Functional medication management in older adults living in the community

by

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Abstract

Many older adults experience difficulties in managing their medications, especially those with reduced functional abilities. Multi-morbidity adds another level of complexity to managing medications successfully. The overall aim of this thesis was to identify functional challenges with medication self-management. In the first study, the objective was to describe different challenges that older adults experience when managing medications at home, such as opening medication packages, breaking tablets, and swallowing pills. In the second study, the objective was to describe the tools available to assess functional medication management and examine the different domains assessed by those tools. The objective of the third study was to explore the most common types of functional challenges experienced by patients with rheumatic conditions.

Two different research methods were used for this thesis. A scoping review of the literature was conducted for the first and second studies, while a cross-sectional survey was conducted for the third study. The scoping review involved screening 4,387 articles in order to identify relevant studies. The survey included detailed questions about the types of functional challenges with medication management experienced by patients with rheumatic conditions.

In this first study, we found that a large number of older people living in the community have difficulties managing medications at home. This was evident in the finding that older adults experienced difficulties with all different dosage forms, including oral, ophthalmic, inhaled and injectable medications. In the second study, fourteen unique tools assessing functional medication management were described. Then, four key domains of medication management were proposed. One domain in particular, function, was not extensively assessed by the existing tools. In the third study, the results showed that 73% of participants with rheumatic conditions experienced at least one functional difficulty managing medications at home.

The main finding of this thesis is that patients with functional impairments, due to older age or rheumatic conditions, experienced functional challenges when managing different medication forms. Furthermore, this thesis revealed that current assessment tools are not robust, as they lack comprehensive functional assessments. Adding a functional assessment to the existing tools or developing a new tool can help identify people with impaired functional ability to manage medications.

Preface

This thesis document is an original work by myself under the supervision of professor Cheryl Sadowski and Allyson Jones. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, Project Name "Functional Medication Management in Rheumatology Patients at Kaye Edmonton Rheumatology Clinic Questionnaire", Pro00088738, March 12,2019.

Some of the research conducted for this thesis forms were done in collaboration with the Alberta SPOR SUPPORT Unit KT Platform with professor Sadowski being the lead collaborator at the University of Alberta. Data collection for chapter 3 and 4 were done by myself and Liza Bialy. Data collection and analysis in chapter 5 are my original work, as well as the literature review in chapter 2.

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Dedications

This thesis is dedicated to my parents, my mother Anwar Flaih and my father Kahtan Askar. They have always been an excellent role model for me. They always believed that education is the only way for any person to be a better version of her/himself. I would like to thank them so much for their support, love and help to finish my degree successfully**.** Without them in my life, my success would not be possible.

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List of abbreviations:

COPD	Chronic Obstructive Pulmonary Disease
DPI	Dry Powder Inhaler
GI	Gastrointestinal
MDI	Metered Dose Inhaler
NR	Not Reported
QoL	Quality of Life
RA	Rheumatoid Arthritis
RCT	Randomized Controlled Trial
FMM	Functional Medication Management
IADL	Instrumental Activities of Daily Living
NPV	Negative Predictive Value
PPV	Positive Predictive Value
SE	Standard Error
SES	Socioeconomic Status

Chapter 1
Introduction

1.1 Statement of problem

The number of chronic conditions increases with age, with approximately 76% of Canadian older adults having one or more chronic conditions (1). Multi-morbidity adds another layer of difficulty to the management of chronic conditions (2). Chronic conditions, such as high blood pressure, arthritis, heart disease, diabetes and cancer, are frequently seen with increasing age and often require multiple medications for optimal management (1). Polypharmacy which is the concurrent use of five or more medications is also a common concern in older adults (3). In 2016, 65.7% of Canadian older adults were prescribed medications from 5 or more different drug classes with cardiovascular medications being the most commonly prescribed (4).

Management of one's own medication is a complex process involving several tasks such as reading and understanding the medical information, opening medication packaging, preparing a dose, or administering the medication (5). It is considered one component of instrumental activities of daily living (IADL) (6). Also, certain medications that require detailed schedules or complex multi-step processes can influence health outcomes negatively if not managed appropriately (7). Injectable therapies, such as insulin have previously been documented as complex multi-step tasks that can be made more difficult by co-existing impairments such as poor vision, decreased mobility, and reduced hand dexterity (8). Inhaler use can also be challenging involving multiple steps (loading dose, priming inhaler, and coordinating breath) to ensure maximal therapeutic benefit of the medication (9).

Older adults may have physical impairments that can impede their ability to correctly administer medications (10). Poor vision, weak handgrip, reduced fine motor skills/hand dexterity, and difficulty swallowing are frequently reported physical disabilities that can make taking medication more challenging for older adults (11-15). According to a large cross-sectional study of 604 older people (mean age 87 years), 14% (n=85) were unable to open a screw cap bottle, 32% (n=192) a bottle with a snap lid, and 10% (n=60) a blister pack (16). Also, certain chronic conditions commonly seen in older adult such as arthritis are also associated with physical disabilities (1,17). Arthritis can cause joint inflammation, pain and swelling leading to impaired hand function such as decreased handgrip and dexterity (18). It can also lead to inflammation in the eyes, potentially leading to vision impairments (19). One study has shown that older adults with impaired hand function related to arthritis experience difficulty opening medication packaging such as child resistant containers and suppository packaging (20). Functional impairments, along with the complexity of medication regimens, can potentially make medication management challenging for some older adults (21). Sino et al. assessed the medication management capacity of 95 geriatric patients receiving five or more medications and found that only 48.4 % were able to independently manage their medication at home (22).

Aging at home is an important component to the overall health and wellbeing in late life; however, a certain level of independence is needed to age in place (23). In order to maintain independence, adequate cognitive and functional capacity to perform medication related tasks is required (21). Several studies reported that having the ability to manage medication successfully can encourage adherence and minimize medication errors (24-26), prevent medication related hospital visits (27) and reduce dependence on family caregiver or nursing services to help with medication management (28).

With a trend toward community-based aged care, the significance of assessing older adults' ability to manage their medications is being highlighted (29-31). Assessment of the ability of older adults to manage medications can provide valuable information so that adherence and medication errors can be minimized (32). Within the healthcare system, physicians, occupational therapists, nurses and pharmacists can assess management of medication (33). One approach to assess the ability to manage medication can be through the use of standardized tools (34). Currently, there is still a need for a tool that assess older adult's ability to manage medications in the community (29,30,34). Such tools will help identify challenges with medication management and plan needed interventions accordingly (32).

1.2 Objectives

The overall aim of this thesis is to identify functional challenges with medication self-management.

Specific objectives:

- To systematically synthesize the literature on physical and sensory functional challenges experienced by community dwelling older adults when managing medications at home.
- To systematically describe and identify gaps in the literature of tools that assess functional medication management in older adults
- To describe the types of functional medication management problems in a group of patients at high risk of having functional challenges and chronic disease and identify the most common challenges for different modes of delivery.

1.3 Thesis outline

Three milestones were developed to address the overall aim (see Specific objectives). Table 1-1 summarizes these milestones.

Table 1-1: Summary of thesis.

Milestone	Research
1	Conducting a scoping review of the literature to summarize the current evidence pertaining to describing the types of physical and sensory functional challenges experienced by community dwelling older adults when managing medications at home and to review how function related to medication management was measured.
2	Conducting a scoping review of the literature to summarize the current evidence pertaining to determining measures available to assess functional medication management in older adults and the domains of functional medication management assessed by these measures.
3	Conducting a cross-sectional survey to describe the types of functional medication management problems rheumatology patients experience when managing medications at home.

Milestone 1: The research of this thesis began by conducting a scoping review on the topic of the physical and sensory challenges older adults experience when managing medications at home (Milestone 1 detailed in Chapter 3). The type of challenges described were experienced by patients with different medical conditions and different dosage forms.

Milestone 2: The second scoping review focused on describing the measures in the literature to assess functional medication management. The review also described domains covered by these measures. The measures were designed for use by any healthcare professional or researchers. (Milestone 2 detailed in Chapter 4).

Milestone 3: A cross-sectional survey to describe the different functional challenges of managing medication for patients with functional impairments seen in the Rheumatology Outpatient Clinic (Milestone 3 is detailed in Chapter 5).

Chapter 2

Literature review

2.1 Older adult demographics

Canadian population is aging quickly with people 65 years and older representing Canada's fastest growing age group (35). In 2015, over 15% of the Canadian population is 65 years or older and is estimated to increase to 25% in 2036 (36). This shift in demographics had a significant impact on health care, social services and the economy (37). Canada's health care system was established to deal largely with acute care for a relatively young population; however, with an increasing aging population the system struggles to deal with chronic and complex health issues seen in older adults (37). As a result, an age-friendly system that decreases dependency, nurtures autonomy and enables older adults' engagement is necessary (37).

2.2 Chronic conditions and older adults

The prevalence of many chronic conditions increases with age (38). It is estimated that in 2007, 76% of Canadian older adults had one or more chronic conditions (1). The report highlights that the most frequently reported chronic conditions among older adults were high blood pressure (47%,) arthritis (27%) and heart disease (19%) (1). Multi-morbidity, the coexistence of multiple health conditions, is a growing challenge that adds another level of complexity to the management of chronic conditions (39). Studies have shown that older adults with three or more chronic conditions report poor health, take more prescription medications and have the highest rate of health care visits (1).

2.3 Medications and older adults

The high prevalence of multi-morbidity results in multiple medications being used as a treatment (40,41). In 2016, 65.7% of Canadian older adults were prescribed greater than 4

different drug classes, with more than 26.5% prescribed 10 or more different drug classes and 8.4% prescribed 15 or more drug classes over a one-year period (4). Cardiovascular medications made up 5 of the 10 most common drug classes prescribed to older adults while the remaining classes consisted of proton pump inhibitors, thyroid hormones, opium, biguanides and benzodiazepines (4). Polypharmacy, that is taking multiple medications, is directly correlated with increased risk of adverse drug reactions, hospitalization and non-adherence resulting in poor management of health conditions (42,43).

2.4 Medication management definition

Medication management is defined as "the extent to which a patient takes medication as prescribed, including not only the correct dose, frequency, and spacing but also its continued, safe use over time" (44). Management of one's own medication involves knowledge, skills, and abilities necessary for successful independent living (45). It is considered one component of instrumental activity of daily living (IADL); it involves several tasks such as obtaining mediations, reading and understanding instruction (46,47). To effectively manage medications one must have physical and cognitive capacity (47).

2.5 The chosen framework-OTFP

According to the Occupational Therapy Practice Framework (OTFP), IADL is one area of occupation (48). IADL is defined as "activities to support daily life within the home and community that often require more complex interaction than self-care used in ADL" (48). Examples of IADL include shopping, managing finances, meal preparation, health management and community mobility (48).

According to OTFP, there are several domains of occupation including client factors, performance skills, performance patterns, context and environment (48). Client factors involve

three domains: (1) values, beliefs and spirituality (2) body structure (3) body function (48)**.** Values, belief and spirituality affects motivation of individuals to engage in occupation and give meaning to life; Body structure "is the anatomical parts of the body"; body functions are described as "physiological functions of body systems" (48). Performance skills include a clients' demonstrated abilities such as cognitive and motor skills. Performance patterns are habits, routines, roles, and rituals used in the process of engaging in occupations or activities. Finally, the environments and context that surround a client can affect performance (48).

In the light of the OTPF framework, medication management can be viewed as one component of IADL. Client factors can involve belief about medications and impaired body function due to aging or certain medical conditions. Performance skills can involve the cognitive and physical abilities required to manage medications. Performance pattern can involve medication taking routine and finally context and environment section of OTPF can involve receiving help with managing medications.

2.6 Functional Medication management

Functional medication management (FMM) involves both the *processes of using medication* such as ordering, picking up, organizing, preparing, administering, and monitoring medication as well as having the *functional capacity* to perform these tasks (21,34,49). It measures the ability to use a medication regimen, when the individuals have the motivation to follow it as prescribed (21).

2.6.1 Processes to using medication

According to a retrospective chart review performed in an acute setting for older adults, there are several processes involved in managing medications (ordering, picking up, organizing, preparing, administering, and monitoring) (33).

- *Ordering the medication*: The first step in filling a prescription involves finding and accessing a pharmacy to hand in the prescription, or the process of identifying a refill is required and following the steps to submit the refill request.
- *Picking up the medication*: The individual needs to come back to the pharmacy after a certain amount of time. At the pharmacy, the individual needs to communicate with pharmacist, understand instructions, possibly ask questions and pay (or provide information related to insurance coverage) for the medicine.
- *Organizing medications*: Once at home, the individual needs to store medication under proper conditions, and organize the medicine in a pill organizer, or dosette as needed.
- *Preparing medications*: Before taking medications, some medications needs to be prepared prior to administration. For example, patients may need to draw certain amount of medication from a vial using a needle.
- *Administering dose*: Most drugs are administered orally such as tablets or capsules; however, there are more complicated dosage forms such as subcutaneous injection or eye drops.
- *Self-monitoring of therapy*: Many individual need to monitor the effect of the medication on their medical condition. For example, if an individual uses medication for diabetes, he/she may need to monitor blood sugars using a glucometer.

2.6.2 Medication management capacity

Medication management capacity was defined as "the cognitive and functional ability to self-administer a medication regimen as it has been prescribed" (21). Functional skills such as fine motor coordination, and vision are few factors that can affect medication outcomes in older adults (10). Decline in these skills is associated with non-adherence and unsafe practices such as leaving medication vials open, and transferring the medication to another unlabeled container

(50,51). Cognitive impairment can also impact the ability to manage medication because it has been associated with medication errors and reduced ability to use a complex medication regimen (52,53). Even after adjusting for other factors such as age, impaired vision and arthritis, people with dementia were at least three times more likely to have reduced ability to remove medication from its packaging (54).

In addition to functional and cognitive abilities, other patient related factors that can affect the ability to manage medications include health literacy and medication knowledge, use of assistive devices such as a calendar, availability of caregiving support and willingness to accept support (54). Furthermore, medication related factors such as the type of medication and complexity of medication regimen can also affect the ability to take medications (54) (See Figure 2-1).

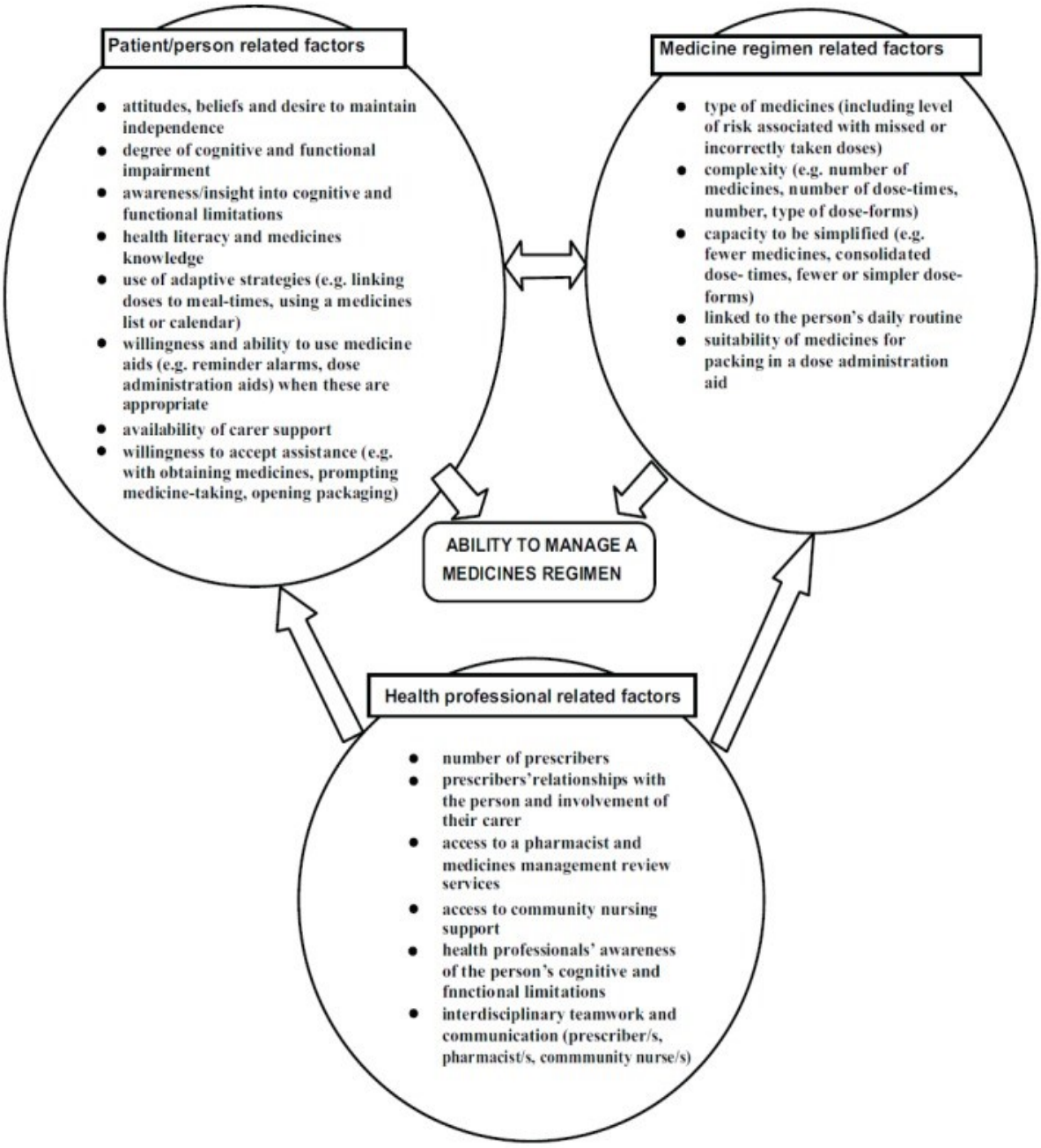

Figure 2-1: Factors affecting ability to manage medications. [54]

2.7 Challenges in medication management

Managing medications can be difficult for older adults especially in the presence of cognitive and physical impairments (55). Poor hand dexterity, visual impairment, cognitive decline, and swallowing difficulties, are commonly seen impairments in older age (11-15).

- *Hand function*

Hand function, such as grip and pinch strength, is reduced with aging in both men and women, particularly for those 65 years and older (56). This can potentially affect the ability to open medication packaging, pick up small pills, or break tablets. Around two-thirds of older adults were not able to break a tablet; 8 to 14% are unable to open a screw-top bottle; 14 to 45% a flip-top bottle, 10 to 21% a blister pack; 17 to 24% a Dosett dose administration aid; and 33 to 64% a child-resistant bottle (50,57,58).

Moreover, conditions such as osteoarthritis, and rheumatoid arthritis can impaire hand function (56). Rheumatoid arthritis, an inflammatory condition, can cause joint damage leading to joint stiffness, swelling, and muscle weakness; all of which can affect hand dexterity (59). Rheumatoid arthritis is also associated with increased risk of visual impairments which can subsequently affect medication taking abilities (60).

- *Vision*

The prevalence of visual impairments increases with age ranging from 2.7% in those 45–54 years old to 15.6% in those 75–84 years old (61). Additionally, age-related eye conditions such as macular degeneration, glaucoma, cataract and diabetic retinopathy may also reduce vision in the older population (62). These conditions can lead to increased sensitivity to glare, difficulty focusing on near objects, loss of contrast sensitivity, and weakened color vision (63). These changes can reduce the ability to manage medications such as not being able to read the small

print on prescription label, or differentiate between medications packaging, color, or shape of the medications (64,65). According a study that looked at 156 patients over the age of 65, about 30% of individuals with visual impairment needed help managing their medications, despite using visual aids and a quarter of them had challenges distinguishing different colored tablets (66).

- *Swallowing ability*

Several age-related changes may contribute to swallowing difficulties in older adults (67). Salivary gland function usually deteriorates leading to dry mouth which can contribute to difficulty swallowing (67). The nerves from the larynx also causes contraction of the upper esophageal sphincter and abnormalities in this reflex can lead to swallowing difficulties (68). Additionally, several age-related conditions such as stroke, Parkinson disease, Alzheimer disease, and cancer can lead to swallowing impairments (69,70). According to one study of 792 older adults aged 60 years and older, 60% of participants experienced difficulties swallowing tablets or capsules (71). Another study reported that up to one-third of residents in nursing homes experienced challenges swallowing medications, resulting in either tablet crushing or capsule opening (72,73).

- *Cognition*

With aging, there is a decline in certain cognitive abilities, such as processing speed, certain memory, language, visuospatial, and executive function abilities (74). Furthermore, age-related conditions such as dementia or mild cognitive impairment can be seen in older adults (74). Impaired cognition can have an impact on the ability to manage medication regimens, potentially leading to medication errors and non-adherence (24-26). Beckman reported that cognitive function (Measured by MMSE) was strongly correlated with the ability to open different types of medication containers (16). Atkin also found a strong relationship between the ability to open

medication containers and MMSE scores (58). Edelberg used an instrument that assesses medication management ability and found that a low total score on the test was related to poor cognition (75).

- *Inhalation technique*

Various inhalation devices available in the market have the same clinical effectiveness as long as they are used properly (76). Using inhalers is a complex process involving several steps such as dose loading, inhaler priming, and breath coordinating. These steps require that patients have adequate dexterity and coordination (77). Physical and cognitive decline in older adults may impede the proper administration of inhaled medications; resulting in inappropriate dosing (78). In a randomized controlled trial of 123 adults aged 55 or older, inadequate inhalation technique was high with 81% of older adults with asthma having at least one error in their inhalation technique (79).

- Other factors
    - *Education*

Research has shown that people with lower education have poor health literacy skills when compared to people with higher formal education (80,81). Health literacy is defined as "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" (82). Poor health literacy is common among older adults, and even those with corrected vision, are unable to read or understand instructions on medication labels (83). This can result in reduced medication management ability (83).

    - *Communication*

Language and culture are important factors in understanding medical information (84). The inability to read, write, or speak a certain language affects one's health literacy (85). People with certain characteristics such as older adults, people with low education or income levels, non-native speakers of English are more likely to have difficulty reading and understanding medical information (86).

2.7.1 Impact of problem

According to one model of patient non-adherence by Horne, the lack of functional abilities or resources to perform certain medication related tasks can lead to unintentional non-adherence (87). Adherence is defined as "the degree to which medication taking actions corresponds with the advice of the health care provider" (88). It has been estimated that adherence rate in older adults can range between 38%- 57% with an average rate of less than 45% (89,90). Non-adherence can lead to worsening of a patient's condition, frequent hospital and clinic visits, and increased health care system spending (91,92). According to a World Health Organization report, medication non-adherence in Canada accounts for 5% of hospital and doctor visits, causing an additional $4 billion in health care cost every year (93).

2.8 Measures of functional medication management

Assessment of patients' ability to safely manage medication is not undertaken routinely by health professionals, and if it is undertaken there is inconsistency in the methods used (55,94). A retrospective chart review by Bolina concluded that FMM components is assessed infrequently by health care professional when older adults are admitted to acute care hospitals and that such assessments need to be incorporated into the hospital-based care of older patients (33). Assessing difficulties with medication management can help prevent the occurrence of significant errors or non-adherence (24).

The method of assessment varies depending on the degree of functional impairment and patients' readiness to cooperate (24). Functional medication management is measured using either self-report or direct observation by a health-professional (95,96). Commonly used self-report measures such as Lawton IADL scale include items relating to medication management (6). However, these scales are limited to only one item assessing medication management ability, and do not define the skills required for medication management (97). Direct unstructured observation involves health professionals observing patients perform medication related tasks to assess their ability to manage medications (32). Even though direct observation method may be more objective than self-report, it is still of limited reliability (96). Subsequently, there is still a need for a structured standardized tool that assess persons' functional ability to manage their own medication to be used by health care professionals (32). The use of such tool will help identify inabilities with the aim of improving older adults' self-care skills to support successful medication management (32).

