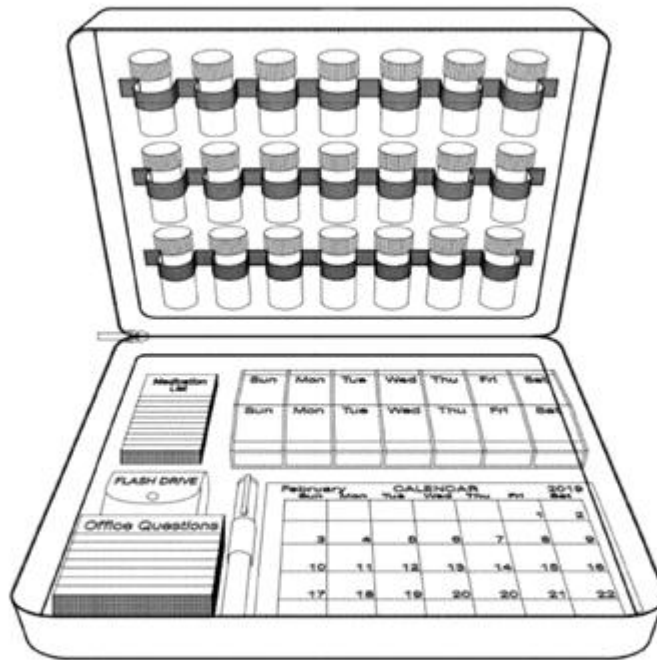


FIG. 1

Provided by PatentStorm, <http://www.patentstorm.us>

Appendix 2: Pre-Production End-User Survey Sample

FROM (SUN)OCT 28 2012 18:40/ST. 18:06/No. 729955004 P 5

(2)

untitled

Patient Survey:

1) How often do you take your medicines as prescribed?

- 100% of the time
- 75%
- 50%
- < 25%

2) Do you have an organized system to track medication use, refills, storage etc.?
 Yes (if yes have explain briefly)
 No
Comment _____

3) What are your biggest challenges to taking medicines correctly?

4) would you purchase this product (attached PDF printed out) to help you organize and track you medication?
(Show them Med Manager portfolio)
 Yes (if yes ask question #5)
 No (if No ask for reasons why)

5) What price range seems reasonable for this product as seen?

- \$50 - \$75
- \$40 - \$49
- \$30 - \$39
- \$20 - \$29

Signature of Patient Chris Bae

Page 1

Appendix 3: Pre-Production Pharmacist Survey Sample

FROM (SUN)OCT 20 2012 10:42/97.10:38/No. 7500050004 P. 14

(1)

untitled

Pharmacist Survey:

1) Roughly how many patients does this Pharmacy service that have 5 or more medications used daily for "chronic conditions"(i.e. HTN, DM etc.)?

500-1000
 1000-2000
 > 2000

2) Does the Pharmacy have or sell a system that assists in medication adherence? Describe (how it works, costs, per cent eligible patients that use the system etc.)

Doc U Dose Packaging \$10 month < 1%

3) (Show product) Based on your initial impression of the Med Manager binder, would this be a product that you would promote? Do you believe it would be successful and useful for patients with multiple chronic conditions on multiple medications?

Yes
 No

Comments possible qid dose

Pharmacists signature Denny Sigmon #9970

Page 1

Appendix 4: MedManager Mass Production Version



Appendix 6: Screening Survey

**EVALUATING THE USABILITY OF A MEDICATION ORGANIZING TOOL ON
MEDICATION MANAGEMENT AT HOME SURVEY**

Part I:

1. Please select your age group:

- <40 40-49 50-59 60-69 >69

2. Gender

- Male
- Female

3. Which city do you live in? _____

4. How did you hear about this study? _____

5. How many chronic medications are you currently taking?

(Chronic medications are those you will be taking for a long period of time such as blood pressure, blood sugar, or cholesterol medications)

- <3 3-5 6-8 >8

6. How many doses of medication do you take each day?

Morning *Afternoon* *Evening* *Bedtime*

#of doses: _____

7. Have you been diagnosed with any of the following chronic conditions: (check all that applies)

- High Blood Pressure
- Diabetes
- High Cholesterol
- Heart Failure
- Epilepsy
- Others (please specify) _____