Chapter 3

Functional challenges with medication management for older adults in the community: a scoping review

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3.1 Introduction

Older adults use more medications than any other age group because of a higher number of chronic conditions [98,99]. In Canada, 65.7% of older adults are prescribed five or more different drug classes making it challenging to adhere to a medication regimen as prescribed [4,100]. Approximately, 3–10% of hospital admission of older adults are due to non-adherence [101,102]. There are several factors that can lead to non-adherence including practical concerns, beliefs about the medication, lack of medication knowledge, complex medication regimen, residence in a private home and absence of assistance with medication administration [103-105]. Unlike adherence, which involves intention, belief and the ability to take medications [104], the idea of functional medication management focuses on unintentional non-adherence due to the lack of physical or cognitive ability to perform certain tasks related to medication administration at home [21].

Several studies reported on the effect of reduced cognitive and physical abilities on several aspects of medication management. Cognitive impairment, measured by Mini Mental Status Exam (MMSE), is associated with a decreased ability to open medication containers [57]. Reduced physical abilities such as impaired vision and low manual dexterity are associated with decreased ability to manage medications [57]. Reduced vision, in particular, was associated with decreased ability to open medicine containers and different blister-pack designs [57,32]**.** Impaired hand function, due to arthritis, has been associated with difficulties opening medication containers [20]. Furthermore, difficulty swallowing oral medications can lead to non-compliance and stoppage of medications [106]. Even with this literature, studies describing the function related to medication management were limited. The functional ability to manage medications is regarded as one component of instrumental activities of daily living (IADL) [46]. Currently,

there is no literature review describing the functional challenges older adults experiment when managing the medications at home. With increasing interest in community-based aged care and recognition that assessing the functional ability of older adults to manage their own medication, is a strong indicator of independence [30,107,108], a scoping review of the literature may provide broader understanding of the types of functional challenges experienced by older adults when managing medications at home.

3.2 Methods

3.2.1 This scoping review was guided by the methods described by Arksey and O'Malley [108]. We focused this scoping review on mapping areas of functional medication management in older adults living at home. The research question was "What is known about functional medication management in older adults", with the following two main objectives:

1. What physical or functional challenges do older adults experience self-administering medications at home?
2. How are functional challenges for older adult self-medication administration being measured?

An experienced information specialist (RF) designed and executed the literature search strategies for the six selected databases: Ovid MEDLINE, Ovid Embase, CINAHL, Ovid PsycInfo, Conference Proceedings Citation Index (Clarivate Analytics), and ProQuest Dissertations & Theses Global. The search was peer-reviewed by a second medical librarian (TL). The searches were performed between Jan 15-22, 2018. Search strategies utilized subject headings (e.g., MeSH) and text words for concepts: older adults, routes of medication administration and adherence (See appendix B for complete search). Searches were not limited by language or study design, but excluded animal studies, studies about pediatric patients or patients with dementia.

Search results were limited to publications from 2000 to present. We exported the search results to EndNote V.X7 (Thomson Reuters) and removed duplicates.

Two reviewers (HA, LB) screened titles and abstracts independently based on the inclusion and exclusion criteria (Table 3-1). The same reviewers then read the full-text of selected studies. When agreement on a citation could not be reached between reviewers, a third reviewer (CS) was consulted for consensus. The inter-rater reliability for the two reviewers was 62.3% representing fair to good agreement between reviewers [109]. All study designs (randomized controlled trials, observational studies, qualitative studies, systematic reviews), and available research reports (i.e., original papers, journal abstracts, mini-papers/ abstracts, conference proceedings and thesis) that described functional challenges related to medication management experienced by older adults were screened for this review. Studies that took place in a hospital setting or included only younger adults (< 65 years of age) were excluded (Figure 3-1). For some of the studies that included both younger and older cohorts, we described older cohorts' data when possible.

Charting the data: The same two reviewers independently extracted data into Microsoft Excel 2016 using a standardized data extraction form.

Collating, summarizing, and reporting the results: We extracted the data based on the general characteristics of the studies, for instance, the publication date, the country of origin, and the study design. Additionally, demographics, population characteristics, package designs, functional challenges with medications and medication management assistance was summarized. Critical appraisal was not a part of this scoping review.

3.3 Results

4373 citations were retrieved after removal of duplicates of which 198 abstracts were identified and 41 (40 studies and 1 review) were retained for the full review (Figure 3-1). Of

these 41 papers, 27 described functional challenges older adults experience when managing medications at home. Publication numbers varied across decades, Twelve studies from 2000 to 2010 and fifteen studies after 2010 to present. The studies come from 15 different counties with the top five countries: Netherlands (n=5), USA (n=4), UK (n=3), Japan (n=3), and Germany (n=2). A variety of study designs were used: cross sectional design (n=10), qualitative study design (n=6), randomized controlled trial (n=6), prospective cohort (n=2), case control (n=1), non-randomized trial (n=1), and factorial clinical trial (n=1) (Table 3-2).

Functional challenges with medication use: Difficulties that older adults encountered when managing medications were identified in 27 studies (Table 3-3) and broadly classified as challenges with using oral medications (n=11), inhalers (n=10), eye drops (n=4) and injections (n=2).

3.3.1 Functional challenges with oral medication: Eleven studies were found in the literature examining and identifying the frequency and range of practical problems that older people experienced with managing oral medications. Only 4 of the 11 studies reported the following medical conditions: rheumatoid arthritis (n=2) [113,16], Parkinson disease (n=2) [113,16], stroke (n=2) [113,46], dementia (n=1) [46], diabetes, circulatory, respiratory, or digestive disorders (n=1) [110], and GI and cancer (n=1) [111]. In addition, only three out of the eleven studies reported on functional limitations such as sensory impairment (n=1) [110], hand grip and manual strength (n=1) [112], and vision impairment (n=1) [46]. The most common challenges older adults reported when managing oral medication included accessing medication from its outer and immediate packaging [5], opening medication containers such as vials [46,110,114,115], blister packs [32,107,46], mouthwash [112], and foil [107, 115]. Four studies reported on difficulties with breaking tablets [107,110,114,116]. Further two studies reported on difficulties swallowing

medications (n=2) [107,117]. Additionally, three studies reported on difficulties reading labels [107,5,114]. Also, two studies reported on difficulties removing medicine from a blister [114, 117]. Finally, one study reported on difficulty using a daily pill box. Qualitative study design using either a semi-structured interview [107,5,117] or a focus group discussion [110,114] was the most commonly reported method in the studies (n=5). Next, performance based assessment, which required the participants to demonstrate some of the skills relating to managing medications such as opening a prescription vial or breaking a tablet, was used in four studies. Finally, questionnaires including self-report or telephone questionnaire were used by two studies.

3.3.2 Functional challenges with inhaler use: Ten studies were found in the literature examining and identifying the frequency and range of problems experienced by patients with respiratory diseases: asthma and COPD. Only three out of the ten studies reported on functional limitations such as hand dexterity [118, 119] and hand arthritis [120]. The studies examined the operation of the inhalation devices and performing the inhalation technique of the following devices: pressurized metered dose inhalers (pMDIs) [118,121,122], nebulizers [119,123,121]. and dry powder inhalers [DPIs] such as Diskus ® [124,125], Genuair® inhaler [120], Handihaler ® [122,126, 125, 126], ELLIPTA DPI ® inhaler and BREEZHALER DPI ® [127]), and Respimat ®inhaler [126]. The studies examined the types of problems older adults encounter when using inhalers such as handling the technical aspect of the operation, administering the inhalers and cleaning the devices**.** Since each inhaler type has unique operating instructions, challenges with inhaler use varied. The most reported problems with pMDI include problems shaking the inhaler [121], failure to inhale deeply and slowly while actuating [118,121], using multiple actuations of the canister [118] and failure to hold breath at the end of inspiration [118]. In addition, two studies identified problems with using Diskus ® including difficulties opening the device [124,

125], sliding lever until it clicks [124,125], closing the device [124,125]. Further, the most common problems reported with BREEZHALER and ELLIPTA include problems opening inhaler, pressing side buttons before inhaling, inserting capsule, and closing inhaler [127]. On the other hand, challenges with single-dose device such as Handihaler ® include peeling open strip with capsule, piercing the capsule, releasing the perforation button, and removing empty capsule [121,125]. Finally, two studies reported on challenges using nebulizers [119,123] which include difficulties assembly of device (filling nebuliser fluid, and connecting tubing to nebulizer), dismantling nebuliser (cap/medication tank/vaporizer head), cleaning of nebulizers and not having confidence that drug was delivered into the lungs.

Performance based was the most common method of assessment (n=7), done by healthcare professionals, and usually in pulmonary clinics, followed by interview/questionnaire (n=2) and qualitative study design (n=1). All of the studies utilized education leaflets or training program about inhaler use prior to assessment of inhalation technique. Six studies used checklists that are either previously published or given by pharmaceutical companies to evaluate inhalation technique [118, 122,124,125,126, 127]. Two studies used pre and post testing of inhaler technique by a healthcare professional [120,126].

3.3.3 Functional challenges with eye drops: Four studies were identified in this scoping review examining challenges with eye drops use for people with the following conditions: glaucoma [128,129,130,131], Sicca [129] and dry eye syndrome [131]. The studies examined challenges with the use of different eye drops including conventional eye drop bottle [128,130,131], upright eye drops bottle [130] and single use eye drops [129]. Most challenges identified with eye drops bottle use include taking lid off, holding the eye drop bottle, squeezing the eye drops out and tipping the head [130]. On the other hand, the main challenge with single use eye drop is

pressing the drop out of the container [129]. None of the studies reported on functional limitations related to eye drops administrations. Performance based assessment was used by two studies with or without a checklist [129, 130]. A patient-completed questionnaire was the second most common method for assessing difficulties with eye drops use [128, 131].

3.3.4 Functional challenges with injection use: Two studies were identified in this review assessing the experience of older adults using insulin pens or vial and syringe [n=2]. The studies included patients with type 1 or 2 diabetes [132,133] with functional limitation such as manual dexterity or hand tremor as well as vision impairment [133]. The studies identified a range of challenges when using injections such as difficulties reading the numbers on the pen or syringe, turning the dose vial in the pen, depressing the push button/plunger and holding the device stable while injecting. Questionnaires were the main method used in these two studies [132,133].

Medication management assistance: A number of studies (n=9) identified that older adults needed help managing their medications [16,110,5,114,115,117,128,129,131]. Older adults required help mostly with opening medication containers [16,5,114,115,117], remembering to take the medication on time [110], removing medicine from a blister [117], administration of eye drops [128, 129, 131], and assembling components of nebulizer [119]. Most help was received from family members, partners, friends, neighbors, caregivers, and pharmacy staff. Five studies listed living arrangement such as living alone or living in an institution [113, 16,119,121].

3.4 Discussion

Our review found 27 studies examining difficulties with medication use. We identified 11 studies focusing on oral medication use, 10 studies on inhaler use, 4 studies on eye drops use and 2 studies on injection use. There was a heterogeneity in the type of challenges identified with different dosage form of medications, making it difficult to identify a clear set of challenges that

applies to all patients. However, studies consistently under-assessed functional limitations. This review also identified that older adults needed help with their medications and most help was provided by family members.

The majority of studies focused on challenges with oral medication vial use as compared to other packaging design. Even though vials are very common medication package and can be challenging to handle, especially if child resistant, difficulties can still exist with other packaging designs such as inhalers, injectable and eye drops, which normally require a multi-step process for handling and administration.

Our scoping review found several studies on inhaler use; however, the majority of these were usability studies that focused on acceptability and marketing aspects of inhalers and rarely assessed functional limitations. This is a significant gap in the literature, as functional limitations, such as poor hand function, have been associated with non- adherence in inhaler use [134]. Additionally, the correct use of an inhaler requires both handling the operation of the device and the required inhalation manoeuvres [135]. A study involving 34 participants with rheumatoid arthritis (RA) showed that people with RA were less likely to be able to operate inhalers properly with metered dose inhaler (pMDI ®), Easi-Breath® and HandiHaler® being most difficult to use. The study found that only 50% of participants were able to complete all the steps necessary to operate pMDI device, which the authors attributed to the difficulty meeting the force required to depress a pMDI canister [136]. Since many inhalation devices require several steps for activation, preparing, using and cleaning of device, assessment of functional abilities needed to perform these steps should be integrated into research and clinical interactions with healthcare professionals.

Additionally, our scoping review found very few studies assessed difficulties using injectable devices. All of the studies we found in this review were done with patients with diabetes. Even though the use of injectable is common this group, we expected to find some studies on people with inflammatory diseases such as rheumatoid arthritis as injection use is also common among this group. However, one possible explanation is that rheumatoid arthritis is a disorder of middle age of 40 to 60 years with a prevalence of 2% of the population older than 60 years [137], and the age limit for our search is those 65 years or older. Furthermore, we found few studies assessing difficulties with eye drops use and none of these studies assessed functional limitations. Three of the studies focused on people with eye disorder and only one of these studies has focused on people with rheumatoid arthritis and eye drop administration [131]. Even though successful eye drops administration depends on physical dexterity, eye hand synchronization and good eyesight [138], none of the studies assessed hand strength or dexterity needed to complete the tasks related to eye drops administration. Finally, we did not find any study describing challenges with other medication forms such as such as creams, patches, sprays or suppositories.

Our study has a number of limitations. Although our search was not restricted by language, some language bias was still inherent as our search was conducted using English-language search terms. Only one papers that was not written in the English language was assessed at full-text level; this was eventually excluded as it did not fit our inclusion criteria [139]. Also, the aim of this scoping review was to identify the breadth of research about functional challenges with medication management and any gaps in the literature as a result the methodological quality of the included studies was not assessed. Additionally, our review excluded studies focusing on patients with dementia even though this patient population may

have several challenges with medication use. However, because this population may have both cognitive and functional impairments; they are mostly cared for by care-givers and self-administration of medication may be rare in this population.

CONCLUSION:

We found 27 unique studies describing functional challenges experienced by older adults in the community. The majority of the studies focused on challenges with oral medication packaging and pulmonary devices.

Fewer studies reported on challenges with eye drops and injectable medication use. Older adults may not have sufficient functional abilities to manage medication regimens. Since assessment of such abilities is not required by regulatory agencies prior to approving the medication for market access and not routinely done by health care professionals, further research should focus on incorporating a comprehensive functional medication management assessment into research and clinical practice in order allow successful medication management at home.

Table 3-1: Inclusion/Exclusion Criteria

	Inclusion criteria	**Exclusion criteria**
Study Design	All study designs Published between 2000-2018	Published prior to 2000
Setting	Taking place in the participant's home and self-administering	If medications is administered in a care facility, hospital, nursing home or caregiver.
Participants/ population	Adults over the age of 65	Under the age of 65
Intervention(s), exposure(s)	Functional challenges with medication management at home	Cognitive impairments Pediatric patients
Outcome(s)	Impact of physical / functional challenges on any outcomes	None

Table 3-2: Aggregate summary of study characteristics

Studies characteristics (n=27)	Studies n (%)
Location	
Netherlands [25,27,28,29,37]	5 (19%)
USA [22,40,42,44]	4 (15%)
UK [33,35,43]	3 (11%)
Japan [38,39,45]	3 (11%)
Germany [13,41]	2 (7%)
Sweden [21]	1 (4%)
Brazil [24]	1 (4%)
Australia [26]	1 (4%)
New Zealand [17]	1 (4%)
Canada [23]	1 (4%)
Bahrain [30]	1 (4%)
Italy [32]	1 (4%)
Denmark [34]	1 (4%)
China [36]	1 (4%)
Kuwait [31]	1 (4%)
Study design	
Cross sectional design [13, 21,27, 28, 30, 31, 33, 36, 43, 40]	10 (37%)
Qualitative study design [17, 22, 25, 26, 29, 45]	6 (22%)
Randomized controlled trial [23, 34, 37, 39, 42, 44]	6 (22%)
Prospective cohort [38, 41]	2 (7%)
Case control [32]	1 (4%)
Non-randomized trial [35]	1 (4%)
Factorial clinical trial [24]	1 (4%)
Diagnoses	
Respiratory conditions	
COPD [30,31,33,34,35,36,37,38, 39]	9 (33%)
Respiratory disease [22,32]	2 (7%)
Asthma [30]	1 (4%)
Neurological conditions	
Stroke [13,21]	2 (7%)
Parkinson's disease [13,21]	2 (7%)
Dementia [21]	1 (4%)
Endocrinology conditions	
Diabetes [22,44,45]	3 (11%)
Gastrointestinal disorders	
Digestive disorders [22]	1 (4%)
GI cancer [23]	1 (4%)
Eye conditions	
Glaucoma [40,41,42,43]	4 (15%)
Vision impairment [21,45]	2 (7%)

Sicca [41]	1 (4%)
Dry eye syndrome [43]	1 (4%)
Inflammatory conditions	
Arthritis [13,32]	2 (7%)
Rheumatism [13]	1 (4%)
Rheumatoid Arthritis [21]	1 (4%)
Other impairments	
Manual dexterity impairment [44]	1 (4%)
Circulatory [22]	1 (4%)
Sensory impairments [22]	1 (4%)
Hand tremors [45]	1 (4%)
Types of medications	
Oral medications [13,17, 21,22,23,24,25,26, 27,28,29]	11 (41%)
Inhaled medications [30, 31,32,33, 34,35, 36,37,38,39]	10 (37%)
Eye medications [40,41,42,43]	4 (15%)
Injectable [44, 45]	2 (7%)

Table 3-3: Summary of study results

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
ORAL – PERFORMANCE BASED (n=4)							
Beckman Sweden 2005 Cross-sectional [16]	To explore elderly people's ability to open medicine containers, and correlations with common disorders that may cause functional or cognitive impairment	86.7 ± NR 469 (77.6%) N = 604	RA (n=28) Stroke (n=66) Parkinson's disease (n=8) Dementia (n=137) Impaired vision (n=227) Almost blind (n=25) Urban area of Stockholm, Sweden in own home (n=493), non-medical accommodation (n=62), or institution (n=49)	Three different types of containers: a plastic bottle with a snap lid, a glass bottle with a screw cap and blister pack	Performance based	Failed to open medication containers: Screw cap bottle 85 (14.1%) Snap lid bottle 192 (31.8%) Blister pack: 59 (9.8%)	Percentage of elderly received help with their medication, among those who were unable to open one or more of the containers according to housing level: Own home (27.2%) Non-medical accommodation (70.6%) Institution (100 %)
Bonfim Brazil 2016 Factorial clinical trial [112]	To evaluate the effects of packaging design, gripping technique and age in the transmission of torque when opening packages with squeeze-and-turn closures	For those over 60: 74.67 ± 9.08 10 (50%) N = 20	Voluntary participants evaluated at Ergonomics and Interfaces Laboratory in Sao Paulo Brazil; those over 60 years were individually invited to participate	Three different packages of mouthwashes (squeeze-and-turn type)	Performance based with biomechanical measurements	Maximum torque measurements of group above 60 years, were lower when compared to adults (30-59 years), with significant difference found only for the packaging with cylindrical cap Average maximum torque for the three different packages (conical, inverted conical, cylindrical consecutively)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
						using two gripping techniques for those over 60 years: Tridigital prehension (N.m): (2.57±0.94,3.35±1.19, 2.96±0.95) Bidigital prehension (N.m): (0.97±0.35, 1.24±0.37, 0.96±0.37)	
Notenboom Netherlands 2016 Cross-sectional [116]	To assess the ability of older people to break scored tablets	84.2 ± 6.8 25 (69.4%) N = 36 (older adults)	Recruited in five residential homes for elderly in the area of Utrecht, the Netherlands	Tablets broken by hands: (1) in between fingers with nails; (2) breaking in between fingers nails; (3) pushing tablet downward with one finger on a solid surface	Performance based on breaking of tablets	Tablets (%) successfully broken by older adults (38.1%) compared to (78.2%) by young adults.	NR
Muhlfeld Germany 2012 Cross-sectional [113]	To examine the relationship between blister pack design and utilization problems among older adults	Age range (n): 55 = 80-82 years 51 = 83-85 years 35 = 86+ years 93 (66%) N = 141; 54 with relevant diseases	Rheumatism (n=18) Stroke (n=20) Arthritis (n=31) Parkinson's disease (n=4)	Five different blister packs designs with different opening mechanism (peel, push-through [20, 25, 38 micrometers], child-resistant peel-off push-through).	Performance based carried out in residence by employees of Boehringer Ingelheim Pharma	Failed to open different blisters, take out 4 tablets within 4 minutes (out of 54 with relevant disease): Push through 20 micrometers = 1% Push through 25 micrometers = 7% Push through 38 micrometers = 16% Open peel blisters = 30% Child resistant peel-off push-through blisters = 44 %	Lived in assisted-living facilities = 18.4%

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
ORAL – QUALITATIVE (n=5)							
August USA 2005 Qualitative – focus group [110]	To evaluate the Liberty 6000, an automated capsule and tablet dispenser that provides proper medication dosages and is intended to encourage and track medication adherence	47% = 65-74 31% = 75-84 22% = over 84 32 (65.3%) N = 49	Diabetes (12.1%) Circulatory (39.4%) Sensory impairments (9.1%) Respiratory (3%) Digestive (3%)	Medication packaging	Focus group discussion; total of 7 groups ranging in size from 5-10 participants; residents living independently or semi-independently in home setting or residential group care setting	Percent of problems reported for those with dexterity problems: Opening bottles (8.6%) Handling medications (2.9%) Cutting tablets (3.8%) Loading a device (41.4%) Seeing medications (4.8%) Swallowing medications (4.8%)	Receiving help remember taking medications (12.9%)
Kippen Australia 2005 Qualitative – focus group [114]	To explore the impact of medication use on the lives of older people	60 years or older 15 (57.7%) N = 26 (Personal communication with Julie Ellis March2,2019)	Focus group participants recruited from groups catering for the needs of older Australians Four in a regional city and one in a small rural town	Medication package	Focus group lasting 1-2 hours, facilitated by one of the authors Participants were asked how they felt about taking medications and the group discussion was allowed to flow	Identified practical issues relating to medications: Difficulty reading fine print due to poor eyesight, difficulty opening caps on childproof bottles, difficulty pushing packaging of medications, and difficulty cutting tablets	Some subjects received help from family members opening medication packaging.
Notenboom	To recognize design features of oral	78.0 ± 6.2	Recruited from community pharmacy	Oral medication packaging	Semi-structured interviews	Percent of elderly who experienced difficulty	Percent needed help or applied strategy to

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
Netherlands 2017 Qualitative - interviews [117]	medicines that cause use problems among older patients in daily practice.	38 (64.4%) N = 59	and geriatric outpatient ward			performing a task but is able to complete the task without help: Swallowing of medicines (37.8%) Removal of medicines from a blister (13.3%).	complete the following tasks: Removal of medicines from a blister (31.9%) Opening of containers (15.9%)
Notenboom Netherlands 2014 Qualitative – interviews [5]	To identify practical problems that older people experience with medication management	78.4 ± NR 38 (64.4%) N = 59	Recruited from community pharmacy and geriatric outpatient ward	Oral medication packaging	Semi-structured face-to-face interview in participants home administered by researcher	Reported difficulties performing following task: Reading and understanding instructions for use (n=37) Handling outer packaging (n=17) Handling immediate packaging (n=38) Preparation before use (n=23) Drug taking (n=17)	Received help opening medication containers from a partner or caregiver (n = 7)
Tordoff New Zealand 2010 Qualitative - Interview [107]	To explore how older adults, manage their medicines at homes	Median age men=71 Median women= 77 10 (50%) N = 20	Recruited from list of people over 65 years (40 men and 40 women) at random from the electoral roll for Dunedin (North and South Dunedin), New Zealand	Medication package	Semi-structured interviews in participants home administered by researcher (hospital pharmacist)	Reported difficulties performing following: Opening blister and foil packaging (n=1) Using eye drops (n=1) Breaking tablets in half (n=1) Reading labels (n=0) Swallowing half-tablets or uncoated tablets (n=6)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
ORAL – INTERVIEWS, SURVEYS, QUESTIONNAIRE (n=2)							
Macintosh Canada 2007 RCT [111]	To investigate whether the use of daily pill boxes can help simplify oral anticancer regimens, compared with conventional pill bottles and to measure patients' satisfaction and preference of the more user-friendly packaging.	Median = 64 15 (60%) N = 25	GI cancer = 21 (84%) Patients approached in ambulatory GI or breast cancer clinics, in chemotherapy daycare unit, or in outpatient pharmacy at the Princess Margaret Hospital, Toronto, Ontario, Canada	Capecitabine packaged in conventional pill bottles and daily pill boxes.	Self-report questionnaire after each round (conventional pill bottles or daily pill boxes)	More satisfied with daily pill boxes (61% versus 11%, *P* =0.027) Preferred daily pill boxes (61% versus 17%, *P* = 0.061) Reported that daily pill boxes were more helpful in reminding them to take medications (50% versus 11%, *P* = 0.070)	Living alone = 2 (8%)
Philbert Netherlands 2014 Cross-sectional [115]	To examine the prevalence of problems experienced by older people when opening medicine packaging	74 ± NR 216 (67.8%) N = 317	Recruited from community pharmacies in the centre, northwest and southwest of the Netherlands, in mostly urban settings	Omeprazole packaged in peel-off blisters, push-through blisters, bottle/container	Telephone questionnaire with questions regarding demographics and open-ended on problems with packaging	Experiencing problems with different medication packaging: Peel-off blisters 36 (66.7%) Push-through blisters 102 (33.3%) Bottle/container 179 (17.9%)	Received help with opening of medication containers from a partner (n = 9), family/neighbors (n = 5), a professional carer (n = 1) or the pharmacy (n = 1).
INHALERS – PERFORMANCE BASED (n=7)							
Alsaffar Bahrain 2002	To evaluate inhalation technique of patients using MDI	Age range: 15-75 years 30 (60%) N = 50	Asthma and/or COPD with satisfactory hand range of movement (dexterity), and have no arthritis that interferes with ability to use inhaler	Pressurized meter dose inhaler, DPI	Performance based, direct and close observation of MDI using a 6-steps checklist	Incorrect use of MDI (88%) Doing rapid inhalation with failure in synchronization (88%)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
Cross-sectional [118]						Using multiple actuation of the canister (74%) Not holding breath at the end of inspiration (66%)	
Asakura Japan 2013 Prospective cohort [126]	To assess the effect of switching from tiotropium HandiHaler to Respimat in patients with COPD	Median age =74 0 (0%) N = 29	COPD Consecutive patients who visited the outpatient clinic of pulmonary medicine	HandiHaler ® and Respimat ® inhaler	Performance based; patients received guidebook for Respimat with a practice device provided; evaluated using a 12-step checklist	Reported their ideas about the usability of Respimat ® compared with HandiHaler ®: Much easier (n=11) Easier (n=10) Same (n=8) More difficult or much more difficult (n=0)	NR
Blasi Italy 2016 Case-control [120]	To investigate the usability of the Genuair® device and patients' subjective viewpoint on the device	Age range (%): 60% = 65-74 years 33% = 75-84 years 7% = >84 years 50% N = 438 self-sufficient	Respiratory diseases (24%) Hand arthritis/arthrosis	Genuair® inhaler	Performance based usability test in respondent's homes using a structured questionnaire developed by a panel of experts Each question answered on 10-point scale with 10 being best	"Is it easy to understand how to use the device?" = 7.8 ± 1.4 "Is it easy to learn to use the device?" = 8 ± 1.3 Those with hand arthritis/ those without hand arthritis: Easy to grip (8.1±1.3)/ (8.6±1.2) The cap is easy to close (8±1.5)/ (8.5±1.3) Easy to hold (8±1.4)/ (8.5±1.2) Easy to handle (8.1±1.3)/ (8.4±1.3)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
						The cap is easy to remove (7.9±1.4)/(8.4±1.3) Easy to operate (7.9±1.4)/ (8.4±1.5) Easy to load the dose (7.9±1.5)/ (8.4±1.4)	
Dahl Denmark 2003 RCT [122]	To compare patient ability to use the HandiHalers or MDI device correctly	67.1 ± 7.9 57 (38%) N = 151	COPD	HandiHaler ® and MDI	Performance based; recruited from 2 outpatient clinics in Denmark; measured using 12-step checklist assessment	After training, subject performed all the inhalation steps and those with at least 1 error; MDI (56.8%); Handihaler ® (46.0%)	NR
Huaidong China 2014 Cross-sectional [124]	To evaluate the handling errors related to the Diskus device, and to explain the importance of educating COPD patients on the proper use of the device	64 ± NR 127 (33%) N = 384	COPD patients recruited from a pulmonary clinic in China	Diskus	Performance based; 13 essential steps for handling the Diskus inhaler observed by investigator	Performing incorrect steps according to the 13 steps Diskus checklist: Failure to open the outer cover or incomplete opening of the outer cover (12.2%) Failure to slide the lever until the ‘‘click’’ sound (17.9%) Not closing the lever and the outer cover (8.1%)	NR
Komase Japan 2014	To assess inhaler preference and handling errors with the ELLIPTA® DPI, compared with	62.8 ± 10.66 75 (50%) N = 150	Japanese volunteers with COPD recruited from clinics	ELLIPTA DPI inhaler and BREEZHALER DPI	Performance based using pre-prepared checklist	Handling errors BREEZHALER: Did not close inhaler until hearing a “click” (3%)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
RCT [127]	the established BREEZHALER™, a single-dose capsule DPI				observed by trained assessor	Could not insert capsule into inhaler capsule chamber without instructions (17%) Did not press side buttons simultaneously until "click" was heard before inhaling (38%) Handling errors ELLIPTA: Could not open cover without instructions (1%) Did not press side buttons simultaneously until "click" was heard before inhaling (1%)	
Van der Palen Netherlands 2007 RCT [125]	To examine the preference and ease of use between Diskus® (DK) and Handihaler® and to explore the acceptability of inhalation resistances	65.4 ± 9.9 NR	COPD patients who attended the pulmonary outpatient department	Diskus® and Handihaler®	Performance based; assessed using a purpose-designed inhaler-specific (Diskus or Handihaler ®) checklist; observed by trained lung function assistant; asked to score ease of inhalation on a	Diskus ® checklist used correctly: Open inhaler (81.7%) Push lever back (60%) Close inhaler (78.3%) Handihaler ® checklist used correctly: Open top cover (100 %) Open mouthpiece (91.7%) Peel open strip with capsule (76.6%)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
					10–point scale from very difficult (1) to very easy (10)	Put capsule in inhaler (93.3%) Close mouthpiece until click is heard (88.3%) Perforate capsule (68.3%) Release the perforation button (75%) Remove empty capsule (83.3%) Close inhaler (81.7%)	
INHALERS – QUALITATIVE (n=1)							
Alhaddad Kuwait 2014 Cross-sectional [119]	To recognize the practicalities and problems associated with nebuliser use by patients with COPD at home	71 ± NR 29 (58%) N = 50	COPD patients recruited from primary care and intermediate care settings in North West London	Nebuliser	Semi-structured interviews and observation of inhaler technique using checklist; administered in patient homes by researcher	Reported problems with filling nebuliser fluid due to confusion and the physical and functional limitations (n=6) Difficulty connecting tubing to compressor or nebulizer due to poor manual dexterity/grip (n=6) Failed to dismantle nebuliser (cap/medication tank/vaporizer head) due to manual dexterity (n=14)	32 lived alone and 15 were assisted by a family carer
INHALERS – INTERVIEWS, SURVEYS, QUESTIONNAIRE (n=2)							
Alhomoud UK 2014	To explore how older patients made decisions regarding the use of inhalers at home, and how those decision and difficulties	77 ± 8.23 22 (47.9%) N = 46	Patients with COPD recruited from large medical practice	pMDIs DPI and nebulisers.	Semi-structured face-to-face interviews conducted in patients homes by researcher	Subjects reporting technical problems with multi-dose devices (Accuhaler and turbohaler): Problems loading dose (n=3)	15 (33%) = living alone 31 (67%) = do not live alone

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
Cross-sectional [121]	contributed to suboptimal outcomes and treatment failures.					Doubts whether active drug actually released and when device activated (n=5) Difficulty reading numbers on dose counter (n=6) Reporting technical problems with single-dose devices (Handihaler): Problems in piercing the capsule (n=5) Problems emptying capsule (n=3) Swallowing capsule rather than inhaling (n=2) Reported technical problems with (pMDI) Shaking inhaler before use (n=7) Actuating while inhaling deeply and slowly (n=4)	
Goodman UK 2010 Non-randomized trial	To compare patient satisfaction, device ease of use, and patient QoL on inhaled COPD therapy delivered via the I-neb AAD System versus the	Median = 68 years 34 (49%) N = 70	COPD	I-neb AAD, jet nebulizer (96%), ultrasonic nebulizer (4%)	Questionnaire (5 point Likert scale) assessing ease of use, patient satisfaction, and QoL; assessed pre and post-treatment	Subjects favored the I-neb AAD System over the patients' previous nebulizer systems for 4/5 questions: ease of assembly (p=0.0001), ease of taking apart (p<0.0001), ease of cleaning	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
[123]	patients' previous nebulizer systems				separated by 3-month treatment period	($p<0.0001$), and confidence that drug was delivered into the lungs ($p=0.001$)	
INJECTION - INTERVIEWS, SURVEYS, QUESTIONNAIRE (n=2)							
Campos USA 2012 RCT [132]	To evaluate the preference and usability of a new prefilled insulin pen FlexTouch (FT) versus vial and syringe (VS)	Age range: 60% = less than 65 40% = 65 and over 32 (53%) N = 60	Type 1 diabetes (18%) Type 2 diabetes: (82%) Manual dexterity impairment (33%) Recruited from health care provider database, fieldwork agency database or via nurses/physicians 33% manual dexterity impaired	FlexTouch and vial and syringe	Written questionnaire in relation to ease of use and confidence in use	Considered FT 'very easy' or 'fairly easy' to use (FT: 97% and VS 53%) Reported following steps to be very easy or fairly easy: Holding device stable when injecting (FT:100% and VS: 77%) Depressing push-button/ plunger (FT: 96% and VS: 82%) Knowing that push-button/ plunger depressed completely (FT: 93% and VS: 85%).	NR
Suzuki Japan 2006 Qualitative – questionnaire [45]	To explore whether QoL in type 2 diabetic patients is improved by switching from NovoPen 300 (cartridge injector) to FlexPen (prefilled injector)	34 = under 60 years 68 = over 60 years 47 (46%) N = 102	All had Type 2 diabetes Visual acuity problems (50.4%) Hand tremors (20.4%)	NovoPen 300 and FlexPen insulin pen	Self-administered questionnaire Questions included: ease of adjusting dosage; ease of turning dosage dial	Number of subjects (n) who reported "poor" rating with the following steps: Ease of reading numbers (n=3) Ease of turning dosage vial (n=6) Ease of gripping injector (n=9)	NR

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
			Recruited from diabetic outpatient clinic			Ease of pushing injector button (n=37)	
EYE DROPS - PERFORMANCE-BASED (n=2)							
Davies USA 2016 RCT [130]	To test the feasibility of use of the upright eye drop bottle versus conventional bottle among experienced eye drop users.	72.4 ± 8.9 24 (60%) N = 40	Glaucoma (100%) Recruited from a single academic glaucoma clinic	Conventional eye drop bottle and upright eye drop bottle	Performance based observing use of eye drop techniques	Difficulties in using eye drops: Aiming the bottle 27 (67.5%) Keeping eyes open 10 (25%) Squeezing out the drop 7 (17.5%) Tipping head 2 (5%) Opening the bottle 2 (5%) Others 4 (10%)	NR
Dietlein Germany 2008 Prospective cohort [129]	To collect data about the self-application of single-use eye drop containers in an elderly population and to compare these data with those gained from younger patients	84.4 ±3.2 34 (77%) N = 44	Glaucoma (61%) Sicca (39%)	Single use eye drops	Performance based checklist during self-application of eye drops (yes/no); monitored by investigator	Did not succeed in pressing a drop out of the single eye drop container (27%)	Able to open: Without help or explanation (34%) Only with explanation (61%) Only with manual help (5%)
EYE DROPS - INTERVIEWS, SURVEYS, QUESTIONNAIRE (n=2)							
Adamson Scotland 2016	To determine the prevalence of difficulty in eye drop administration in people with RA	Age range: 69 = 31-60 years 131 = 61-90 years	Glaucoma (20%) Dry eye syndrome (73%) Other conditions (7%)	Eye drops	Questionnaire informed by previous research; speaking with people who use	Experiencing overall difficulty using eye drops: RA clinic (62%) Ophthalmology clinic (31%) (p<.001).	Received help from family member or friend: Ophthalmology clinic (25%) RA clinic (26%)

First Author Country Year Study design	Objective	DEMOGRAPHICS Mean ±SD in years Female n (%) Number included (N)	Population characteristics Diagnosis, place recruitment, co-morbidities	Packaging / Device	Mode of administration	Functional challenges with medication use	Medication management assistance
Cross-sectional [131]	who experience dry eye syndrome	132 (64%) N = 206	Patients attending ophthalmology and rheumatology clinics at major public health facilities within 2 regions in Scotland		eye drops; feedback from an expert panel Piloted with ophthalmology and RA patients	RA having difficulties with: Type of bottle/dispenser (17%) Taking lid off (21%) Holding bottle/dispenser (7%) Squeezing bottle (48%) Keeping hands steady (10%) Handling bottle (28%).	
Balkrishnann USA 2003 Cross-sectional [128]	To assess the associations between factors of topical medication use and health-related QoL	75.8 ±7.3 247 (69%) N = 358	Glaucoma (100%) Enrolled in a Medicare health maintenance organization in southeastern USA	Eye drops	Mailed self-reported eye medication treatment questionnaire	14% experienced difficulty self-administering eye drops	17% needed help with eye drop use

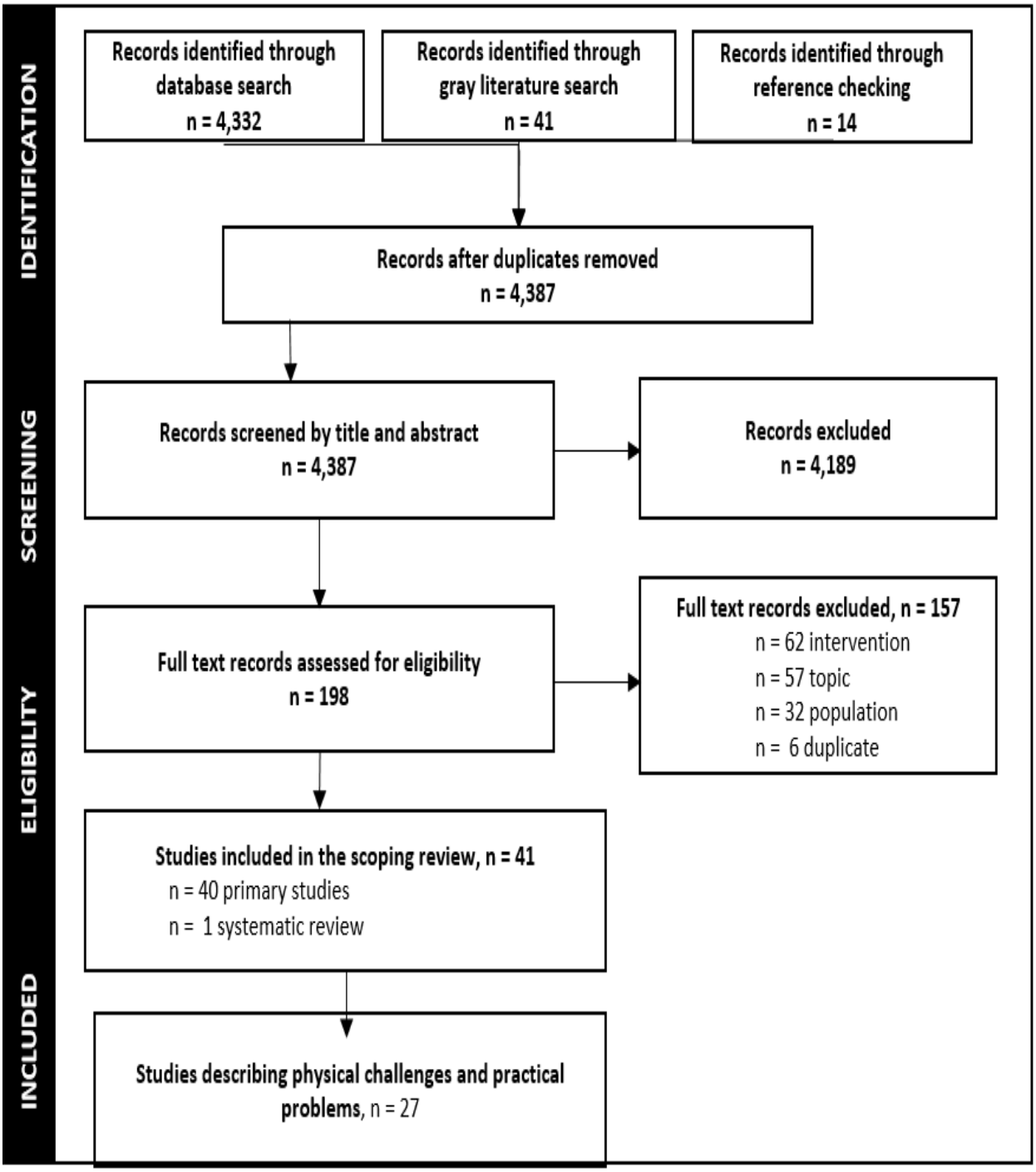

Figure 3-1: PRSIMA diagram

Chapter 4

Functional management of medications for older adults in the community: a scoping review of measures

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Key Points:

- Both performance based and self-reported measures are available to assess functional medication management.
- Currently available measures for functional medication management are not robust.
- Although measures cover different domains; one domain in particular, function, was not assessed extensively.

4.1 Introduction

The prevalence of chronic conditions increases with age such as hypertension (47%), arthritis (27%), and cardiovascular diseases (19%) being most commonly reported conditions for older adults 65+ years [1]. The presence of multiple chronic conditions is associated with functional impairments [140]. The higher number of chronic conditions predispose older adults to use more medications than any other age group averaging 6.9 different drug classes [4,99]. Functional capacity to manage medications requires both cognitive and physical function to perform different medication related tasks [21]. These tasks include ordering, picking up, organizing, preparing, administering, and monitoring the medications [33].

Limited physical function that may accompany aging can lead to negative impact on patients' outcomes. Functional limitations such as difficulty reading prescriptions labels and opening medication vials have been associated with non-adherence [141]. In addition, reduced capacity to self-administer medications is associated with greater number of hospital visits and requirement for assisted living [142]. Evaluating the specific functional issues to manage medications can provide a targeted treatment plan to address those functional deficits.

To evaluate one's functional ability to manage medication is regarded as one component of instrumental activities of daily living (IADL)*;* Many of the measures of medication management have been general evaluations and not specifically addressed the various components of management medications [143]. A study by Bolina showed that there are many functional components needed to manage medications that should be addressed by various members of the medical team [33]. For those older adults are admitted to acute care hospitals, few disciplines evaluated the various components of managing medications. They suggest that assessment of functional abilities to manage medications need to be incorporated into hospital

based care [33]. Because functional management of medication is not a frequently assessed IADL for older adults, a scoping review of the literature may provide broader understanding of functional medication management domains assessed by the existing measures with the aim of identifying gaps and all important components for the assessment.

4.2 Methods

4.2.1 Development of the research question: This scoping review was guided by the methods described by Arksey and O'Malley [108]. We focused this scoping review on mapping areas of functional medication management in older adults living at home. The research question was "What is known about functional medication management in older adults?" Two main objectives were identified:

1. What measures are available to assess functional medication management in older adults?
2. What domains of functional medication management are assessed by these measures?

4.2.2 Identifying relevant studies: The research team in collaboration with Alberta Strategy for Patient Oriented Research (SPOR) SUPPORT Unit KT Platform developed the search strategy. An experienced information specialist (RF) designed and executed the literature search strategies for the selected databases, which were peer-reviewed by a second medical librarian (TL). Studies were identified by conducting comprehensive searches of bibliographic databases: Ovid MEDLINE and Embase, CINAHL, and Ovid PsycInfo. Other grey literature sources included Conference Proceedings Citation Index (Clarivate Analytics), and ProQuest Dissertations & Theses Global. The searches were performed between Jan 15-22, 2018. Search strategies utilized subject headings (e.g., MeSH) and text words for concepts: older adults, routes of medication administration and adherence (See appendix B for complete search). Searches were not limited by language or study design but excluded animal studies, studies about pediatric patients or

patients with dementia. Searches were limited to documents published since Jan 1, 2000. We exported the search results to EndNote V.X7 (Clarivate Analytics) and removed duplicates.

4.2.3 Screening and selection of publications: Two reviewers (HA, LB) independently screened titles and abstracts in EndNote X7 (Clarivate Analytics) based on the pre-defined inclusion and exclusion criteria. (Table 4-1). The same reviewers then read the full-text of selected studies. Reviewers also checked the reference lists of relevant systematic review [34]. When agreement on a citation could not be reached between reviewers, a third reviewer (CS) was consulted for consensus. The inter-rater reliability for the two reviewers was 62.3% representing fair to good agreement between reviewers [109]. All study designs (randomized controlled trials, observational studies, qualitative studies, systematic reviews) and available research reports (i.e., original papers, journal abstracts, mini-papers/ abstracts, conference proceedings and theses) that included a measure of older adult's capacity to manage medications were screened for this review. Studies that took place in a hospital setting or included younger adults (<65 years of age) were excluded (Figure 4-1).

4.2.4 Abstracting the data: The same two reviewers independently extracted data into Microsoft Excel 2016 using a standardized data extraction form. Since the purpose of this review was to identify assessment tools, the validity and reliability data was extracted from the included studies only. We contacted the authors to get additional details on one tool [Home-Rx] because of the inability to find sufficient description from the published paper [144]

4.2.5 Collating, summarizing, and reporting the results: We extracted the data based on the general characteristics of the studies, including the publication date, the country of origin, and the study design. Results were then summarized based on the research question and specific objectives. Measures that assesses functional medication management (objective 1), and domains

of functional medication management assessed by these measures (objective 2) were summarized. Critical appraisal was not a part of this scoping review.

4.3 Results

In total, 4373 citations were retrieved after removal of duplicates of which 198 abstracts were identified and 41 (40 studies and 1 review) were retained for the full review (Figure 4-1). Of these 41 papers, 14 papers were included for this review. Publication numbers varied across decades, with eleven studies were from 2000 to 2010 and three studies after 2010 to the present. The studies came from four different counties with more than half (n=11) from the USA. A variety of study designs were used: cross sectional design (n=9), prospective cohort (n=3), qualitative study design (n=2), and a systematic review (n=1) (Table 4-4).

4.3.1 Measures assessing older adult capacity to manage medications

This review identified fourteen published reports describing development and/or application of fourteen measures (Table 4-2). A further 22 measures did not meet the inclusion criteria and were excluded from this review (Table 4-3). The following were the reasons for excluding these measures: focused on assessing physical ability without medication domains (n=13), designed for use in a hospital setting (n=2), focused on people with cognitive impairments (n=3), or people younger than 65 years of age (n=1) and finally not fitting our inclusion dates (n=3).

The 14 measures fell in two broad categories: Performance based (n=10) and self-report measures (n=4). The performance based measures, DRUGS [145,30,146], MedMaIDE [147], MedTake Test [148], HOME-Rx [144], HMS [149], MMAA [146, 150], Manage Med Screening [151], MMPT [58], Medication Regimen Adherence Capacity Test [30] and MMEI [34,30], involved asking older adults to complete different tasks related to medication management while

being observed using either their own medications as a basis of assessment (n=4) or a simulated kit or placebo medication (n=6). In contrast, self-report measures, MMC [22], Practical Drug Management Capacity Questionnaire [154], Medication Knowledge and Skills Questionnaire [155,141] and Medication Assessment Tool [142], relied on self-reported or informant-reported medication management ability rather than direct observation (n=4). A description of the included measures is provided in (Table 4-4).