8. Does any of the following apply to you?

- Take blood thinner medication
- Have some degree of cognitive impairment
- Impaired vision/difficulty seeing
- Dexterity problems
- Language difficulties

9. Do you take any of the following medications (check *all that apply*)

Warfarin

Anti-seizure medications

Mood stabilizers

Digoxin

10. On average, how many times per week do you forget to take your regular medications?

0-1

2-4

5-7

8-10

>10

11. Where do you store your medications? (check all that applies)

Kitchen

Bedroom

Bathroom

Others (please specify) _____

12. Do you keep a list of your current medications?

Yes No

13. Do you use a pillbox or blister pack? (*check all that applies*)

Pillbox

Blister pack

Neither

14. Do you have any difficulties reading the medication names and instructions as printed on prescription vials?

Yes No

Please specify: _____

15. How many pharmacies do you use to pick up your medications? (*fill in the blank*)

16. How many office visits did you have last year? (*fill in the blank*)

17. When you go to your doctor's appointment, do you bring any of the following with you?

- My medications**
- My medication list**
- My list of questions for my doctor**
- Other (please specify) _____**

18. Do you take readings of any of the following? (check all that applies)

- Blood pressure**
- Fasting blood sugar**
- Weight**
- INR**
- Other (please specify)**

Please provide the usual reading of each in the space below if remembered:

Blood Pressure: _____

Fasting Blood Sugar: _____

Weight: _____

INR: _____

Part II: Please answer these Yes/No questions

1. Do you ever forget to take your medicine? Yes / No

2. Are you careless at times about taking your medicine?

Yes / No

3. When you feel better do you sometimes stop taking your medicine? Yes / No

4. Sometimes if you feel worse when you take the medicine, do you stop taking it? Yes
/ No

5. It is easy for me to take my medicine on time. Yes / No

6. It is easy to remember to take all my medicines. Yes / No

7. It is easy for me to set a schedule to take my medicines each day. Yes / No

8. It is easy for me to take my medicines every day.

Yes / No

9. It is easy for me to ask my pharmacist questions about my medicine. Yes / No

10. It is easy for me to understand my pharmacist's instructions for my medicine. Yes /
No

11. It is easy for me to understand instructions on medicine bottles. Yes / No

12. It is easy for me to get all the information I need about my medicine.

Yes / No

Part III:

Please fill out the contact form below if you are interested in evaluating the "MedManager" tool (pictures attached) designed to help simplify medication management at home.

Name

Address

Contact phone number

Email (optional)

***** Due to the limited number of the tools available and to best evaluate the project objectives, we limit enrollment to participants who meet one or more of the following criteria:**

-Taking 5 or more chronic medications

-Take 12 or more doses per day

-Have 3 or more chronic conditions

-Difficulty with remembering to take medications

-Taking the following medications (Warfarin, anti-seizures medications, Mood stabilizers, Digoxin)

*-Vision problem, dexterity problem (arthritis, etc.), mild cognitive impairment or language difficulties.****

Thank you very much for taking your time to complete this survey and your interest in this project!

Appendix 7: *The Morisky Scale*

Do you ever forget to take your medicine?	Yes / No
Are you careless at times about taking your medicine?	Yes / No
When you feel better do you sometimes stop taking your medicine?	Yes / No
Sometimes if you feel worse when you take the medicine, do you stop taking it?	Yes / No

Interpretation:

Score 1 point for every YES answer

- o 0 points = high adherence**
- o 1-2 points = intermediate**
- o 3-4 points = low adherence**

Appendix 8: Follow-up Session Observation and Interview Guide

Picture of the MedManager?

	Categories	Current system	MedManager feedback
1	Medication List <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Picture	Description: Advantage: Disadvantage:	Comments
2	Medication Storage	Description: (Locations) Advantage: Disadvantage	Comments
3	Adherence Aid	Description:	Comments

	<input type="checkbox"/> Pill Box <input type="checkbox"/> Blister Pack	Advantage: Disadvantage:	
4	Clinical Tracking System <input type="checkbox"/> Blood Pressure <input type="checkbox"/> Blood Sugar <input type="checkbox"/> Weight <input type="checkbox"/> Others (Specify) Pictures?	Description: Advantage: Disadvantage:	Comments
5	Communication strategies with healthcare team <i>(any difficulties in communication with healthcare team a.k.a MDs or pharmacists)</i>	Description: Advantage: Disadvantage:	Comments