4.3.2 Purpose of the measures: The purpose of the majority of the performance based measures, DRUGS, Medtake, HMS, MMPT, Medication Regimen Adherence Capacity Test, and MMEI, was to assess the cognitive and physical ability of older adults to manage their medications independently. Additionally, two measures, MedMaIDE and Home-Rx, aim to identify deficiencies or functional barriers in older adults' ability to self-medicate at home. Furthermore, two of the performance based measures were used in a specific population including older adults having mental health problems [146,150] or taking moderately difficult medication regimen [151]. In contrast, the purpose of the questionnaire based measures, MMC, Medication knowledge and skills questionnaire, and Medication Assessment Tool, was to assess knowledge and behaviours related to managing medications at home. Similar to performance based measures, two of the questionnaire based measures were used in a specific population including older adults having chronic diseases [26] or taking five or more medications [22].

4.3.3 Administration of the measures: Some measures such as DRUGS, Medtake, HMS, MMAA, Practical drug management capacity, Medication Regimen Adherence Capacity Test and MMEI can be administered in a clinical setting such as such as a community pharmacy or medical clinic, where a health care professional can administer the tool as a part of medication review. On the other hand, other measures such as MedMaIDE, Home-Rx, ManageMed, MMC,

Medication Knowledge and Skills Assessment Questionnaire and Medication Assessment Tool, were designed to be administered in a home setting by either home health occupational therapists [144] or people with no medical background [147]. One particular measure, MMPT, can be used both in a home or institution setting. The majority of the measures were administered by people with a healthcare background (n=12) including health care professional (n=5) or researchers (n=7).

4.3.4 Scoring of the measures: All performance based measures except MMPT had a scoring system. Each of them follow a unique scoring system depending on the number and type of medication management domains tested as well as whether the domains were equally weighted or not. For most of the performance based measures, higher scores indicate better ability to manage medications independently. For example, scoring of both DRUGS and Medtake test is out of 100 and the composite score is calculated. Higher scores for both of these tools indicate greater independence with medication management. On the other hand, for performance based tools that aim to identify deficiencies with medication management, higher score indicates lower ability to manage medications, as with the MedMaIDE where the highest score of 13 points indicates maximum deficiency score. For the questionnaire based measures, only two out of the four tools had a scoring system. For the MMC tool, the higher the number of "Yes" answers reported by older adults, the better ability to manage medications. On the other hand, the Medication Knowledge and Skills Questionnaire used a two-point scale, with a higher number indicating better ability to manage medications.

4.3.5 Administration time: There is a variation in the time it takes to administer different measures. For the performance based measures using patients' own medications, administration time can take between 5-30 minutes depending on the number of medications. For performance

based tools that use simulated kits, it can take from 5 minutes [MMEI] to 15 minutes [MMAA and MangeMed]. One measure, MMAA, has additional 45-90 minutes' delay time between instruction and actual test. Two performance based measures, HMS and MMAA, had a time limit in which participants had to finish the test within a certain period of time. For questionnaire based tools, no administration time was reported.

4.3.6 Reliability and validity: From the included studies in this review, reliability and validity data was reported for the following tools: MedMaIDE, HMS, Home-RX, ManageMed, and Medication Regimen Adherence Capacity. Two measures reported reliability data: MedMaIDE had both inter-rater reliability data (0.74) and test-retest reliability (0.93), and ManageMed had inter-rater reliability data (0.859-0.965). Internal consistency was reported for two measures: MedMaIDE (0.71), and ManageMed (0.89). Furthermore, five measures had validity data. Construct validity was shown through association with medication adherence (pill count) [147], self-reported instrumental activities of daily living (IADL) [149], and cognitive function (MMSE) [30,152]. Content validity index of 0.95 and 0.84 was reported for two tools [144,142] consecutively.

4.3.7 Functional Medication management domains: Several domains were assessed by the measures including medication management skills, medication management processes, function and risk factors to medication mismanagement (Figure 4-2).

Medication management skills: Several measures are described assessing a wide range of medication management skills. The most frequently assessed skills include the ability to access medication from a package (n=14), comprehend instructions (n=12), identify medication (n=10), recall information (n=9), and administer medication (n=6).

Accessing medications from a package: All fourteen measures assessed the ability of older adults to open different medication packages. Measures that used a simulated regimen assessed only a specific packaging design such as standard screw top medication vials [149, 146, 151, 34, 30], flip-top vial [58, 155], child resistant vial [34, 30, 155], blister packs [154], pharmacy vial with reversible caps [30], and fluid bottle with a push down and turn child resistant lid [155]. Opening medication vials was assessed as part of the overall test and was not scored separately for two of the measures [149,146]. On the contrary, tools that used patients' own medications [144,145,147, 148] asked older adults to open their own medication containers. For self-report measures [58, 154, 155, 142], older adults were asked to self-report difficulties opening vials or blisters. Finally, all of the tools except [58, 22, 154, 155, 142] required patients to remove or withdraw a dose from packaging.

Comprehending medication instructions: All measures except [154, 155] assessed comprehension of medication instructions. Understanding was tested by asking older adults to either explain certain instructions, plan a schedule for taking medications, implement a medication regimen, or perform calculation. Seven measures tested the ability to describe or follow a dose regimen [148, 147, 34, 30, 144, 22 ,142]. An additional two tools assessed the ability to describe a hypothetical dosing regimen explained earlier [156, 146]. A further two tools [145,149] tested the ability of older adults to plan a 24-hour schedule for a medication using a paper-based schedule. Six tools tested the ability to implement a medication regimen by setting out medication for one dose [145, 148], one day [144, 146, 149], and one week [151]. Two tools [151,58] required patients to do a calculation, such as number of tablets, maximum dose, day supply or amount of money paid for the medication.

Medication identification: Ten measures assessed patients' ability to identify their medications. Variation was found in the way that medication identification was both measured and reported. Some of the tools such as DRUGS, ManageMed and MMC allow patients to identify or distinguish the correct medication by any means they choose including reading a prescription label, distinguishing color of tablets, or recognizing the package of medication. Other tools assessed only a specific skill related to identifying medication such as the ability to read prescription label [34, 144, 156, 58, 155, 142], differentiate tablets by colors [34, 155], or recognize package of medications [154].

Recalling of information: Nine measures assessed the ability to recall information [147, 148, 144, 151, 30, 142, 155, 146, 154]. A number of measures [147, 148, 144, 151, 142, 155] assessed older adults' ability to recall their medication names, indication for use, food or water co-ingestion or dose regimen. One tool [146] examined short term memory by asking older adults to recall given instructions about a medication regimen after certain time elapsed. In addition, ManageMed used a self-report method by asking older adults how good their memory is. One tool used a hypothetical scenario to test memory [30].

Medication administration: Six measures assessed various tasks of medication administration. Two tools [144,147] assessed the ability to physically administer medication. Three tools [147, 154, 142] assessed the ability to swallow medications. Two tools assessed the ability to split a tablet [147,154]. Only one tool [147] assessed the ability to prepare or administer a non-oral dose form such as eye drops, inhaler, insulin, or topical patch.

Medication management processes: Five measures assessed medication management processes. Three of these assessed the ability to arrange medication supply on time by ordering the medication from a pharmacy [147,144,22]. Additionally, two of these measures assessed the

ability to pick up medications from pharmacy [144,142]. Further four of these measures assessed the use any medication management tools that help organize medications or make medication routine easier such as a prescription card, alarm or a pillbox [147, 144, 154, 142]. In addition, three tools assessed the ability to store medication correctly [144, 147, 142]. Finally, the ability to self-monitor therapy and contacting the prescriber if the medication is not effective is assessed by one tool [22].

Function: Eight measures assessed some aspects of function including hand dexterity, vision, cognition and swallowing abilities. Dexterity was measured by examining the ability of older adult to open medication packaging. On the other hand, vision was assessed by either examining the ability to read a prescription label [58, 34, 144, 30, 155, 142], discriminate color of the pills [34, 155], or report any visual impairment [154]. Cognition was assessed by examining comprehension of medical instructions and ability to recall information [See Comprehending medication instructions]. Swallowing abilities were measured by either asking an older person to sip enough water to swallow medications [147] or self-report any difficulties with swallowing [154,142].

Risk factors for medication mismanagement: Five measures assessed risk factors in regard to medication mismanagement. Two measures assessed the use of multiple prescribing physicians, and filling pharmacies, financial barrier to obtaining medications, sharing medications with others, and beliefs and satisfaction with medications [144,142]. One measure [144] assessed taking medication differently than prescribed or stopping medications without instruction to do so. Four measures assessed medication management assistance from other people [144, 147, 154, 142]. Finally, home environment was assessed by one measure [142].

4.4 Discussion

In our scoping review, we found fourteen unique measures that assess functional medication management. Even though many measures have been developed, there is no gold standard used in clinical practice. Further, we identified four unique medication management domains covered by these measures: medication management skills, medication management processes, functional skills and risk factors to medication mismanagement. The degree to which different functional medication management domains were assessed varied between tools. One domain in particular, function, was under assessed by the measures. Further, only one medication management skill, accessing a medication from a package, was included in all measures.

Our findings are consistent with an earlier systematic review by Elliot and Marriott who stated that there is no published tool with sufficient reliability and validity to be recommended for routine use in clinical practice [34]. Several measures (n=7) were also described in this review published in 2009 [34]; however, this review was limited by the omission of newer performance based measures and all questionnaire based measures. In addition, this review focused on describing validation data of the measures, and included only medication management skills covered by the measures. To our knowledge this is the first scoping review that describes all medication management domains covered by the measures: medication management skills, medication management processes, functional skills required to manage medications as well as risk factors to medication mismanagement. Thus, our review adds to the literature by including self-report measures in addition to performance based ones. In addition, our review covered newly developing tools such as the Home-Rx [144]. Furthermore, our review focused on medication management domains with a focus on functional skills and how they were measured.

Our review found seven additional assessment measures due to the recency of the search and broader inclusion criteria. Three measures were performance based [144, 30, 151] and another three were self-report [22, 154, 142]. The Home-Rx is a developing measure in the United States with three subsections: risk factors to medication mismanagement, Medication list and Medication Management Assessment [144]. This tool is intended for use by occupational therapists [144]. The ManageMed is designed for people with a moderately difficult medication regimen, defined as using three different medications, all with different dosages and schedules [151]. Further, Medication regimen adherence capacity is the only measure that is designed to assess adherence to a medication regimen prior to initiating therapy [30].

Moreover, we found three self-report measures [22,154,142]. The MMC is designed for people with polypharmacy, defined as more than 5 medications [22]. It was interesting to find that MMC, even though not validated, is being used as a standard practice in the Netherlands to determine the kind of medication support nursing home patients require [22]. Further, the Practical drug management capacity is designed for use in older adults with chronic diseases [154]. The Medication assessment tool is unique in that it assesses some physical skills such as medication administration and storage as well as medication management processes such as purchasing habits, attitude, home environment and life style habits [142].

Interestingly, we found more measures using a performance based than a self-report method; nevertheless, there are limitations with both. In particular, performance based measures that use a standardized scenario do not necessarily reflect patients' experience in taking medications at home [21]. In addition, most of the performance based tools were limited by lack of assessment of non-oral dosage forms such as eye drops, inhalers, and injections, even though, challenges with these dosage forms were reported in the literature [130, 118,132]. Although

unique device-specific tools were beyond our scoping review, it is important to factor in functional medication management with all forms of mediation devices. Using a unique tool for each device would not be efficient, nor would using only one tool provide adequate information about a patient's overall regimen in order to make decisions.

What are the gaps in the existing measures?

In order to assess medication management skills extensively, it is important to examine the functional abilities required to perform these tasks. The majority of the measures were limited in identifying functional challenges related to managing medications. For example, dexterity was only measured by testing the ability to open a medication vial but such inability may be due to pain, stiffness, or not knowing how to overcome the safety features or open the vial, rather than dexterity. In addition, other functional limitations such as vision impairment or swallowing abilities were rarely assessed by the tools. Vision was mostly tested by asking older adults to read a prescription label; however, difficulty reading can be attributed to multiple factors such as poor lighting, small print, inadequate health literacy, or the environment in which the tools is administered (e.g. level of lighting). Most of these were not taken into account or explicitly stated in any of the measures. One study even assumed that since literacy in Sweden is very high, the inability to read prescription labels was seen as a test of vision rather than reading abilities [58]. This lack of functional assessment shows that the measures had gaps in assessing functional medication management. This indicates the need for interdisciplinary collaboration between pharmacists, physicians, nurses, and allied health care professionals such as physiotherapists or occupational therapists, in order to assess functional limitation more extensively. Identifying the underlying cause of inability to manage medications will help health professionals to plan intervention accordingly. For example, when a health professional is

administering the measure and observes that an older person is unable to open a medication vial, it is important to document whether this inability is due to functional limitation (e.g. hand dexterity, vision impairment) or challenging packing design and refer the patients to another health provider for further assessment. Documenting in this way will help health professional design intervention such as providing the proper support for medication assistance.

Based on this review, there were very few measures that focused on aspects of medication management processes such as the ability to order and pick up the medication from pharmacy, organize medication using medication management tools, store the medication correctly, receive medication assistance from other people, and monitor therapy and contact a physician as needed. In order to perform these tasks successfully, it is essential to assess instrumental activities of daily living, such as the ability to use the phone to order medications or the ability to take transportation to get access to the pharmacy. According to a retrospective review conducted by our group, functional medication management includes not only assessing functional and cognitive abilities but also the ability to order, pick up, organize, prepare, administer, and monitor medication outcomes [33]. Consistent with our findings, several components of medication taking processes were rarely assessed by healthcare professionals [33]. The complexity of medication management in older adults with multiple comorbidities indicates the need for a comprehensive assessment measures. According to [47], medication management is complex and requires assessment of several domains areas such as medication procurement, medication knowledge, physical and cognitive ability, intentional non-adherence and ongoing monitoring. As a result, we believe that a comprehensive tool that will cover both cognitive and functional skills as well as medication taking processes and risk factors will be the

best option to reflect real life challenges with medication management and allow health care professional to plan an intervention accordingly.

The application of the measures in real practice can be impacted by whether they are used as assessment measures by clinicians or screening tools by administrators or policy makers in a broader system applications. Majority of the measures seemed to target clinicians; nevertheless, MMC is an example of a screening tool to determine medication support needs for nursing home patients [22]. In the future, a survey of the health practitioners and patients can be done to assess the need of the healthcare system for assessment versus screening measure. In addition, a study can be done to examine whether these measures have meaningful and reliable impact on patients' care such as identifying the need for home care or medication assistance. Removing the independence of an older adult in terms of the ability to take medications could have implications on the perception of that patient, or how the family, spouse, or caregivers might view that patient.

Our study has a number of limitations. Although our search was not restricted by language, some language bias was still inherent as our search was conducted using English-language search terms. In addition, our review was limited to measures used to assess functional medication management for people living in the community and excluded hospital based measures such as SAMP [170]. We also limited our search dates, and some older tools were not included. However, those tools we deem to be less relevant, as they had no publications that appeared in our search. Also, the aim of this scoping review was to identify the breadth of research about functional medication management and any gaps in the literature as a result the methodological quality of the included studies was not assessed.

Further research is required in this area, including the validation of measures, incorporating more robust functional assessment, and determining the role of measures as screening versus assessment of older adults. In addition, application of these tools in different patient groups should be considered.

Conclusion

We found fourteen unique measures of functional medication management for older adults in the community. We also identified four main domains assessed by the measures. One domain of functional medication management, function, was not assessed extensively by the measures. To provide the most appropriate interventions for independent medication management for older adults, assessment of function should be incorporated into the existing measures and further research should focus on creating a comprehensive functional medication management covering all important domains is needed.

Table 4-1: Inclusion/Exclusion Criteria

	Inclusion criteria	**Exclusion criteria**
Study Design	All study designs Published between 2000-2018	Published prior to 2000
Setting	Taking place in the participant's home and self-administering	If medications is administered in a care facility, hospital, nursing home or caregiver.
Participants/ population	Adults over the age of 65	Under the age of 65
Intervention(s), exposure(s)	Measures assessing functional medication management at home Measure must contain both physical ability and medication domains	Cognitive impairments Measures of physical ability only with no medication domain Measures designed and administered in a hospital setting
Outcome(s)	Impact of physical / functional challenges on any outcomes	None

Table 4-2: Included Functional Medication Management Measures

Instrument short name	Instrument long name
DRUGS	Drug Regimen Unassisted Grading Scale [145,30,146]
MedMaIDE	Medication Management Instrument Deficiencies in the Elderly [147]
MedTake Test	MedTake Test [148]
HOME-Rx	In-Home Medication Management Performance Evaluation [144]
HMS	Hopkins Medication Schedule [149]
MMAA	Medication Management Ability /Administration Assessment [146,150]
ManageMed Screening	ManageMed Screening [151]
MMPT	Medication Management Performance Tests [58]
Medication Regimen Adherence Capacity Test	Medication Regimen Adherence Capacity Test [30]
MMEI	Medication Management Evaluation instrument [34,30]
MMC	Medication Management Capacity questionnaire [22]
Practical Drug Management Capacity Questionnaire	Practical Drug Management Capacity Questionnaire [154]
Medication knowledge and skills assessment	Medication knowledge and skills assessment [155,141]
Medication assessment tool	Medication assessment tool [142]

Table 4-3: Excluded measures

Instrument	Author	Reason for exclusion
Activities of daily living (ADL)	Bozek [1156]	Assessment of physical ability only
Direct Assessment of Functional Status (DAFS)	Patterson [143]	Population (cognitive impairments)
Expanded disability status scale (EDSS)	Kleiter [157]	Assessment of physical ability only
Grooved-Pegboard	Adams [158]	Assessment of physical ability only
Health assessment questionnaire (HAQ)	De klerk [159]	Assessment of physical ability only
Health Related Quality of Life (HRQoL)	Choi [150]	Assessment of physical ability only
Ideomotor dyspraxia test (IMD)	Allen [151]	Assessment of physical ability only
Instrumental activities of daily living	Bozek [156]	Assessment of physical ability only
Jebsen-Taylor Hand Function Dexterity (JHFD)	Pfutzner [58]	Assessment of physical ability only
Katz Index of Independence in Activities of Daily Living	Hegde [152]	Assessment of physical ability only
Lawton's scale	Tavares [153]	Assessment of physical ability only
Medication Administration Test (MAT)	Schmidt [165]	Population (cognitive impairments)
Medication Management Test (MM)	Gurland [166]	Population (cognitive impairments)
Medication Management Test (MMT)	Albert [167]	Not within our inclusion dates
Medication Management Test-Revised (MMT-R)	Heaton [168]	Age (Younger than 65)
Motor Performance Series (Motorischer Leistungstest, MLS, dexterity)	Pfutzner [162]	Assessment of physical ability only
Pharmacy Assessment (PA)	Romonko [169]	Not within our inclusion dates
Quality of Well-Being Scale (QWB)	Patterson [9]	Assessment of physical ability only
Self-Administration of Medications Program (SAMP)	Tran [30]	Setting (Hospital)
Self-Medication Assessment Tool SMAT	Irvine-Meek [19]	Settings (Hospital)

Self-Medication Task (SM)	Isaac [20]	Not within our inclusion dates
Townsend disability score	Lee [21]	Assessment of physical ability only

Table 4-4: Summary of study results

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
ACTUAL REGIMEN - TOOLS THAT USED PATIENTS' OWN MEDICATIONS (n=4)									
Drug Regimen Unassisted Grading Scale – DRUGS [145,30,146]	Measurement to assess the individual's ability to identify, access, and determine the dosage and timing of their medications. Can be used in a clinic setting.	Performance-based 0 – 100	Performance observed by professional as part of 'brown bag' medication review	Patients perform four tasks with each medication: (1) identify their own medication; (2) open container; (3) withdraw correct number of tablets for dose; (4) report appropriate timing of doses using grid. Depending on number of medications DRUGS can be administered within 5 to 15 minutes.	To assess older adults' current use of, knowledge of, and preferences for medication management tools and supports	Lakey USA 2009 Cross-sectional [14]	85.9 ± 5.1 87 (79.8%) N = 109	Residing in independent-living apartments in a continuing care retirement community	NR
					Compared the MMAA and DRUGS as standardized tools to assess medication management skills in elderly patients with a range of cognitive function and evaluated the association between the	Hutchinson USA 2006 Cross-sectional [16]	75.8 ± 6.2 36 (69%) N = 52	Reported medical problems: Eyeglasses/ problems: 48 (92%) Memory problems: 22 (42%) Hearing: 11 (21%) Depression: 9 (17%) Diabetes: 7 (13%) Stroke: 7 (13%) Recruited from the University of Arkansas for Medical	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
					results obtained from these scales and self-reported drug-related problems.			Sciences Memory Research Center's longitudinal study of Alzheimer's disease	
Medication Management Instrument Deficiencies in the Elderly – MedMaIDE [147]	Addresses potential issues surrounding medication compliance and management. Can be used in home setting.	Performance based IADL- 0-13 The higher the score the less capable the patient is. Maximum deficiency score = 13	Designed to be used in patients' homes by people with nonmedical background or training	20 questions covering three areas: (1) medication knowledge (such as names, indications and dose); (2) medication taking ability (such as accessing medication, drinking water); (3) access to ongoing supply of medication (such as awareness of refills and arranging supply). Approximately	The purpose of this study was to describe the MedMaIDE and to provide results of reliability and validity testing	Orwig USA 2006 Cross-sectional [147]	78.18 ± 7.21 36 (72%) N = 50	Comorbidities (range 0-30) = 6.14 ± 2.54 Recruited from several high rise apartments in Baltimore, and local retirement community	<u>Reliability, Mean (SE)</u>: Test-retest (interclass correlation) = 0.93 (0.02) Interrater (intraclass correlation) = 0.74 (0.12) Internal consistency (Cronbach's alpha) = 0.71 <u>Validity:</u> Two cut points for deficiency score: (a) 0 = compliant; ≥ 1 noncompliant, (b) 0 or 1 =

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
				30 minutes to administer					compliant; ≥ 2 noncompliant Sensitivity: (a) 80%; (b) 68% Specificity: (a) 44.4%; (b) 83.3% PPV: (a) 0.65; (b) 0.83 NPV: (a) 0.60; (b) 0.66
MedTake Test [148]	Assess patients' ability to correctly take oral prescriptions. Designed for use in clinic setting as part of a 'brown bag' (bringing medications for review by pharmacist/ physician)	Performance-based (1922) 0 – 100% (25% for each of the four tasks)	Administered by health care professional as part of 'brown bag' medication review.	Patients perform four tasks with each medication: (1) open container and simulate taking the first dose of day; (2) describe indication; (3) describe food or water co-ingestion; (4) describe regimen.	To quantify seniors' ability to take oral medications safely and correlations with factors such as age, education, and cognitive impairment	Raehl USA 2002 Prospective cohort [148]	79.49 ± 7.26 41 (72%) N = 57	Required eyeglasses = 55 (97%) Color blind = 4 (7%) Recruited from 3 comprehensive retirement communities (independent living cottages, apartments) and an adult day care centre	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
	medication review.								
In-Home Medication Management Performance Evaluation – HOME-Rx [144]	To identify functional barriers to medication management for community-dwelling older adults	Performance-based (1639) Part 1: Yes (1)/No (0) scale Part 2: Medication list (scored with part 3) Part 3: 5-point Likert scale with 0 indicating inability to complete the task and 4 indicatin	Intended to be administered by professional (occupational therapists) in Home setting	Patients perform three tasks: (1) medication management interview questions that assess an older adult's risk factors in regard to medication mismanagement (e.g., multiple prescribing physicians, multiple filling pharmacies). (2) medication management assessment – 17 questions performance-based task. (3) medication list – 10 information points for each medication (name, dosage,	Develop a novel, performance-based medication adherence assessment and assess initial psychometric properties of HOME-Rx	Murphy USA 2017 Qualitative - interviews [144]	75.6 ± 4.4 3 (60%) N = 5	Community-dwelling older adults	<u>Content Validity Index:</u> Content experts (n=7) were in agreement that overall tool was valid for measuring older adult medication management (CVI = 0.95) Older adults (n=5) unanimously reported the tool was relevant, acceptable, and easy to understand

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
		g independence [50]		time of day, frequency, special instructions, and any additional information for each prescription and over-the-counter medications, or vitamins/supplements) (Personal communication with **Emily Somerville,** Dec 28, 2018) Can be administered within 25 to 35 minutes					
SIMULATED REGIMEN – USING PLACEBO OR KIT									
Hopkins Medication Schedule – HMS [149]	A standardized test of the ability to understand (schedule) and	Performance-based 0-11 (Schedule scored	Scenario given by healthcare professional, otherwise performance-based	Part 1 – Schedule: subject is given hypothetical scenario where prescribed medications to	To develop and validate the HMS, a new objective test of one's ability to understand and implement a	Carlson USA 2005	77.5 ± 2.8 360 (100%) N = 360	Community dwelling	<u>Validity:</u> HMS had concurrent validity for participant-reported IADL

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
	implement (pillbox) a complex IADL critical to health: managing medications	out of 9, and pillbox out of 2)		treat infection, subject is asked to prepare a schedule for taking medications and water over course of day using paper-based schedule, maximum 8 minutes allowed; Part 2 – Pillbox: subject given labelled, non-child resistant vials containing aspirin and antibiotic placebo pills and four-compartment pillbox (morning, lunch, dinner, bed), and instructed to set out 1 day of tablets into appropriate	routine prescription medication	Prospective cohort [149]			difficulty. In community dwelling older women who largely reported no difficulty in taking medications, the HMS identified nearly 22% who could not write or implement a routine medication regimen. This standardized measure may identify those at increased risk for poor medication adherence and IADL difficulty

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
				compartments, maximum 4 minutes allowed					
Medication Management Ability Assessment / Medication Management Administration Assessment – MMAA [146,150]	Is a role-play task that simulates a prescribed medication regimen to assess ability of older adults with mental health issues.	Performance-based 0-25 Total number of correct responses for each drug is totaled to get MMAA score	Can be administered independently or with various levels of supervision	A fictitious medication regimen using four labeled prescription bottles and colored beans for capsules, interviewer describes medication regimen, 45-60 minutes later subject asked to walk through day, required to dispense pills for each dose. Approximately 15 minutes to administer to those with normal cognition, in addition to 45-90 minutes	Compared MMAA and DRUGS as standardized tools to assess medication management skills in elderly patients with a range of cognitive function and evaluated the association between the results obtained from these scales and self-reported drug-related problems	Hutchinson USA 2006 Cross-sectional [146]	75.8 ± 6.2 36 (69%) N = 52	Reported medical problems [n (%)]: Eyeglasses/ problems: 48 (92%) Memory problems: 22 (42%) Hearing: 11 (21%) Depression: 9 (17%) Diabetes: 7 (13%) Stroke: 7 (13%) Recruited (people with Alzheimer's disease and a control group) from the University of Arkansas for Medical Sciences Memory Research Center's longitudinal study of Alzheimer's disease	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
				between prescription presentation and actual assessment.					
ManageMed Screening [151]	To assess one's ability to manage a moderately difficult medication routine. For example three different medications all with different dosages and schedules.	Performance-based 32 cognitive questions given score of 1 for correct, 0 for incorrect; The higher level organizing task was worth 10 points based on correct dosage, correct	one-on-one in any relatively quiet area; no writing required, but they asked to complete functional tasks such as opening pill containers, counting and distributing	Kit containing three simulated pill vials (with candy imitation pills), a mock prescription, three realistic medication information sheets, a pill organizer, the test form, and a magnifying glass. The test consists of three distinct segments: (1) 4 metacognitive questions to self-assess skills; (2) 32 questions covering various cognitive	Complete initial reliability and validity psychometric analyses on ManageMed Screening using convenience sample of older adults; Compare scores on ManageMed Screening with same person scores on an established and well-accepted neuropsychological assessment	Robnett USA 2007 Cross-sectional [151]	76 ± NR NR N = 67	Convenience sample of volunteers	Reliability analysis on internal consistency of ManageMed Screening demonstrated a Cronbach's Alpha of 0.89 (42 items) in the highly reliable range Interrater reliability measures on individual questions ranging from 0.859 to 0.965. These ranges were in the satisfactory to high range.

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
		schedule, and correct number of pills. A perfect score on Manage Med Screening is 42		abilities; (3) Setting up a weekly medication organizer Approximately 15-20 minutes to administer					
Medication Management Performance Tests – MMPT [58]	To assess cognitive, visual and physical abilities related to taking medications in the elderly population	Performance-based NR	Survey administered in home or institution setting	Participants asked to (1) Read instructions on label of plastic bottle; (2) Open bottle by removing plastic collar and flipping lid open (3) Read instructions on box of aspirin and answer "what is the maximum number of times you may take	Uses performance tests of hand function, vision and medication competence to assess the limitations in these dimensions in a population-based sample of elderly people. The prevalence of these limitations can be seen as an estimate of the extent of potential	Beckman Sweden 2005 Cross-sectional [58]	83.3 ± NR 59.3 (368) N = 621	Swedish Panel Study of Living Conditions of the Oldest Old (SWEOLD II) is a nationally representative sample of the population aged 77+ Subjects were directly interviewed in their home or institution.	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
				this aspirin during one day?"; (4) Read instruction on how to take penicillin and answer "How many days the pills would last?"; (5) Read receipt from pharmacy with the sum of two items billed for a total of 64 Crowns, and calculate how much change they would receive if paid with a 100-Crown note.	problems with medication management.				
Medication Regimen Adherence Capacity Test [30]	To evaluate cognitive and functional abilities	Performance-based Test 1: 1 point for each correct	Administered by trained investigators	Participants are asked to: Test 1: read and comprehend labeled prescription medications vials (5 main	To develop and instrument that will facilitate and focus the assessment of a patient's capacity to adhere to a medication	Fitten USA 1995 Cross-sectional	<u>Outpatients</u>: 69.33 ± 8.71 0 (0%) N = 15 <u>Comparison</u>:	<u>Outpatients</u>: selected from outpatient services at Department of Veterans Affairs Medial Center-Sepulveda	Interrater reliability testing of 5 subjects showed no significant difference in

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
		label and explanation. Maximum score = 14 Test 2: 1 point for each task for 5 different types of vials. Maximum score = 15 Test 3: 3 points for correct answers without cueing, 2 points for correct answer with cueing, 1 point for		labels and 2 auxiliary labels read aloud, the meaning of the labels described in the patient's own words) Test 2: open, and withdraw the proper amount of medication, and then close the medication vial. Five different types of vials were used (three Pharmacy Mates ® with reversible caps, a Screw Lock, and a Clark Safety Cap). Test 3: test of ability to understand hypothetical medication	regimen before its initiation	[30]	69.95 ± 7.46 13 (65%) N = 20	Comparison: generally healthy, independent, community-dwelling comparison subjects	performance for Scenario 1 or 2. The interrater correlation coefficient for Scenario 1 was I = .70. For the small number (n = 5) of subjects tested on Scenario 2, the correlation was I = .16. 20 healthy comparisons, only one subject (5%) fell below the cutoff point (1.5 SD below mean score) for Scenario 1, and none were below the cutoff point for Scenario 2. The outpatients had the most difficulty

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
		partially correct answers with cueing, 0 points for incorrect answers Maximum score for scenario 1 = 33 Maximum score for scenario 2 = 27		regimens: 2 scenarios of varying difficulty followed by questions to test 3 areas (memory, estimation of consequences, and judgment)					completing Scenario 1, with six subjects (40%) unable to reach the cutoff point. Two of these subjects fell below the cutoff point of Scenario 2, indicating a more serious impairment.
Medication Management Evaluation instrument – MMEI [34,30]	To evaluate older adults' medication management skills	Performance-based 1 point for performing the task	Administered by trained healthcare provider	Participants perform following tasks: (1) read 12-point font prescription label; (2) open and close child resistant cap on 7-dram vial; (3)	Cross-sectional study to determine patients with compliance difficulties [153]	Fritsch USA 1998 Cross-sectional [153]	All ≥ 65 0 (0%) N = 22	Recruited from outpatient interdisciplinary Geriatric Evaluation and Management Clinic at the Kansas City Veterans Affairs Medical Center	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
		0 points for uncompleted tasks Maximum score = 4		open and close non-child-resistant cap on 7-dram vial; (4) remove 2 tablets from opened 7-dram vial; (5) describe 3-time daily regimen; (6) Differentiate tablets by color Takes 5 minutes to administer.					
Self-report									
Medication Management Capacity questionnaire– MMC [22]	To assess knowledge and skills that are relevant to manage and use drugs correctly among elderly people living at home	17 statements addressing the management and use of medications, that can be answered 'yes', 'no', or 'not applicable'	Homecare employees or other caregivers	Summary of questions: (1) know what medications being used; (2) names of doctors; (3) easily operate phone; (4) order medication on time; (5) contact pharmacy if medication not delivered; (6) easily read pharmacy label;	To determine the medication management capacity of independently living older people (≥75 years) on polypharmacy (≥ 5 medications) in relation to their cognitive- and self-management skills.	Sino Netherlands 2014 Cross-sectional [22]	84.1 ± NR 63 (66.3%0 N = 95	Random sample of older patients receiving homecare services from two different Dutch homecare organizations,	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
		Total score based on number of times 'yes' answered, ranging from 0–17, with 17 reflecting optimal medication management capacity		(7) make sure right drugs delivered; (8) distinguish between different drugs; (9) contact doctor is something is wrong with medication; (10) contact doctor if drug not working; (11) contact doctor if unusual symptoms; (12) get medications out of package; (13) take on correct days; (14) use at right times; (15) check expiry date after opening; (16) never use old drugs; (17) follow					

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
				instructions on label					
Practical Drug Management Capacity Questionnaire [154]	To assess medication management in older patients with chronic diseases	IADL, yes or no answers No scoring system.	Self-administered	A questionnaire collecting the following items: medication management tool use (e.g., pill organizer), medication management assistance, self-reported visual and cognitive impairment, and self-reported problems with tablet swallowing, tablet splitting, blister opening and distinction between different drug packages.	To describe medication management among home-dwelling older adults. these data should allow us to identify potential problems and to indicate target areas for community pharmacist intervention.	Mehuys Belgium 2012 Cross-sectional [154]	78-80 = 69.2% 81-90 = 29.6% >90 = 1.2% 181 (54%) N = 338	Randomly selected community pharmacies in Flanders, Belgium. Consecutive older patients visiting the pharmacies were invited to participate	NR
Medication knowledge and skills assessment	To assess medication knowledge and skills	IADL, Likert scale	Administered by health care professional	Information was gathered on the ability to: 1. Open 3 types of medicine vial	To determine knowledge and skill-based factors pertaining to medications that	Hope USA 2004	65.43 ± 8.69 44 (72.1%) N = 61	Receiving medications through Wishard Health Services	NR

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
questionnaire [155,141]		Medication knowledge assessment 0-2 where 2 indicates perfect score Medication skills assessment 1-5 where 5 indicates perfect score.		(a pill container with a push-down and turn type child-resistant lid, pill container with a flip off, easy-open lid and four-fluid ounce bottle with a push-down and turn type child resistant lid) 2. read standard and auxiliary prescription labels 3. distinguish tablets by color including dark and light shades of the same color 4. know indication, dosage and frequency of medication.	could be barriers to adherence	Qualitative survey [155]			
Medication Assessment Tool [184]	To examine medical knowledge	Questions with various	Self-administered	40 questions covering 6 topic areas: (1)	To examine medication knowledge and	Jennings-Sanders	75.9 ± NR 32 (80%)	55% had at least 2 chronic illnesses	Content validity (0.84)

MEASURE DESCRIPTION					STUDY ASSESSMENTS				
Instrument name	**Purpose**	**Scoring**	**Mode of administration**	**Description**	**Study objective**	**First Author** **Country** **Year** **Study design**	**Study cohort characteristics**	**Population characteristics** **Dx, place recruitment, co-morbidities**	**Reliability / validity**
	and behavior of older African-Americans' in adult day cares	options (yes/no; on a daily basis/ less than on a daily basis, etc.); percentage given for each answer		administration and storage; (2) medication purchasing habits; (3) attitudes; (4) lifestyle habits; (5) home environment; (6) medication profile	behavior of older African-American adult daycare clients	USA 2001 Prospective cohort [184]	N = 40	45% had more than 2 chronic illnesses Convenience sample of older African-Americans attending adult day care at two urban geriatric centers	

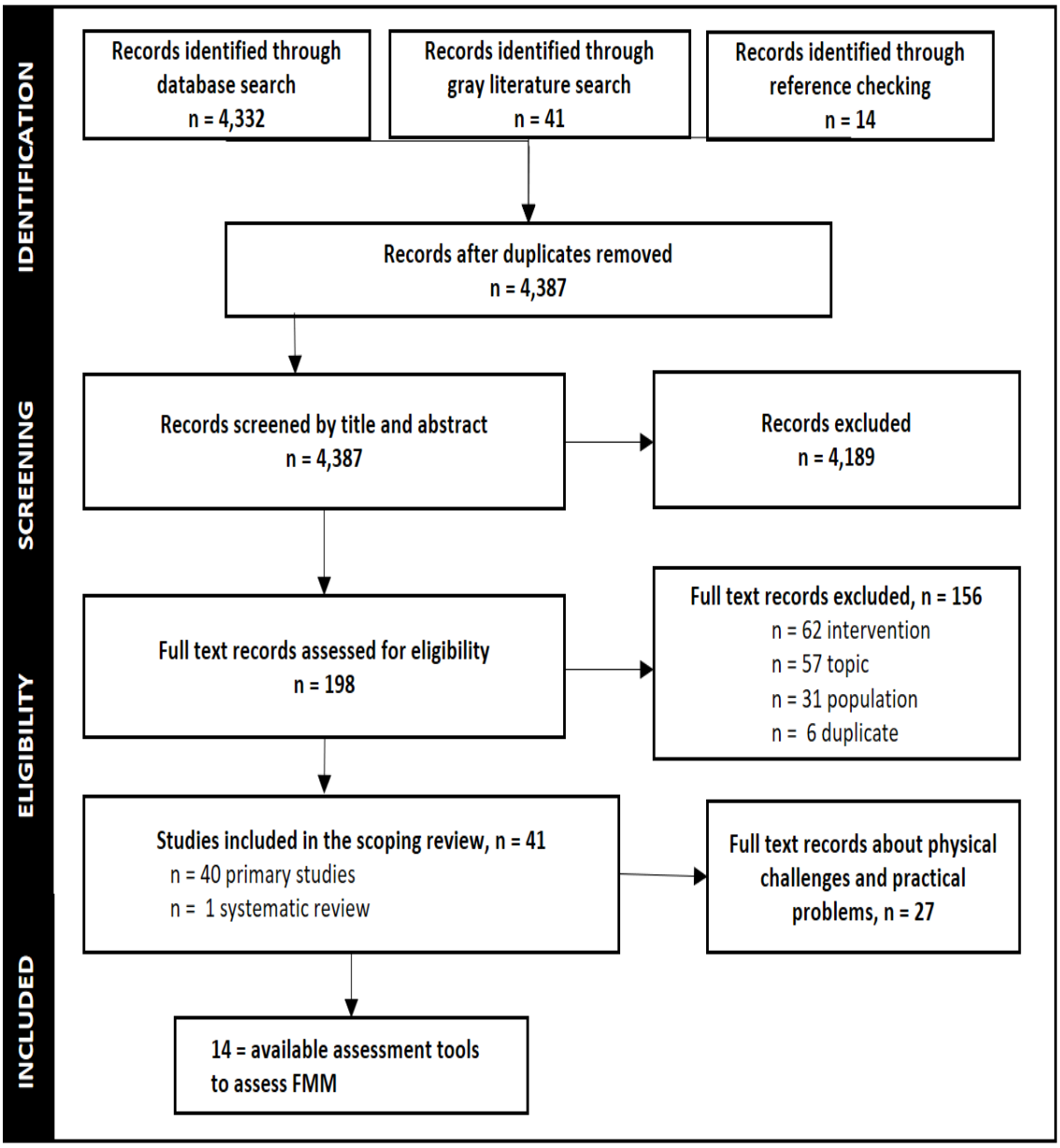

Figure 4-1: PRISMA diagram

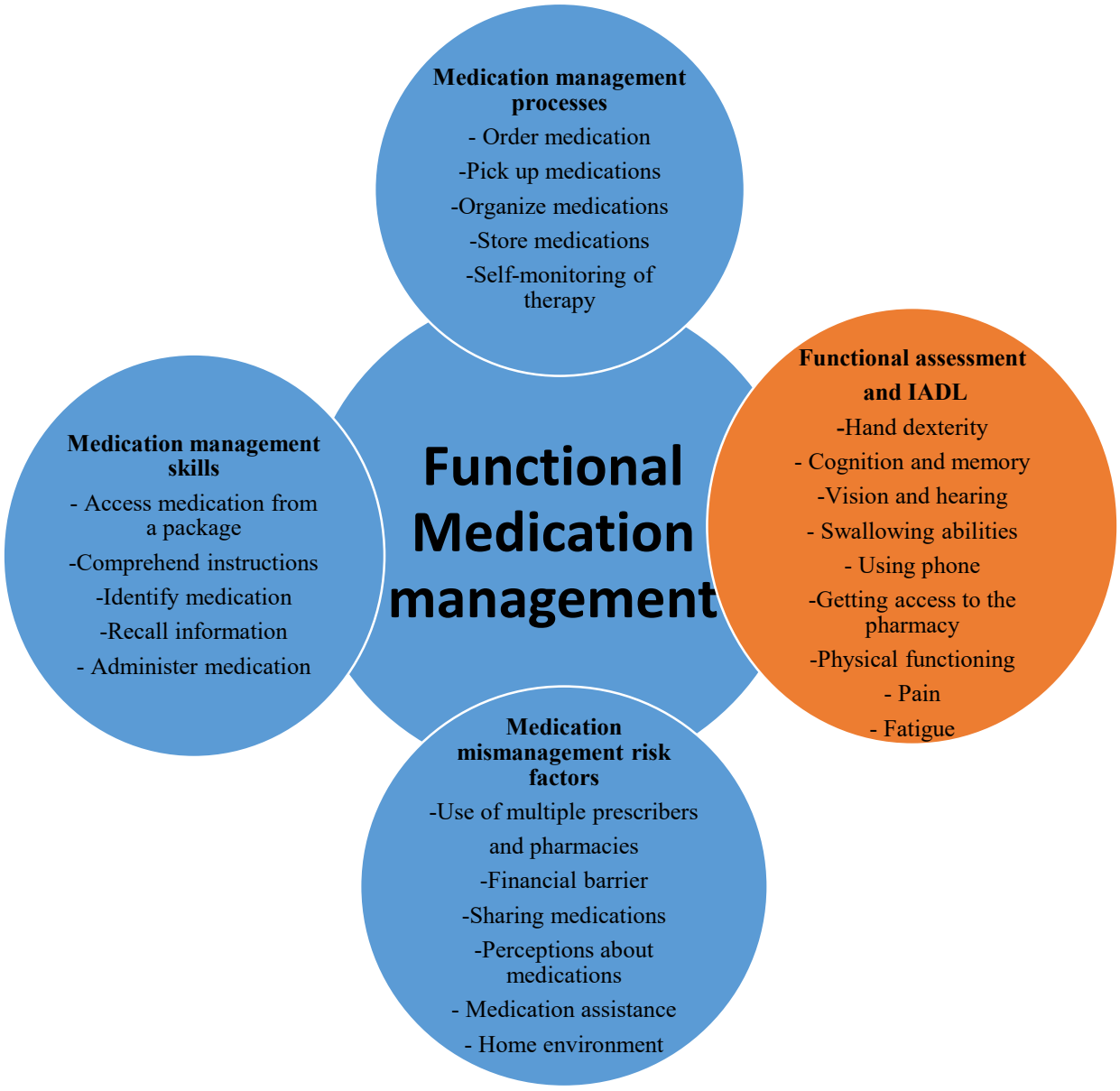

Figure 4-2: Functional medication management domains

Chapter 5

Difficulty in managing medications: A study of people with rheumatic conditions

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Significance & Innovations

- The majority of patients with rheumatic conditions reported difficulty physically managing their medications.
- All types of medication formulations posed challenges for patients with rheumatic diagnoses.

5.1 Introduction

Arthritis is prevalent chronic condition affecting 16% of the Canadian population aged 15 years and older in 2008 and with an aging population it is expected to increase to 20% in 2031 (174). In Canada, the most prevalent forms of arthritis in the general population include osteoarthritis (>10%), gout (3%) and rheumatoid arthritis (RA) (1%) (174). Reduction in physical function and health-related quality of life is common in rheumatic conditions due to pain, stiffness and swelling of the joints (175). RA, for instance, can affect hand function and hand strength (grip and pinch strength) due to inflammation in joints of the fingers and thumb (176). In addition to joint involvement, many rheumatic conditions such as RA can have extra-articular manifestations affecting pulmonary, neurologic, digestive, cardiovascular, cutaneous, hematologic, and ocular system (177-179). Ocular inflammation associated with RA, for example, can cause dry eye, episcleritis, scleritis and peripheral ulcerative keratitis (PUK); potentially leading to various degrees of visual impairment (180). Subsequently, functional impairments related to rheumatic conditions can lead to difficulty in performing activities of daily living (181).

Managing one's own medication regimen is regarded as an instrumental activity of daily living (IADL) because it is a complex process involving several tasks such as opening medication packaging, preparing a dose or administering the medication (6,10). To perform these steps, one should have adequate function such as hand dexterity and vision (33). However, people with impaired hand function related to arthritis experience opening medication packaging such as safety vials and suppositories (20). People with rheumatoid arthritis are often required to use medications with different formulation to treat their arthritis and its complications; these formulations may include oral medications and/or local therapies, such as injections, inhalers, eye drops, or topical creams and ointments. Some of these formulations that require detailed

schedules or complex multi-step processes can influence health outcomes negatively if not managed appropriately (7). Inhaler use, necessary to treat respiratory diseases associated with arthritis, involves several steps such as dose loading, inhaler priming, and breath coordinating (136). Eye drops are also commonly used formulation in patients with arthritis due to their predisposition to dry eye and other ocular diseases, can be difficult due to reduced fine motor capability (131).

Literature on functional challenges that people with rheumatic diseases experience with the use of their medications and strategies addressing these problems is limited. The few studies that addressed managing one's medication investigated only few specific problems in this patient population such as challenges with child-resistant vials (20,183). The aim of this cross-sectional survey was to identify the types of physical challenges people with arthritis experience with different types of medication and whether people require assistance with managing their medications.

5.2 Materials and Methods

5.2.1 Participants

Between March 15 and April 16 2019, a cross-sectional survey of 100 patients attending Kaye Edmonton Rheumatology Clinic (Edmonton, AB, Canada) was conducted. This clinic is a referral based clinic providing health services to the residents of Edmonton and northern Alberta area**.** The clinic has thirteen rheumatologists working and the average number of patients seen in the clinic per day ranges from 60-80 patients. Patients were asked to complete the survey if they (1) were aged 18 years or older (2) had any rheumatologic conditions (4) take medications (5) able to communicate and read English.

5.2.2.Instrument

The survey design was informed by: previous research (22,184) and feedback from a rheumatologist and nurses working at the clinic. The questionnaire consisted of 34 questions which assessed four major areas: (1) Detailed medication management challenges questions about both oral and non-oral dosage form including oral, ophthalmic, inhalers, injectable and other forms such as creams or nasal sprays (147); (2) Medical and medication history questions including questions about the type of rheumatic conditions and any medical condition related to nervous system, eye conditions, lung conditions or mental conditions; (3) Demographics;(4) medication assistance including details about person providing assistance with medication management and the type of assistance received (184). The survey included a series of questions with a combination of multiple choice and checklist questions design (See Appendix D).