6	Any other existing problems/difficulties	Description: Barriers to improve:	

Appendix 9: Information Letter and Consent Form



Information Letter

EVALUATING THE USABILITY OF A MEDICATION ORGANIZING TOOL ON MEDICATION MANAGEMENT AT HOME

Dear patient(s),

My name is Tuan Phan, a Master's student at the University of Waterloo - School of Pharmacy under supervision of Dr. Feng Chang, PharmD. As part of my Master's degree requirement, we are conducting a study titled "Evaluating the Usability of a Medication Organizing Tool on Medication Management at Home". The first part of the study is a survey (attached) designed to provide us with insights on how patients manage medications at home. I would appreciate if you would complete the attached brief survey. *Participation in the survey is completely voluntary* and expected to take about 10-15 minutes of your time. Most of the questions will be multiple choices, and you can omit any question you prefer not to answer. *Should you choose to participate, please seal completed survey in the provided envelope and deposit in the nearby drop box. Only the researchers will have access to the secure lockbox and survey forms. There are no known or anticipated risks from participating in this survey.*

As a survey participant, you may be eligible to participate in phase two of the study to test-use the MedManager, a medication management tool designed to help improve the way medications and medical information are *organized (pictures attached at the end of survey)*. This phase is expected to last two months and I will schedule a home interview with you mid-way to obtain feedbacks on the usefulness of the tool. At the end of the study period, you will be invited to complete an evaluation questionnaire to help us determine the effectiveness of the tool on certain outcomes such as compliance, medication knowledge and communication with physicians. *Your participation in this phase is also optional and voluntary.* The tool will be provided free-of-charge as the manufacturing cost is underwritten by the owner, Dr. Harry Wingate III, MD.

The study is in compliant with the University of Waterloo Information Security Policy. Identifiable information such as your name or contact information if ever collected will be treated as confidential and stored separately from other information. Data collected will be stored in a locked cabinet at the University of Waterloo for 2 years. More information on the Policy can be found at the following web address: <http://uwaterloo.ca/secretariat/policies-procedures-guidelines/policy-8>

This study has been reviewed by and received ethics clearance through a University of Waterloo Research Ethics Committee. The Director of Office of Research Ethics, Dr. Maureen Nummelin, can be contacted at 519-888-4567 ext. 36005 or by email at maureen.nummelin@uwaterloo.ca. If you have any questions about this study, I can be reached at 519-888-4567 ext. 21390 or by email at t4phan@uwaterloo.ca. My faculty supervisor, Dr. Feng Chang can be reached at 519-888-4567 ext. 21321 or by email at feng.chang@uwaterloo.ca.

Thank you *in advance* for your interests in this study.

Sincerely,

Tuan Phan - 2014 MSc. Candidate in Pharmacy Practice at University of Waterloo-School of Pharmacy

CONSENT OF PARTICIPATION IN THE STUDY

“EVALUATING THE EFFECTIVENESS OF A MEDICATION ORGANIZING DEVICE ON MANAGING
MEDICATIONS AT HOME”

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

I have read the information presented in the information letter about a study being carried out by Tuan Phan, MSc. student under direction of Dr. Feng Chang at the University of Waterloo-School of Pharmacy. I have had the opportunity to ask any questions related to this study and received satisfactory answers to my questions and any additional details I wanted. I am aware that I may withdraw from the study without penalty at any time by advising the researcher(s) of this decision and that in the case of early withdrawal, I would still be given the option to keep the tool, and data obtained from my participation may or may not be used in the study result. I further understand that I can contact the student investigator by phone at 519-888-4567 ext. 21390, by email at t4phan@uwaterloo.ca and the Faculty Supervisor, Dr. Feng Chang at 519-888-4567 ext. 21321 or feng.chang@uwaterloo.ca with any concerns or questions during the study period.

This project has been reviewed by, and received Ethics Clearance through the University of Waterloo Research Ethics Committee. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact the Director of Office of Research Ethics, Dr. Maureen Nummelin at 519-888-4567 ext. 36005.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

.....
Please Print Name

.....
Signature of Participant

.....
Date