5.2.3 Procedure

Participants who met the inclusion criteria were approached by clinic nurses while they waited for their consultation. Informed, written consent was obtained and the person was asked to complete the survey and return it to the research assistant. The research assistant was available to assist with completing the survey by reading questions and completing the questionnaire for any patient who required assistance. The study was approved by the University of Alberta Ethics Board and Northern Alberta Clinical Trials and Research Center [Pro00088738].

5.2.4 Statistical analyses.

An IBM SPSS software 2018 [185] was used to produce descriptive summaries for categorical and continuous variables.

5.3 Results

Of the 100 participants who completed the survey, the mean age was 57 (SD 14) years with a range of 24 to 90 years old. Thirty percent of participants were 65 years or older and 76% were women. The majority of participants were married (74%) (Table 5-1).

The median of the number rheumatic conditions reported per person was 1 (SD 0.75). The three most commonly reported rheumatic conditions were rheumatoid arthritis (n=52), osteoarthritis (n=21), and psoriatic arthritis (n=10). The median of functional impairments reported per person was 2 (SD 3.75). The most commonly reported functional impairments were joint stiffness (n=43), grip strength (n=41) and pain (n=40). Other than rheumatic conditions: dry eyes (n=23), asthma (n=19) and depression (n=16) were also commonly reported comorbidities. When asked to self-report about general health, the three most common answers were good (n=39), fair (n=29) and very good (n=21).

All participants were taking prescription medication and about half of them (n=57) taking 5 or more prescription medications. In addition to prescription medications, patients commonly (n=83) were taking over the counter medications and (n=33) were taking natural health products (Table 5-2).

5.3.1 Medication management assistance

Seventeen participants indicated that they received assistance with their medications. Of participants receiving assistance, 14 received help from an informal caregiver, 2 by formal caregiver and 1 by both formal and informal caregivers. Of all participants receiving assistance, the most commonly reported types of help include opening medication packages (n=11), taking medications (n=7) and picking up medication (n=4). Also, the majority (n=86) reported that they pick up the medication from the pharmacy by themselves. The most commonly reported use of

medication management aid is pill organizer (n=52), prescription list (n=21) and pill splitter (n=16). Ten participants required assistance with filling the survey due to pain and/or hand dexterity issues (Table 5-3).

5.3.2 Medication management challenges

Thirty-seven participants reported problems with remembering medication names and 19 of them had problems remembering the correct time to take medications. Another 16 reported problems reading prescription labels. The types of difficulty using different medication forms is presented in Table 5-4.

Oral medications use

Sixty-nine of the 98 people who used oral medications reported having at least one difficulty. Opening safety vials (n=58), breaking tablets (n=23) and opening tablet blisters (n=21) were the most common reasons given by RA clinic attenders for having difficulty with oral medication use.

Eye drop use

Eighteen of the 36 participants who used eye drops reported having at least one challenge. The most commonly reported challenges were squeezing the eye drop bottle (n=37), instilling correct number of eye drops (n=22) and holding the eye drop bottles (n=17).

Inhaler use

Ten of the 26 participants who used inhalers reported having at least one difficulty. Coordinating breath with dose release (n=30), opening cover of the inhaler (n=15) and pressing to release the dose (n=15) were the three most reported difficulties. Surprisingly, none of the

participants reported challenges with the following: gripping inhaler, shaking inhaler, twisting inhaler, and pressing perforation button.

Injection use

Nineteen of the 44 participants who used injections reported having at least one challenge. Depressing plunger (n=27), gripping injection device (n=25) and withdrawing medication from vial (n=22) were the most common types of challenges.

On further analysis, the only significant association found was between OA and age (P 0.001) (See Table 10 Appendix G). This is predictable as OA is an age related condition.

5.4 Discussion

We found that over half of patients with rheumatic conditions reported having difficulty with at least one physically challenge managing their medications. The types of challenges identified varied with using different delivery system. More participants were using oral medications and injections compared to eye drops and inhalers. Challenges with oral medication use was the highest when compared to other dosage forms. For participants who required assistance with their medication, most help was needed with opening medication packaging.

Previous research related to concerns about medications in rheumatic patients has focused on safety aspects, such as adverse events, rather than the functional ability to manage medications (200). More recent evidence has purported functional aspects of medication may play a role in self-discontinuation, poor adherence, or poor management (193). This study is unique in that it evaluates functional challenges by examining a detailed sequence of administering different medication forms for people with inflammatory arthritis. Through this approach, previously unreported functional challenges were identified, such as difficulties opening tablet blisters,

breaking tablets, opening pill boxes, and withdrawing medication from an injection vial. The only previously published research describing detailed practical challenges with different medication forms focused on older adults aged 70 years or older (5). In contrast, our study identified that most people with rheumatic conditions, across all age groups, experienced challenges with medication management. It is important to note that 70% of the patients in this study were under the age of 65, yet most still had at least one difficulty with medication management. Joint stiffness, reduced grip strength and pain were the most commonly reported functional impairments in our study. Subsequently, difficulty with managing medications in this group could therefore be attributed to other factors such as reduced strength and fine motor skills as opposed to aging.

Many patients with rheumatic conditions have impaired hand function that can affect their ability to open medication vials (56). Opening safety vials was the most commonly reported challenge with oral medication use in our study. Similar to our findings, safety vials were reported to be challenging for people with arthritis (20). A study by Agnholt reported that rheumatic patients take 40-180% longer time than healthy controls to open the same medication containers (186). Our study also found that the most commonly reported problem regarding eye drop use is squeezing the eye drop bottle. Another cross sectional study of 206 people reported that 62% of people with rheumatic conditions reported difficulty instilling eye drops and 48% had challenges squeezing the eye drop bottle (131). Since people with arthritis have reduced hand dexterity, the process of squeezing the eye drop bottle can be difficult, if not impossible (187).

Inhalers were another type of medication that participants reported difficulty with. Coordinating the breath with release of the dose associated with metered dose inhaler use was the

most frequently reported challenge. Contrary to our findings, a study of 34 patients with RA found that the most difficult task with meter dose inhaler use was depressing the canister (136). Surprisingly, none of the participants reported challenges with any of the following: inserting the capsule in the inhaler, pressing perforation button or twisting the inhaler, which are steps required to operate certain inhaler devices such as HandiHaler® or turbuhaler ®. There are few possible explanations for such observation. First, we had only small subset of the sample using inhalers (26 of 100 participants) and our sample was younger (70% are less than 65 years of age) compared to other trials (136). Second, the use of HandiHaler® device may be limited in our sample as previous research suggested that the use of this device in people with arthritis is unsuitable as it is significantly difficult to perform all the steps to activate the device (136). A previous study of 34 patients examining the physical ability of people with RA to use commonly prescribed inhaler devices, found that fewer participants with RA (15%) were able to complete all the steps necessary to operate the HandiHaler® versus people without RA (94%) (136).

Our study also identified that the most common challenge with injection use is depressing the plunger of the injection. Other studies showed that people with reduced hand strength and dexterity associated with arthritis frequently have difficulty administering the injection (188). Depressing the plunger can be particularly difficult task for people with arthritis; this may be as a result of the force required to depress a plunger (188). Since injectable products are becoming increasingly common for administration of biological products for inflammatory conditions, difficulty in self-administering injections present a real challenge in this population.

A small proportion of participants (17%) reported that they received help with managing medications. During the study, 10% of the participants needed help from the research assistant to

fill out the survey due to either pain and/or hand dexterity issues. This further highlights the real impact of functional limitations on everyday activities including management of medications.

Strength and limitations

Previous studies focused on functional challenges experienced with only one specific dosage form or device (14,15). Our study is unique in that it described self-reported functional challenges experienced with different dosage forms including oral, ophthalmic, injectable and inhalers. Most previous studies included people with only one specific condition such as rheumatoid arthritis (136,131); however, our inclusion criteria are more broad and included people diagnosed with different rheumatic conditions. Our study is also the first to identify more details about type of person providing help and types of assistance people received.

One limitation of our study is that there is a risk of reporting bias and recall bias when filling surveys (189,190). Patients may have perceived their use and technique were adequate, but this was not validated against an expert healthcare professional assessment. Also, rare practical challenges, such as measuring the correct volume of liquid medication, might have been missed. Since this study included a convenience sample, selection bias cannot be ruled out. It is possible, that those who agreed to fill the survey had more challenges with medications than those who did not. It is also possible that those who attended the clinic are more likely to have difficulty managing their inflammatory arthritis, generally, than those who did not, which could give rise to an over-estimate of the prevalence of difficulty managing medications.

Conclusion

People with rheumatic conditions reported several challenges with every dosage form of medications. Understanding the challenges people with rheumatic conditions experience can be

the first step toward putting measures in place to make medication management easier for everyone.

Table 5-1: Characteristics of study participants

Participants	n=100
Age, mean ± SD	57±14
Sex	
Female	76
Level of Education	
University	31
Completed high school	28
College	28
Did not complete high school	9
Apprenticeship	4
Marital status	
Married/common-law	74
Divorced/separated/widowed	19
Never married	7
Living arrangement	
In own residence	98
In a supported living residence	2
Self-reported rating of health	
Good	39
Fair	29
Very good	21
Poor	7
Excellent	4

Table 5-2: Medications and medical conditions

Characteristics	n (%)
Median number of rheumatic condition per person ±IQR	1±0.75
Rheumatic conditions	
Rheumatoid arthritis	52
Osteoarthritis	21
Other IA	n=45
Psoriatic arthritis	10
Gout	8
Vasculitis	7
Systematic lupus erythematosus	5
Scleroderma	4
Polymyalgia rheumatica	2
Erosive arthritis	1
Mixed Connective Tissue Disease	1
Sjogren's syndrome	1
Behcet disease	1
Ankylosing spondylitis	1
Reactive arthritis	1
Polymyositis and dermatomyositis	1
Adult-onset Still's disease (AOSD)	1
Chronic recurrent multifocal osteomyelitis (CRMO)	1
Median number of other medical conditions per person±IQR	1±2
Other medical conditions	
Nervous system	**n=11**
Stroke	5
Epilepsy	2
Essential tremor	2
Migraine	2
Parkinson disease	0
Alzheimer disease	0
Multiple sclerosis	0
Eye conditions	**n=39**
Dry eyes	23
Cataracts	10
Glaucoma	2
Macular degeneration	**2**
Blindness	**1**
Eye cancer	**1**
Respiratory	**n=29**
Asthma	19
COPD	5
Lung cancer	1
Cystic fibrosis	1

Pulmonary fibrosis	1
Interstitial lung disease	1
Bronchitis	**1**
Mental health	
Depression	**n=3**618
Anxiety	17
Post traumatic disorder	1
Others	**n=11**
High blood pressure	3
Diabetes	2
Chronic kidney disease	1
Hyperthyroidism	1
Skin ulcer	1
Chronic staph infection	1
Kidney transplant	1
Atrial fibrillation	1
Median number of functional impairments reported per person ±IQR	2±3.75
Functional challenges	
Joint stiffness	43
Grip strength	41
Pain	40
Moving your hands	30
Muscle weakness	22
Vision problem	17
Memory problem	12
Difficulty hearing	6
Others	3
Prescription medications	100 (100)
Number of prescription medications	
≥5	57 (57)
< 5	41 (41)
Non-prescription medications	83 (83)
Herbal or natural health products	33 (33)

Table 5-3: Assistance with medication management

Medication assistance	**n (%)**
Receiving assistance	17 (17)
Feeling for needing assistance	7 (8.5)
Person providing assistance	
Informal	14 (82.4)
Formal	2 (11.8)
Both	1 (5.9)
Type of assistance	
Opening package	11
Taking medicine	7
Picking up medicine	4
Organizing medicine	3
Reminding you to take medicine	3
Preparing medication	3
Ordering medicine	2
Reading Rx labels	1
Observing effect of medicine	0
Picking up medicine	
Self	86
Family members	33
Friends	2
Other caregiver	0
Delivery	7
Medication management aids	
Pill organizer	52
None	29
Prescription list	21
Pill Splitter	16
Calendar	15
Alarm	13
Blister pack	4
Receiving help filling the survey	10

Table 5-4: Medication management challenges

General challenges with medications	n (%)
Remembering medicine name	37 (37.4)
Remembering medicine time	19 (19.2)
Remembering purpose of the medicine	6 (6)
Reading Rx labels	16 (16)
Understanding Rx labels	7 (7)
Oral medication use	98(98)
Number of people with at least one challenge with oral medication use	69 (70%)
Opening safety vial	57 (60.6)
Breaking tablet	23 (33.3)
Opening tablet blister	21 (31.8)
Opening blister packs	17 (26.6)
Swallowing tablets	16 (18.8)
Removing tablet from blister	14 (20.6)
Opening non safety vial	11 (13.3)
Opening pill boxes	11 (15.5)
Crushing tablet	7 (13.2)
Removing tablet from vial	7 (9.6)
Filling a pillbox	4 (5.6)
Eye drops use	36 (36)
Number of people with at least one challenge with eye drop use	18(50%)
Squeezing bottle	13 (35.1)
Instilling correct number of eye drops	8 (21.6)
Holding bottle	6 (16.7)
Keeping hand steady	6 (16.7)
Holding eyelids	6 (16.7)
Taking the lid off	3 (8.6)
Inhaler use	26 (26.3)
Number of people with at least one challenge with inhaler use	10 (38%)
Coordinating breath with dose release	8 (33.3)
Opening cover of inhaler	4 (16.7)
Pressing the release of dose	4 (18.2)
Closing inhaler	2 (9.1)
Gripping inhaler	0 (0)
Shaking inhaler	0 (0)
Loading the capsule	0 (0)

Twisting inhaler	0 (0)
Pressing perforation button	0 (0)
Injection use	44 (44.9)
Number of people with at least one difficulty with injection use	**19 (43%)**
Depressing plunger	12 (29.3)
Gripping injection device	11 (27.5)
Withdrawing medicine from vial	10 (30.3)
Holding device stable when injecting	7 (17.1)
Rotating site of injection	6 (14.6)
Cleaning injection area	2 (5.1)
Other formulation use	
Creams or lotions	53 (53)
Nasal sprays	17 (17)
Patches	4 (4)
Suppositories	3 (3)
None of the above	38 (38)
Difficulties with other formulation listed above	5 (8.9)

Chapter 6

Discussion

The overall findings of this thesis are that older adults with functional impairments living in the community experience difficulties with managing their medications and that current tools assessing functional ability to manage medications have several limitations.

With an aging population and growing use of multi-drug regimen for chronic conditions, medication management is becoming increasingly challenging (191). For example, a patient with hypertension, chronic obstructive pulmonary disease, osteoarthritis, type 2 diabetes and osteoporosis may require up to 12 drugs and 19 doses, taken at 5 different times of the day, based on the clinical practice guidelines for those conditions (192). In order to manage medications successfully, one should have adequate physical and cognitive abilities (21). As people get older, they encounter a number of barriers to successful medication management. Many older adults experience some degree of age related physical impairments such as impaired motor coordination, and reduced vision; potentially affecting the ability to manage medication successfully (10). Impaired cognition also has been associated with medication errors, and reduced ability to manage complex medication regimen (24,52). If patients lack the functional ability to manage their medications, strategies such as providing more education, simplifying their medication regimen, providing medication assistance and suggesting the use of medication aids may be useful (34).

Certain chronic conditions commonly seen in older adults such as arthritis are also associated with physical impairments (1,17). Arthritis can cause joint inflammation, pain and swelling leading to impaired hand function such as decreased handgrip and dexterity (18). Functional impairments related to arthritis can lead to difficulty in performing activities of daily

living including medication management (8). These barriers can lead to unintentional non-adherence and medication errors (55).

Previous research exploring functional challenges with medication management in older adults has mostly focused on describing challenges experienced with oral medication use (16). Even though the oral route is a very common method of administering medications, other dosage forms such as inhalers, eye drops, and injectable can also be challenging for older adults experiencing functional decline. Our scoping review involved searching six electronic databases, to describe the types of functional challenges older adults experience with different medication forms. Older adults experience functional challenges with all different medication forms and the majority of the studies (11 of 27) focused on describing challenges with oral medication use. The most commonly reported challenge was accessing medication from its outer and immediate packaging. Specifically, we found that more physical challenges dealt with opening oral medication vials (child resistant vials, screw top, snap vials) than other oral packaging such as blister packs, mouthwash and foil. Our results agree well with earlier studies. In a cross sectional study of 604 older adults, 14% were unable to open a screw cap bottle, 32% a bottle with a snap lid, and 10% a blister pack (16). Another study also reported that as many as 63% of a sample of older adults could not open one or more of the medication vials tested (57). In addition to physical challenges, studies have shown that dementia and impaired cognition (as identified by lower MMSE score) were strongly associated with reduced ability to open medicine containers (54). People with dementia were reported to be at least three times more likely to have reduced ability to open medication vials even after adjusting for other factors such as age, impaired vision and arthritis (54). We excluded studies involving patients with cognitive impairments because (1) our review focused on describing physical and sensory challenges only (2) self-administration of

medication may be rare in this population. Given the unique caregiving needs and supportive living environments, this population requires studies specifically addressing their and their caregivers' processes.

Additionally, several studies (10 out of 27) focused on describing challenges with inhaler use. The studies described different types of problems older adults encounter when using various inhaler devices. These challenges included handling the technical aspect of the operation, administering the inhalers and/or cleaning the devices**.** Since each inhaler type has unique operating instructions, challenges with different inhalers varied. The most commonly reported problems with pMDI, for example, was coordinating the breath while actuating the device. Similar to our findings, previous studies have reported that physical decline in older adults may impede the proper administration of inhaled medications; resulting in inappropriate dosing (78). In a randomized controlled trial of 123 adults aged 55 or older, inadequate inhalation technique was high with 81% of older adults with asthma having at least one error in their inhalation technique (79).

In the second review, we described published tools designed to assess older adults' abilities to manage their medications at home and identified gaps in these measures. Fourteen unique tools were reported; ten tools were performance based and four were self-report. Performance based tools (n=10) either used patients' own medications as a basis of assessment (n=4) or a simulated kit or placebo medication (n=6). Seven of the performance based tools we found (DRUGS, MedMaIDE, MedTake Test, HMS, MMAA, MMPT, MMEI) were also described by an earlier systematic review published in 2009 (34). However, our review described seven additional tools (HOME-Rx, ManageMed Screening, Medication Regimen Adherence Capacity Test, MMC, Practical Drug Management Capacity Questionnaire, Medication knowledge and skills assessment

and Medication assessment tool). This is because our inclusion criteria are more broad and our scoping review is more recent. In contrast to previous reviews in the literature that included performance based measures only, our scoping review included both performance based and self-report tools. Even though performance based tools can be more reliable, self-report tools can still be useful as a starting point for identifying challenges with medication management (i.e. screening tool) (95). Subsequently, it was important for our review to include and describe both types of tools.

Self-report measures are quick and easy to administer; however, they are more prone to bias (95). People may overestimate their ability to manage medications or are reluctant to admit their inability to manage their medications independently (94). Also, some older adults may have difficulty evaluating their competence due to cognitive impairment (94). Performance based measures, on the other hand, may be more objective as health care professionals observe patients while they perform different tasks related to medications and assess their ability accordingly (34). However, performance based measures can take a longer time to administer and may be stressful for older adults especially if the outcome of the test may result in loss of independence (34). Since performance based measures provide a snap shot of patient capacity to manage medications during the time of the test, they do not necessarily reflect patient's real capacity over time as their cognitive and physical function deteriorate. Previous reviews describing domains assessed by the tools were limited to only describing one domain, medication management skills, such as accessing medication from a package, comprehending instructions and identifying medications (55). In addition to medication management skills, our review identified three additional medication management domains: medication management processes, function and risk factors to medication mismanagement. The degree to which different functional medication management domains were

assessed varied between tools. This shows that there is very little consensus among developers of the tools about the domains and/or skills that should be assessed. This is can be attributed to the lack of a gold standard tool of medication management ability against which other tools can be compared (55). Since medication management is a complex process involving areas such as medication procurement, medication knowledge, physical and cognitive ability, and intentional non adherence (47), it is important to consider all different domains of medication management when developing a tool.

Previous studies have also identified some gaps in the published tools including limited reliability and validity data of the measures, and limited data on acceptability of these assessment tools to patients (34). Interestingly, our review found a unique limitation to both performances based and self-report tools, which is the lack of assessment of functional abilities required to perform medication related tasks. Very few tools specifically asked for or assessed function related to medication management such as hand dexterity and vision; even though impaired vision and low manual dexterity were shown to be associated with poor medication self-management (47). The majority of tools described in the literature only allow health professional to documents ability/inability to perform certain medication related tasks without assessing or asking for the underlying reason for such inability. Identifying the underlying cause of inability to manage medications can help health professionals plan interventions accordingly.

Another limitation of majority of the tools is the lack of assessment to use non-oral dosage forms such as eye drops, inhalers, and injections, challenges with these dosage forms were reported in the literature (118,130,132). The majority of the tools focused on assessing the ability to open oral medication vials such as flip-flop and/or child resistant vials. One possible explanation is that

many of the tools were developed in the United States, where vials are the most common form of packaging (55).

Previously published self-report tools examining functional challenges with medications use were considered (22,142,155) but they were not validated and found not to focus on the factors of particular interest in this study. Therefore, a questionnaire was developed specifically for this study. The questionnaire design was informed by: studies from the scoping reviews; previous studies from rheumatology, and feedback from expertise in rheumatology and pharmacy. Content and face validity was established through consultation with the expert panel. The questionnaire is intended to describe the types of functional medication management problems rheumatology patients experience. Understanding the types of challenges with medication management can be a starting point to direct future research on important aspects to consider in order to develop a comprehensive tool.

We conducted a cross sectional study by administering the questionnaire to a convenience sample of 100 patients diagnosed with various forms of inflammatory arthritis to explore the types of functional challenges with medication use and administration. We chose to survey people with arthritis because they are commonly known to have reduced physical function and health-related quality of life due to pain, stiffness and swelling of the joints (165). Also, extra-articular manifestations associated with various forms of inflammatory arthritis can also affect multiple body systems leading to various disabilities such as vision impairment (180). Because of the physical and sensory limitations that are seen with arthritis and associated comorbidities, management of medications and subsequent adherence may be affected (193).

This study revealed that the majority of patients with rheumatic conditions, despite being relatively young, report difficulty physically managing their medications and all types of

medication formulations pose challenges for patients with rheumatic conditions. Our review showed that the two most commonly used modes of delivery were oral route and injectable. This is expected as the majority of anti-rheumatic medications are administered either orally or via intravenous or intramuscular injections. The most commonly identified challenges were with the use of oral medications and eye drops. Regarding oral medications, opening safety vial was the most reported challenge. Our findings are consistent with previous research that show that many patients with inflammatory arthritis have impaired hand function that can affect their ability to manage their medications such as opening medication vials (56). A study by Agnholt and associates reported that rheumatic patients take 40-180% longer time than healthy control subjects to open medication vials (186). In addition, the most commonly identified challenges with the eye drop use is squeezing the bottle. Similar to our finding, a cross sectional study of 206 people showed that 62% of people with rheumatoid arthritis reported difficulty instilling eye drops and that 48% had challenges squeezing the eye drop bottle (131). Because most eye drops in Canada are no more than 5-15 mL, and very small in size, very fine motor skills are required. Since people with arthritis have reduced fine motor capacity, the process of squeezing the eye drop bottle can be difficult (187).

Overall, the objective of our study was to describe functional challenges with medication management and published tools assessing functional medication management. Our study highlighted that people with functional impairments due to older age or certain medical conditions are specially at risk of experiencing functional challenges with medication management and that all dosage forms pose a challenge to this population. Also, congruent with many previous research, our study confirmed that published tools assessing functional ability to manage medications have

many limitations and proposed that one important limitation of these tools is the lack of assessment of function necessary to manage medications successfully.

Strengths of the study

Our study has many strengths. First, our scoping reviews adhered to the recommendation made by Arskey and O'Malley for conducting our scoping review (108). This method is designed to map literature on fields of interest, as well as identify and clarify the key concepts, theories, and sources of evidence and gaps in the research (108). We followed the six stages recommended by the review: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) data charting; (5) collating, summarizing, and reporting results; and (6) consultation (108). Another strength is that we had a dual independent review during study selection and data charting stage; this reduces the risk of selection bias for our scoping reviews. Our scoping review was not limited by language, medical conditions/medication or type of tool (self-report or performance based); subsequently, our search captured all relevant studies and gave us a good overall understanding of the issue of functional medication managements and the available tools to measure functional ability to manage medications.

For the rheumatology survey, we utilized our knowledge from the two scoping reviews to build a comprehensive questionnaire about functional challenges with different delivery forms (oral, ophthalmic, inhalation and injectable). All other tools or questionnaires described in the literature were limited by focusing on challenges with oral medication use. Participants included in the study were diagnosed with various forms of arthritis; while previous research mostly focused describing challenges for patients with rheumatoid arthritis. Our study also elicited more details about type of person providing help and types of assistance people received.

Limitations of study

There were limitations of this study that should be considered. For the scoping reviews, although our search was not restricted by language, some language bias was still inherent as our search was conducted using English-language search terms. Only one paper that was not written in the English language was assessed at full-text level; was eventually excluded as it did not fit our inclusion criteria. Our review included only studies focusing on patients from the community, and therefore tools assessing functional medication management used in other settings such as hospital or nursing homes were not described. Finally, since this scoping review synthesizes the literature on area of function medication management, our review did not assess the included studies for methodological quality.

For the rheumatology survey, we selected a convenience sample of patients visiting the rheumatology clinic and as a result, it remains uncertain whether the study was adequately powered to detect meaningful differences. As the majority of participants were female, married, and completed university education, it remains unclear whether the limited sample of participants was representative of all arthritis patients in Canada. Finally, the questionnaire was based on published tools; however, it was not validated prior to this study.

Even though the survey involved detailed questions about difficulties managing various formulations (oral, ophthalmic, injectable and inhaled medications), it contained only a single question about difficulty with all other formulations such as creams, nasal sprays, or suppositories. Also, our survey did not include any question about challenges with formulations such as SL tablets, or buccal tablets. Future studies that focus on the difficulties experienced by people with RA should ask these detailed questions so as to better inform the development of suitable interventions. However, it is less likely that some of these formulations are used in a

younger rheumatology patient population, versus in a geriatric setting, which may be a consideration for where to administer the questionnaire in the future.

Contribution to existing knowledge

To our knowledge, this study includes the first scoping review that examined the types of functional challenges older adults experience when managing medications at home. In addition, information about the types of published tools, domains covered by the tools, and limitations in these tools were reported. Finally, the rheumatology survey examined challenges people with inflammatory arthritis experience with various medication delivery forms. Moreover, it is one of very few studies that have explored caregiver contribution in the assistance of patients with their medication use at home. This study adds to the field of pharmacy practice research in the following ways:

- It has identified the range of functional challenges experienced by older adults living in the community.
- It included challenges with different dosage form (oral, ophthalmic, injectable and inhaler).
- It has reported on two types of published tools (self-report and performance based) that are designed to assess functional medication management at home.
- It has reported on four unique domains of medication management covered by these tools: medication management skills, medication management processes, function and risk factors to medication mismanagement.
- It reported several gaps or limitations of published tools and highlighted one important limitation which is the lack of comprehensive functional assessment.
- It has reported on types of functional challenges experienced by people at risk of functional impairment, specifically people with inflammatory arthritis.

Implication of the study

To enhance the safety, efficacy and adherence to medication, functional challenges with managing medications should be considered during developing/manufacturing, prescribing and dispensing of medications (5). Several studies have shown that certain populations such as older adults and people with disabilities experience multiple challenges when managing their medications; yet this problem remains unsolved (194,195,20,196). To obtain approval for a medication, the industry must demonstrate efficacy and safety, and for generic formulations, bioequivalence. However, there is no requirement to demonstrate acceptability of medication packaging to patients. The pharmaceutical industry needs to address the needs and concerns of older people during the development of medications. First, manufacturers should seek input from patients, especially older adults and people with disabilities during manufacturing process about accessibility of medication packaging (197). Second, manufacturers, in collaboration with other experts (e.g. occupational therapy, industrial designers) can come up with innovative child resistant packaging that is accessible by older adults (197). Consideration of suitability of medication for use by older adults should also be required by regulatory agencies.

There have been some efforts from the pharmaceutical industry to redesign medication packaging and update formulations to make them easier for use. For example, methotrexate was originally provided in vials for injection. For manual injections, patients needed enough grip and dexterity to handle the vial, and depress the plunger of the syringe (201). This can be difficult for patients with functional limitations due to joint pain and inflammation commonly encountered in RA patients (201). To overcome this issue, the industry introduced a new methotrexate prefilled pen (MetoJect ®) for greater patient convenience and easier use (202). Another example is the introduction of a newer inhaler for COPD patients (ELLIPTA DPI ®) which is easier to use than

conventional dry powder inhaler (DISKUS DPI ®); given that it is smaller in size and requires fewer steps to deliver the powder (203). However, it is important to note that these new devices are quite costly; subsequently, some patients may not be able to afford them.

In addition, since people do not voluntarily report functional challenges with medication management to their health care providers, health professional should routinely screen for people at risk of having challenges and assess them accordingly (198). Health care professionals should also take into consideration the accessibility of medication packing during prescribing and dispensing process and help patients select medications with appropriate formulation and packaging.

Chapter 7

Conclusions and recommendations

Functional impairments can have a profound impact on the quality of life for patients (199). Older adults can be particularly prone to functional impairments such as poor vision, and weak handgrip leading to difficulty managing medications (11-15). Difficulty managing medications is one component of IADL which has importance in managing independence in the community (6). Reduced ability to manage medications independently can lead to increased burden on the individual, dependence on family caregivers and the need for health care services (28). Therefore, researchers have invested a huge effort in trying to determine ways to assess the ability of a person to manage medication independently. One approach is through the use of a specific tool designed to assess medication management ability (34). Using a specific tool can help in early detection of deficits, and improving interventions to support independent medication management (32). Over the past few years, developing a standardized tool to assess the ability to manage medication independently has been an area of focus for many research groups (34,55). However, no published tool has evidence to be recommended for use in routine clinical practice (34).

This thesis work provides description of types of functional challenges experienced by older adults when managing medications at home and describes published tools designed to assess medication management ability and identify gaps in these tools.

The findings of the previous three projects in this study showed that people with functional impairments (including older adults and people with inflammatory arthritis) are more prone to experience challenges when managing all different medication forms. This study also revealed that there are several limitations in published tools other than validation issues that make the tools not

robust enough to measure ability to manage medications independently. The main limitation identified is the lack of comprehensive functional assessment.

7.2 Future direction

Research Recommendations:

There have been many attempts to develop a standardized tool that measures patients' ability to manage their own medications, but published tools currently have limited evidence of reliability and validity (34). Studies validating the tools were limited to one research group and selected populations; subsequently more research is needed to confirm the reliability and validity of published tools by testing the tool in multiple populations and by more than one research group. More validation studies need to be conducted by researchers other than the tools developers.

Since our review determined that current published tools have limited assessment of function needed to manage medication successfully, more research is needed to explore incorporating more robust functional assessment. For example, none of the published tools asked for or assessed function, such as hand dexterity or vision needed to successfully manage medications. Future research is needed to either (1) incorporate functional assessment to the existing tools (2) Create a new tool with more robust functional assessment. Assessment of function is especially important for people with high risk of functional impairment such as older adults and people with rheumatic conditions.

Clinical Recommendations:

There are several challenges to consider when trying to incorporate the use of a specific tool into routine clinical practice. Since our review identified two types of tools: performance based and self-report tools, more research is needed to identify the potential use of these tools in clinical practice as either screening or assessment tools. Even though performance based is a more

reliable method of measuring ability to manage medications; self-report tools can still be useful as a starting point for identifying people at risk of having challenges (95). Future research can focus on examining the potential use of self-report tools as a screening tool to identify people at high risk of medication management such as older adults and people with rheumatic condition. Once those people are identified, they can, for example, be referred to another health care provider such as occupational therapist for full assessment using a performance based assessment tool.

Since the tools provides little or no indication to health professionals about the kind of interventions to be considered based on the tools' results, more research is needed to determine the real meaning of the tools' results in real life. For example, if a person performs poorly with respect to a certain tool, does that mean that the person needs home care, more education, or needs to be placed in residential care? Currently, it is challenging to incorporate these tools in clinical practice without learning more about true meaning of the tool's results.

There is also limited evidence about acceptability of these tools to patients and health care professionals. If patients think that poor performance can lead to loss of independence, many people may be reluctant to disclose their inability to manage their medications. Also, health care professional working in a busy environment such as community pharmacy may find it challenging to administer these tools to patients due to time constraints and work overload. In the future, a survey of the health practitioners and patients can be done to assess the acceptability of these tools.

Finally, future research is also needed to identify the potential benefit of inter-professional collaboration in assessing functional medication management. Most of the tools from the scoping review focused on administration by physicians, pharmacists, or nurses, with one tool specific for occupational therapists. Further work is needed to understand the role of each profession in assessing functional medication management.

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Appendix A: Study protocol

Functional Medication Management in Older Adults: Development of a Framework and Assessment Tool
A scoping review protocol

Purpose

Taking medications may be challenging for older adults. Managing medications can be particularly difficult for those with functional limitations, other health conditions, and frailty. The concept of functional medication management (FMM) has been described as the processes involved in using medications which includes obtaining, preparing, administering, and monitoring the medication. A number of challenges need to be acknowledged when a patient takes medication, such as difficulties opening packaging, administering injections, or following the sequencing for taking multiple medications. Because of the physical challenges, and complexity of the medication products (e.g. inhalers, insulin pens), individuals are predisposed to incorrectly managing their medications and subsequent non-adherence. To provide the best care and ensure that people gain the most from their medicines, it is important to know what sort of challenges people have with their medicines. We will undertake a scoping review to synthesize the literature available to guide a framework for functional medication management.

Background

Problem: Older adults take many medications that may be challenging to functionally manage. Products are provided in dosage forms such as inhalers, drops, injections, pens, patches, etc. Sometimes these products are difficult to use if a patient has functional impairment, frailty, sensory impairment, or other co-morbidities. These conditions can limit vision, grip strength, dexterity, or other functions necessary to use medications. There are currently no tools available to support older adults or health professionals in assessing functional management of medications, including ordering and obtaining medications, through monitoring the effects of those medications.

Significance: Developing a tool in consultation with seniors, individuals with various disabilities, and health professionals would provide support and guidance to patients and health professionals on interventions and making decisions about functional medication management. The tool could be used by a variety of health professionals (e.g. physicians, pharmacists, occupational therapists), in many settings (e.g. acute care, ambulatory care, home care). While there are many implicit and explicit tools to guide appropriate medication choices, there are no tools available to assess and guide functional medication management.

Primary questions
What physical challenges do older adults experience self-administering medications?
What assessment measures are available for functional medication management?

PROPOSED METHODS
Scoping reviews

Literature Search
The literature search will be developed and executed by an information specialist (RF) and peer-reviewed by a second research librarian (TL). We will search electronic databases: Ovid Medline (1946-), Ovid Embase (1996-), CINAHL via EBSCOhost (1937-), and Ovid PsycINFO (1987-). Search results will be restricted to publications from 2000 to current. No language limits will be applied. Other search sources will include Conference Proceedings Citation Index (Clarivate Analytics) and ProQuest Dissertations & Theses Global. Search results will be exported and screened in EndNote X7 (Thomson Reuters). See appendix for Medline strategy.

Study Selection
A two-stage selection process will be used to select primary studies reviews for inclusion, following a set of a-priori inclusion and exclusion criteria (Table 1). The first level of screening will include the title and abstract of each primary study by two reviewers. Any study classified as 'include' or 'unsure' will be retrieved for second-level screening. Those that are obviously irrelevant will be excluded. At the second level of screening, the full text of each article will be examined by two reviewers for eligibility. Any disagreements will be resolved via discussion or involvement of a third reviewer if differences in interpretation exists. All decisions regarding inclusion or exclusion will be documented as they occur.

Table 1: Inclusion/Exclusion Criteria

	Include	**Exclude**
Study Design	All study designs	None
Setting	• Taking place in the participants home and self-administering	• If administered by caregiver, nurse, healthcare provider, etc. • If administered in care facility, nursing home, etc.
Participants/ population	• Adults over the age of 65	• Under the age of 65
Intervention(s), exposure(s)	• Any assessment tool / process for assessing functional medication management • Focus on physical / functional challenges	• Cognitive impairments
Outcome(s)	• Impact of physical / functional challenges on any outcomes	• None

Data Extraction (Charting the data)
A data extraction form will be developed and piloted on a sample of included records to ensure that it will adequately capture the characteristic and findings of the included studies. One reviewer will extract data from each study independently, and a second reviewer will verify the data extracted from studies to ensure all the appropriate data is being extracted.

Descriptive information will be extracted from each study, including: author, year and country of publication, type of data (qualitative and quantitative), study design, sample size, population characterizes (e.g., age, ethnicity), functional challenges (strength and dexterity to open safety caps, popping blister packs, shaky hands trying to auto-inject medications, inability to depress inhalers, etc.), assessment tools, and pre-defined outcomes such as dosing errors, non-compliance, etc.

Data Analysis and Reporting
The findings of the included primary studies will be presented as a descriptive summary and frequencies within tables.

Estimated Timelines

Task	Responsibility	Timeline (completion date)
Search strategy development	RF, TL	January 15, 2018
Screening training	LB, HA	January 19, 2018
Finalize methods/protocol	LB, HA, CS, AJ	January 22, 2018
Primary screening	LB, HA	April 19, 2018
Consolidate responses	LB	April 23, 2018
Full text retrieval	LB, HA, MH	May 3, 2018
Secondary screening	LB, HA	May 14, 2018
Consolidate responses	LB	May 17, 2018
Data extraction	LB, HA	Aug 30,2018
Report preparation	LB, HA, CS, AJ	Jan 30,2019
Prepare manuscript	LB, HA, CS, AJ	March 30,2019

HA: Hadeel Abed; LB: Liza Bialy; RF: Robin Featherstone; MH: MacKinna Hauff; AJ: Allyson Jones; CS: Cheryl Sadowski; TL: Tara Landry

Appendix B: Search Strategies

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present
Date conducted: Jan 15, 2018
Strategy:

1 Age Factors/ (453706)
2 exp Aged/ (3063165)
3 Aging/ (231852)
4 Geriatric Assessment/ (25359)
5 ((adult* or citizen* or individual* or people or person* or resident*) adj1 (older* or senior*)).tw,kf. (106072)
6 community dwelling*.tw,kf. (20043)
7 elderly*.tw,kf. (237285)
8 frail*.tw,kf. (17310)
9 ((post-menopausal or postmenopausal) adj women).tw,kf. (40069)
10 or/1-9 [Combined MeSH & text words for older adults] (3590553)
11 Administration, Inhalation/ (30355)
12 exp Administration, Oral/ (147022)
13 exp Administration, Topical/ (86650)
14 Capsules/ (12404)
15 exp Colloids/ (120029)
16 Dosage Forms/ (6079)
17 Drug Administration Routes/ (5794)
18 Drug Delivery Systems/ (54450)
19 Drug Packaging/ (4935)
20 Inhalation Spacers/ (138)
21 Injections/ (43711)
22 Injections, Subcutaneous/ (33852)
23 Metered Dose Inhalers/ (1341)
24 "Nebulizers and Vaporizers"/ (9089)
25 Ointments/ (13016)
26 Pharmaceutical Preparations/ (52853)
27 Suppositories/ (4151)
28 exp Tablets/ (23896)
29 Technology, Pharmaceutical/ (15168)
30 "Vaginal Creams, Foams, and Jellies"/ (1320)
31 ((administ* or appl* or cream* or drop* or gel* or lotion* or inject* or insert* or spray*) adj2 (aural* or buccal* or cutaneous* or dermal* or ear* or eye* or inhal* or intramuscular* or intravaginal* or intraocular* or muscular* or mucosal* or nasal* or nose or ophthalm* or oral* or otic* or parenteral* or rectal* or sublingual* or subcutaneous* or topical* or transdermal* or vagina*)).tw,kf. (254668)
32 (auto-inject* or autoinject* or self-inject* or selfinject*).tw,kf. (2472)
33 blister pack*.tw,kf. (244)
34 ((bottl* or box* or container* or pack*) adj2 (drug or medicat* or medicine* or pharma*)).tw,kf. (1801)
35 ((bottl* or container* or pack*) adj2 (child resist* or tamper*)).tw,kf. (184)
36 ((cap* or packag*) adj1 safe*).tw,kf. (300)
37 capsule*.tw,kf. (75928)
38 calendar pack*.tw,kf. (29)
39 dosette*.tw,kf. (15)
40 emulsion*.tw,kf. (30212)
41 inhaler*.tw,kf. (8623)
42 lozenge*.tw,kf. (1116)
43 nebuli#er*.tw,kf. (4565)
44 (ointment* or unguent*).tw,kf. (12115)
45 (pill or pills).tw,kf. (20326)
46 spacer*.tw,kf. (31778)

47 suppositor*.tw,kf. (4744)
48 tablet*.tw,kf. (50231)
49 vapori#er*.tw,kf. (1353)
50 or/11-49 [Combined MeSH & text words for drug administration routes or packaging] (921832)
51 Medication Adherence/ (16064)
52 Medication Errors/ (12978)
53 Motor Skills/ (24007)
54 *Patient Compliance/ (24511)
55 Patient Medication Knowledge/ (150)
56 Psychomotor Performance/ (65802)
57 Self Administration/ (11692)
58 Self Care/ (32709)
59 Treatment Refusal/ (12057)
60 ((able* or abilit* or capab* or capacit* or inabilit* or incapab* or incapacit* or inabilit* or unable*) adj2 physical*).tw,kf. (7566)
61 ((accident* or uninten*) adj2 (over dos* or overdos*)).tw,kf. (925)
62 ((adher* or nonadher* or complian* or comply or noncompl*) adj3 (drug* or medicine* or medication* or pharmaceutical* or prescription*)).tw,kf. (22178)
63 ((challeng* or difficult* or problem*) adj2 (experience* or opening* or using* or utili*)).tw,kf. (27636)
64 ((correct* or error* or improper* or incorrect* or proper*) adj2 (method* or technique* or use*)).tw,kf. (48869)
65 ((dose* or dosing* or drug* or medicine* or medication* or pharmaceutical*) adj2 (error* or incorrect* or mistak*)).tw,kf. (8121)
66 ((drug* or medicine* or medication* or pharmaceutical* or prescription*) adj3 misus*).tw,kf. (3419)
67 ((lack* or insufficie*) adj2 (motor skill* or strength*)).tw,kf. (427)
68 usabilit*.tw,kf. (9803)
69 or/51-68 [Combined MeSH & text words for administration problems] (302450)
70 and/10,50,69 [Combined concepts for older adults, drug routes & administration problems] (4331)
71 (Alzheimer* or ((cogniti* or mental* or neuro*) adj2 (declin* or deteriorat* or dysfunction* or impair*)) or ((deficit* or disorder* or loss*) adj2 memor*) or dement*).ti. (134670)
72 70 not 71 [Exclude studies about dementia] (4279)
73 exp Child/ not exp Adult/ (1207924)
74 (child* or p?ediatric*).ti. (873847)
75 72 not (73 or 74) [Exclude pediatric studies] (4139)
76 exp Animal/ not Human/ (4815681)
77 (animal model* or bovine or canine or capra or cat or cats or cattle or cow or cows or dog or dogs or equine or ewe or ewes or feline or goat or goats or horse or hamster* or horses or invertebrate or invertebrates or macaque or macaques or mare or mares or mice or monkey or monkeys or mouse or murine or nonhuman or non-human or ovine or pig or pigs or porcine or primate or primates or rabbit or rabbits or rat or rats or rattus or rhesus or rodent* or sheep or simian or sow or sows or vertebrate or vertebrates or zebrafish).ti. (2362909)
78 75 not (76 or 77) [Exclude animal studies] (4072)
79 limit 78 to yr="2000-Current" (3093)
80 remove duplicates from 79 (2663)

Database: Ovid Embase 1996 to 2018 Week 03
Date conducted: Jan 16, 2018
Strategy:
1 exp aged/ (2025598)
2 aging/ (180667)
3 geriatric assessment/ (12217)
4 postmenopause/ (52274)
5 ((adult* or citizen* or individual* or people or person* or resident*) adj1 (older* or senior*)).tw,kw. (110127)
6 community dwelling*.tw,kw. (21897)
7 elderly*.tw,kw. (240734)

8 frail*.tw,kw. (21432)
9 ((post-menopausal or postmenopausal) adj women).tw,kw. (43568)
10 or/1-9 [Combined Emtree terms & text words for older adults] (2272375)
11 agents used intravaginally/ (201)
12 exp colloid/ (21038)
13 drug administration route/ (6715)
14 drug capsule/ (7574)
15 drug delivery device/ (1970)
16 drug delivery system/ (97321)
17 drug dosage form/ (12029)
18 drug packaging/ (7520)
19 ear drops/ (477)
20 eye drops/ (8813)
21 exp inhalation drug administration/ (12644)
22 exp inhaler/ (12662)
23 exp nebulizer/ (7811)
24 microcapsule/ (6662)
25 nose drops/ (352)
26 nose spray/ (2287)
27 exp ointment/ (7186)
28 oral drug administration/ (75649)
29 pill/ (6800)
30 self injection/ (1293)
31 subcutaneous drug administration/ (24028)
32 suppository/ (2405)
33 exp tablet/ (29532)
34 exp topical drug administration/ (34804)
35 ((administ* or appl* or cream* or drop* or gel* or lotion* or inject* or insert* or spray*) adj2 (aural* or buccal* or cutaneous* or dermal* or ear* or eye* or inhal* or intramuscular* or intravaginal* or intraocular* or muscular* or mucosal* or nasal* or nose or ophthalm* or oral* or otic* or parenteral* or rectal* or sublingual* or subcutaneous* or topical* or transdermal* or vagina*)).tw,kw. (219588)
36 (auto-inject* or autoinject* or self-inject* or selfinject*).tw,kw. (3243)
37 blister pack*.tw,kw. (418)
38 ((bottl* or box* or container* or pack*) adj2 (drug or medicat* or medicine* or pharma*)).tw,kw. (2401)
39 ((bottl* or container* or pack*) adj2 (child resist* or tamper*)).tw,kw. (127)
40 ((cap* or packag*) adj1 safe*).tw,kw. (297)
41 capsule*.tw,kw. (69254)
42 calendar pack*.tw,kw. (15)
43 dosette*.tw,kw. (34)
44 emulsion*.tw,kw. (27213)
45 inhaler*.tw,kw. (10875)
46 lozenge*.tw,kw. (1006)
47 nebuli#er*.tw,kw. (5039)
48 (ointment* or unguent*).tw,kw. (9388)
49 (pill or pills).tw,kw. (20092)
50 spacer*.tw,kw. (27125)
51 suppositor*.tw,kw. (2832)
52 tablet*.tw,kw. (57698)
53 vapori#er*.tw,kw. (1034)
54 or/11-53 [Combined Emtree terms & text words for drug administration routes or packaging] (661971)
55 drug self administration/ (9253)
56 medication compliance/ (20288)
57 medication error/ (14626)
58 motor performance/ (55713)

59 *patient compliance/ (15344)
60 psychomotor performance/ (15630)
61 *self care/ (12101)
62 treatment refusal/ (13383)
63 ((able* or abilit* or capab* or capacit* or inabilit* or incapab* or incapacit* or inabilit* or unable*) adj2 physical*).tw,kw. (6806)
64 ((accident* or uninten*) adj2 (over dos* or overdos*)).tw,kw. (962)
65 ((adher* or nonadher* or complian* or comply or noncompl*) adj3 (drug* or medicine* or medication* or pharmaceutical* or prescription*)).tw,kw. (30844)
66 ((challeng* or difficult* or problem*) adj2 (experience* or opening* or using* or utili*)).tw,kw. (27619)
67 ((correct* or error* or improper* or incorrect* or proper*) adj2 (method* or technique* or use*)).tw,kw. (50600)
68 ((dose* or dosing* or drug* or medicine* or medication* or pharmaceutical*) adj2 (error* or incorrect* or mistak*)).tw,kw. (11424)
69 ((drug* or medicine* or medication* or pharmaceutical* or prescription*) adj3 misus*).tw,kw. (3648)
70 ((lack* or insufficie*) adj2 (motor skill* or strength*)).tw,kw. (429)
71 usabilit*.tw,kw. (10890)
72 or/55-71 [Combined Emtree terms & text words for administration problems] (270860)
73 and/10,54,72 [Combined concepts for older adults, drug routes & administration problems] (2708)
74 (Alzheimer* or ((cogniti* or mental* or neuro*) adj2 (declin* or deteriorat* or dysfunction* or impair*)) or ((deficit* or disorder* or loss*) adj2 memor*) or dement*).ti. (140934)
75 73 not 74 [Exclude studies about dementia] (2657)
76 exp juvenile/ not exp adult/ (1281411)
77 (child* or p?ediatric*).ti. (673780)
78 75 not (76 or 77) [Exclude pediatric studies] (2639)
79 exp Animal/ not Human/ (2567969)
80 (animal model* or bovine or canine or capra or cat or cats or cattle or cow or cows or dog or dogs or equine or ewe or ewes or feline or goat or goats or horse or hamster* or horses or invertebrate or invertebrates or macaque or macaques or mare or mares or mice or monkey or monkeys or mouse or murine or nonhuman or non-human or ovine or pig or pigs or porcine or primate or primates or rabbit or rabbits or rat or rats or rattus or rhesus or rodent* or sheep or simian or sow or sows or vertebrate or vertebrates or zebrafish).ti. (1308269)
81 78 not (79 or 80) [Exclude animal studies] (2605)
82 limit 81 to yr="2000-Current" (2342)
83 remove duplicates from 82 (2293)

Database: CINAHL Plus with Full Text via EBSCOhost
Date conducted: Jan 16, 2018
Strategy:

#	Query	Limiters/Expanders	Results
S1	(MH "Age Factors")	Search modes - Find all my search terms	96,082
S2	(MH "Aged+")	Search modes - Find all my search terms	637,487
S3	(MH "Aging")	Search modes - Find all my search terms	38,457
S4	(MH "Geriatric Assessment+")	Search modes - Find all my search terms	13,620
S5	TI((adult* or citizen* or individual* or people or person* or resident*) N1 (older* or senior*)) or AB((adult* or citizen* or individual* or people or person* or resident*) N1 (older* or senior*))	Search modes - Find all my search terms	62,445
S6	TI("community dwelling*") or AB("community dwelling*")	Search modes - Find all my search terms	10,588

S7	TI(elderly*) or AB(elderly*)	Search modes - Find all my search terms	67,936
S8	TI(frail*) or AB(frail*)	Search modes - Find all my search terms	7,710
S9	TI(("post-menopausal" or postmenopausal) N1 women) or AB(("post-menopausal" or postmenopausal) N1 women)	Search modes - Find all my search terms	9,515
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9	Search modes - Find all my search terms	745,173
S11	(MH "Administration, Inhalation")	Search modes - Find all my search terms	5,709
S12	(MH "Administration, Intraocular")	Search modes - Find all my search terms	247
S13	(MH "Administration, Oral+")	Search modes - Find all my search terms	15,736
S14	(MH "Administration, Topical+")	Search modes - Find all my search terms	12,317
S15	(MH "Capsules")	Search modes - Find all my search terms	683
S16	(MH "Colloids+")	Search modes - Find all my search terms	14,310
S17	(MH "Creams")	Search modes - Find all my search terms	1,930
S18	(MH "Dosage Forms")	Search modes - Find all my search terms	1,895
S19	(MH "Drug Administration Routes")	Search modes - Find all my search terms	949
S20	(MH "Drug Delivery Systems")	Search modes - Find all my search terms	4,602
S21	(MH "Drug Packaging")	Search modes - Find all my search terms	1,009
S22	(MH "Injections, Intramuscular")	Search modes - Find all my search terms	3,225
S23	(MH "Injections, Subcutaneous+")	Search modes - Find all my search terms	3,356
S24	(MH "Nebulizers and Vaporizers")	Search modes - Find all my search terms	3,979
S25	(MH "Ointments")	Search modes - Find all my search terms	1,362
S26	(MH "Suppositories")	Search modes - Find all my search terms	314
S27	(MH "Tablets")	Search modes - Find all my search terms	1,146
S28	(MH "Technology, Pharmaceutical")	Search modes - Find all my search terms	716
S29	(MH "Vaginal Creams, Foams and Jellies")	Search modes - Find all my search terms	314
S30	TI((administ* or appl* or cream* or drop* or gel* or lotion* or inject* or insert* or spray*) N2 (aural* or buccal* or cutaneous* or dermal* or ear* or eye* or inhal* or intramuscular* or intravaginal* or intraocular* or muscular* or mucosal* or nasal* or nose or ophthalm* or oral* or otic* or parenteral* or rectal* or sublingual* or subcutaneous* or topical* or transdermal* or vagina*)) or AB((administ* or appl* or cream* or drop* or gel* or lotion* or inject* or insert* or spray*) N2 (aural* or buccal* or cutaneous* or dermal* or ear* or eye* or inhal* or intramuscular* or intravaginal* or intraocular* or muscular* or mucosal* or nasal* or nose or ophthalm* or oral* or otic* or parenteral* or rectal* or sublingual* or subcutaneous* or topical* or transdermal* or vagina*))	Search modes - Find all my search terms	23,552

S31	TI("auto-inject*" or autoinject* or "self-inject*" or selfinject*) or AB("auto-inject*" or autoinject* or "self-inject*" or selfinject*)	Search modes - Find all my search terms	510
S32	TI("blister pack*") or AB("blister pack*")	Search modes - Find all my search terms	50
S33	TI((bottl* or box* or container* or pack*) N2 (drug or medicat* or medicine* or pharma*)) or AB((bottl* or box* or container* or pack*) N2 (drug or medicat* or medicine* or pharma*))	Search modes - Find all my search terms	631
S34	TI((bottl* or container* or pack*) N2 ("child resist*" or tamper*)) or AB((bottl* or container* or pack*) N2 ("child resist*" or tamper*))	Search modes - Find all my search terms	50
S35	TI((cap* or packag*) N1 safe*) or AB((cap* or packag*) N1 safe*)	Search modes - Find all my search terms	240
S36	TI(capsule*) or AB(capsule*)	Search modes - Find all my search terms	7,688
S37	TI("calendar pack*") or AB("calendar pack*")	Search modes - Find all my search terms	6
S38	TI(dosette*) or AB(dosette*)	Search modes - Find all my search terms	6
S39	TI(emulsion*) or AB(emulsion*)	Search modes - Find all my search terms	1,372
S40	TI(inhaler*) or AB(inhaler*)	Search modes - Find all my search terms	2,195
S41	TI(lozenge*) or AB(lozenge*)	Search modes - Find all my search terms	280
S42	TI(nebuliser* or nebulizer*) or AB(nebuliser* or nebulizer*)	Search modes - Find all my search terms	770
S43	TI(ointment* or unguent*) or AB(ointment* or unguent*)	Search modes - Find all my search terms	1,165
S44	TI(pill or pills) or AB(pill or pills)	Search modes - Find all my search terms	5,738
S45	TI(spacer*) or AB(spacer*)	Search modes - Find all my search terms	1,216
S46	TI(suppositor*) or AB(suppositor*)	Search modes - Find all my search terms	389
S47	TI(tablet*) or AB(tablet*)	Search modes - Find all my search terms	6,351
S48	TI(vaporiser* or vaporizer*) or AB(vaporiser* or vaporizer*)	Search modes - Find all my search terms	260
S49	S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48	Search modes - Find all my search terms	101,344
S50	(MH "Medication Compliance")	Search modes - Find all my search terms	14,517
S51	(MH "Medication Errors")	Search modes - Find all my search terms	11,572
S52	(MH "Motor Skills+")	Search modes - Find all my search terms	7,994
S53	(MM "Patient Compliance")	Search modes - Find all my search terms	11,088
S54	(MH "Psychomotor Performance")	Search modes - Find all my search terms	9,805
S55	(MH "Self Administration")	Search modes - Find all my search terms	2,641

S56	(MH "Self Care")	Search modes - Find all my search terms	29,384
S57	(MH "Treatment Refusal")	Search modes - Find all my search terms	4,303
S58	TI((able* or abilit* or capab* or capacit* or inabilit* or incapab* or incapacit* or inabilit* or unable*) N2 physical*) or AB((able* or abilit* or capab* or capacit* or inabilit* or incapab* or incapacit* or inabilit* or unable*) N2 physical*)	Search modes - Find all my search terms	2,751
S59	TI((accident* or uninten*) N2 ("over dos*" or overdos*)) or AB((accident* or uninten*) N2 ("over dos*" or overdos*))	Search modes - Find all my search terms	317
S60	TI((adher* or nonadher* or complian* or comply or noncompl*) N3 (drug* or medicine* or medication* or pharmaceutical* or prescription*)) or AB((adher* or nonadher* or complian* or comply or noncompl*) N3 (drug* or medicine* or medication* or pharmaceutical* or prescription*))	Search modes - Find all my search terms	9,234
S61	TI((challeng* or difficult* or problem*) N2 (experience* or opening* or using* or utili*)) or AB((challeng* or difficult* or problem*) N2 (experience* or opening* or using* or utili*))	Search modes - Find all my search terms	12,062
S62	TI((correct* or error* or improper* or incorrect* or proper*) N2 (method* or technique* or use*)) or AB((correct* or error* or improper* or incorrect* or proper*) N2 (method* or technique* or use*))	Search modes - Find all my search terms	10,572
S63	TI((dose* or dosing* or drug* or medicine* or medication* or pharmaceutical*) N2 (error* or incorrect* or mistak*)) or AB((dose* or dosing* or drug* or medicine* or medication* or pharmaceutical*) N2 (error* or incorrect* or mistak*))	Search modes - Find all my search terms	5,445
S64	TI((drug* or medicine* or medication* or pharmaceutical* or prescription*) N3 misus*) or AB((drug* or medicine* or medication* or pharmaceutical* or prescription*) N3 misus*)	Search modes - Find all my search terms	1,563
S65	TI((lack* or insufficie*) N2 ("motor skill*" or strength*)) or AB((lack* or insufficie*) N2 ("motor skill*" or strength*))	Search modes - Find all my search terms	156
S66	TI(usabilit*) or AB(usabilit*)	Search modes - Find all my search terms	3,558
S67	S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66	Search modes - Find all my search terms	121,131
S68	S10 AND S49 AND S67	Search modes - Find all my search terms	1,246
S69	TI(Alzheimer* or ((cogniti* or mental* or neuro*) N2 (declin* or deteriorat* or dysfunction* or impair*)) or ((deficit* or disorder* or loss*) N2 memor*) or dement*)	Search modes - Find all my search terms	48,555
S70	S68 NOT S69	Search modes - Find all my search terms	1,222
S71	(MH "Child+") NOT (MH "Adult+")	Search modes - Find all my search terms	388,090
S72	TI(child* or paediatric* or pediatric*)	Search modes - Find all my search terms	266,795

S73	S71 OR S72	Search modes - Find all my search terms	486,902
S74	S70 NOT S73	Search modes - Find all my search terms	1,189
S75	(MH "Animals+") NOT (MH "Human")	Search modes - Find all my search terms	73,057
S76	TI("animal model*" or bovine or canine or capra or cat or cats or cattle or cow or cows or dog or dogs or equine or ewe or ewes or feline or goat or goats or horse or hamster* or horses or invertebrate or invertebrates or macaque or macaques or mare or mares or mice or monkey or monkeys or mouse or murine or nonhuman or "non-human" or ovine or pig or pigs or porcine or primate or primates or rabbit or rabbits or rat or rats or rattus or rhesus or rodent* or sheep or simian or sow or sows or vertebrate or vertebrates or zebrafish)	Search modes - Find all my search terms	71,106
S77	S75 OR S76	Search modes - Find all my search terms	126,081
S78	S74 NOT S77	Search modes - Find all my search terms	1,182
S79	S74 NOT S77	Limiters - Published Date: 20000101-20181231 Search modes - Find all my search terms	1,088

Database: Ovid PsycINFO 1987 to January Week 3 2018
Date conducted: Jan 19, 2018
Strategy:
1 exp Aging/ (50649)
2 Geriatric Assessment/ (913)
3 Geriatrics/ (9078)
4 Gerontology/ (7981)
5 ((adult* or citizen* or individual* or people or person* or resident*) adj1 (older* or senior*)).ti,ab. (54251)
6 community dwelling*.ti,ab. (8005)
7 elderly*.ti,ab. (47137)
8 frail*.ti,ab. (3761)
9 ((post-menopausal or postmenopausal) adj women).ti,ab. (1855)
10 or/1-9 [Combined index terms & text words for older adults] (123691)
11 Drug Administration Methods/ (3837)
12 Drug Dosage/ (7433)
13 Drug Self Administration/ (1950)
14 Injections/ (2946)
15 Intramuscular Injections/ (217)
16 Prescription Drugs/ (3707)
17 Subcutaneous injections/ (184)
18 ((administ* or appl* or cream* or drop* or gel* or lotion* or inject* or insert* or spray*) adj2 (aural* or buccal* or cutaneous* or dermal* or ear* or eye* or inhal* or intramuscular* or intravaginal* or intraocular* or muscular* or mucosal* or nasal* or nose or ophthalm* or oral* or otic* or parenteral* or rectal* or sublingual* or subcutaneous* or topical* or transdermal* or vagina*)).ti,ab. (9288)
19 (auto-inject* or autoinject* or self-inject* or selfinject*).ti,ab. (176)
20 blister pack*.ti,ab. (8)
21 ((bottl* or box* or container* or pack*) adj2 (drug or medicat* or medicine* or pharma*)).ti,ab. (166)
22 ((bottl* or container* or pack*) adj2 (child resist* or tamper*)).ti,ab. (12)
23 ((cap* or packag*) adj1 safe*).ti,ab. (40)
24 capsule*.ti,ab. (2562)
25 calendar pack*.ti,ab. (0)

26 dosette*.ti,ab. (3)
27 emulsion*.ti,ab. (189)
28 inhaler*.ti,ab. (314)
29 lozenge*.ti,ab. (161)
30 nebuli#er*.ti,ab. (35)
31 (ointment* or unguent*).ti,ab. (80)
32 (pill or pills).ti,ab. (2860)
33 spacer*.ti,ab. (48)
34 suppositor*.ti,ab. (92)
35 tablet*.ti,ab. (3492)
36 vapori#er*.ti,ab. (40)
37 or/11-36 [Combined index terms & text words for drug administration routes or packaging] (36560)
38 Error of Measurement/ (1270)
39 Errors/ (7618)
40 Motor Control/ (1052)
41 Motor Coordination/ (4072)
42 Motor Performance/ (6080)
43 Motor Skills/ (3205)
44 Self-Care Skills/ (3494)
45 Treatment Barriers/ (3927)
46 Treatment Compliance/ (12698)
47 Treatment Refusal/ (706)
48 ((able* or abilit* or capab* or capacit* or inabilit* or incapab* or incapacit* or inabilit* or unable*) adj2 physical*).ti,ab. (1850)
49 ((accident* or uninten*) adj2 (over dos* or overdos*)).ti,ab. (191)
50 ((challeng* or difficult* or problem*) adj2 (experience* or opening* or using* or utili*)).ti,ab. (16531)
51 ((correct* or error* or improper* or incorrect* or proper*) adj2 (method* or technique* or use*)).ti,ab. (6184)
52 ((dose* or dosing* or drug* or medicine* or medication* or pharmaceutical*) adj2 (error* or incorrect* or mistak*)).ti,ab. (719)
53 ((drug* or medicine* or medication* or pharmaceutical* or prescription*) adj3 misus*).ti,ab. (2099)
54 ((lack* or insufficie*) adj2 (motor skill* or strength*)).ti,ab. (77)
55 usabilit*.ti,ab. (4194)
56 or/38-55 [Combined index terms & text words for administration problems] (72838)
57 and/10,37,56 [Combined concepts for older adults, drug routes & administration problems] (172)
58 (Alzheimer* or ((cogniti* or mental* or neuro*) adj2 (declin* or deteriorat* or dysfunction* or impair*)) or ((deficit* or disorder* or loss*) adj2 memor*) or dement*).ti. (62548)
59 57 not 58 [Exclude studies about dementia] (162)
60 (child* or p?ediatric*).ti. (238229)
61 59 not 60 [Exclude pediatric studies] (161)
62 limit 61 to yr="2000-Current" (125)
63 remove duplicates from 62 (125)

Other Source: Conference Proceedings Citation Index – Science (CPCI-S) & Conference Proceedings Citation Index – Social Science & Humanities (CPCI-SSH) Indexes
Platform: Clarivate Analytics
Date conducted: Jan 19, 2018
Strategy:

# 8	**51**	#6 NOT #7 *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*
# 7	**88,465**	TI=(child* OR paediatric* OR pediatric*) *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*
# 6	**56**	#4 NOT #5 *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*

# 5	21,647	TI=(Alzheimer* OR ((cogniti* OR mental* OR neuro*) NEAR/2 (declin* OR deteriorat* OR dysfunction* OR impair*)) OR ((deficit* OR disorder* OR loss*) NEAR/2 memor*) OR dement*) *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*
# 4	58	#1 AND #2 AND #3 *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*
# 3	97,006	TS=(((able* OR abilit* OR capab* OR capacit* OR inabilit* OR incapab* OR incapacit* OR inabilit* OR unable*) NEAR/2 physical*) OR ((accident* OR uninten*) NEAR/2 ("over dos*" OR overdos*)) OR ((adher* OR nonadher* OR complian* OR comply OR noncompl*) NEAR/3 (drug* OR medicine* OR medication* OR pharmaceutical* OR prescription*)) OR ((challeng* OR difficult* OR problem*) NEAR/2 (experience* OR opening* OR using* OR utili*)) OR ((correct* OR error* OR improper* OR incorrect* OR proper*) NEAR/2 (method* OR technique* OR use*)) OR ((dose* OR dosing* OR drug* OR medicine* OR medication* OR pharmaceutical*) NEAR/2 (error* OR incorrect* OR mistak*)) OR ((drug* OR medicine* OR medication* OR pharmaceutical* OR prescription*) NEAR/3 misus*) OR ((lack* OR insufficie*) NEAR/2 ("motor skill*" OR strength*)) OR usabilit*) *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*
# 2	38,678	TS=(((administ* OR appl* OR cream* OR drop* OR gel* OR lotion* OR inject* OR insert* OR spray*) NEAR/2 (aural* OR buccal* OR cutaneous* OR dermal* OR ear* OR eye* OR inhal* OR intramuscular* OR intravaginal* OR intraocular* OR muscular* OR mucosal* OR nasal* OR nose OR ophthalm* OR oral* OR otic* OR parenteral* OR rectal* OR sublingual* OR subcutaneous* OR topical* OR transdermal* OR vagina*)) OR auto-inject* OR autoinject* OR self-inject* OR selfinject* OR "blister pack*" OR ((bottl* OR box* OR container* OR pack*) NEAR/2 (drug OR medicat* OR medicine* OR pharma*)) OR ((bottl* OR container* OR pack*) NEAR/2 ("child resist*" OR tamper*)) OR ((cap* OR packag*) NEAR/1 safe*) OR capsule* OR "calendar pack*" OR dosette* OR emulsion* OR inhaler* OR lozenge* OR nebuliser* OR nebulizer* OR ointment* OR unguent* OR pill OR pills OR spacer* OR suppositor* OR vaporiser* OR vaporizer*) *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*
# 1	208,040	TS=(aged OR aging OR geriatric OR ((adult* OR citizen* OR individual* OR people OR person* OR resident*) NEAR/1 (older* OR senior*)) OR "community dwelling" OR elderly OR frail* OR ((post-menopausal OR postmenopausal) NEAR/1 women)) *Indexes=CPCI-S, CPCI-SSH Timespan=2000-2018*

Other Source: ProQuest Dissertations & Theses Global (1861 to present)
Platform: ProQuest
Date conducted: Jan 22, 2018
Strategy:
ab(aging OR geriatric OR ((adult* OR citizen* OR people OR person* OR resident*) NEAR/1 (older* OR senior*)) OR elderly OR frail*) AND ab(((administ* OR appl* OR drop* OR inject* OR insert*) NEAR/2 (cutaneous* OR ear OR eye* OR intramuscular* OR intraocular* OR muscular* OR nasal* OR oral* OR parenteral* OR rectal* OR sublingual* OR subcutaneous* OR topical* OR vagina*)) OR "auto inject*" OR autoinject* OR "self inject*" OR ((bottl* OR container* OR pack*) NEAR/2 ("child resist*" OR drug OR medicat* OR medicine* OR pharma* OR tamper*)) OR ((cap* OR packag*) NEAR/1 safe*) OR capsule* OR inhaler* OR nebuliser* OR nebulizer* OR ointment* OR pill OR pills OR spacer* OR suppositor* OR vaporiser* OR vaporizer*) AND ab(((abilit* OR capacit* OR inabilit*) NEAR/2 physical*) OR ((accident* OR uninten*) NEAR/2 overdos*) OR ((adher* OR nonadher* OR complian* OR noncompl*) NEAR/3 (drug* OR medication* OR prescription*)) OR ((challeng* OR difficult* OR problem*) NEAR/2 (experienc* OR opening* OR using*)) OR ((improper* OR incorrect*) NEAR/2 (method* OR technique*)) OR ((dose* OR dosing* OR drug* OR medication* OR prescription*) NEAR/2 (error* OR incorrect* OR mistak* OR misus*)) OR ((lack* OR insufficie*) NEAR/2 ("motor skill*" OR strength*))) (12) Limits: 2000-2018

Appendix C: Rheumatology protocol

Functional Medication Management in Rheumatology Patients at Kaye Edmonton Rheumatology Clinic Questionnaire

SCIENTIFIC ABSTRACT

Background: Managing a medication regimen may be challenging for individuals with inflammatory arthritis (IA) because of limitations related to administering the medication, comprehending written or verbal directions, handling the dosages or adjustments, and/or physically taking the medications managing/monitoring the therapy. The concept of functional medication management (FMM) has been described as the processes involved in using medications which includes obtaining, preparing, administering, and monitoring the medication. FMM is reported to be poorly documented in acute care older patients. A screen of local practices in rheumatology in Edmonton indicates that assessment of FMM is not routinely being conducted for IA patients. A number of challenges need to be acknowledged when a patient takes medication, such as difficulties opening packaging, administering injections, or following the sequencing for taking multiple medications.

Functional impairment associated with IA can lead to difficulties with medication management, which can be attributed to several factors such as physical deficits, cognitive, or sensory (e.g. visual) changes. Because of the physical and sensory limitations that are seen with IA and associated comorbidities, individuals are predisposed to incorrectly managing their medications and subsequent non-adherence. Although medicinal products such as oral tablets or capsules may be straightforward (such as an analgesic or antihypertensive medication), an assortment of devices used, such as pill splitters, inhalers, dosettes or blister packages, injections, patches, glucose meters may be problematic. Not only is the physical management of the medications challenging, but the regimen complexity and underlying functional impairments of IA may lead to frustration and poor adherence of medications

Methods: This project will involve sampling a convenience sample of 100 patients attending a local rheumatology clinic, [Kaye Edmonton Rheumatology Clinic]. Patients who agree to participate and provide written consent will be given a questionnaire including demographic, medical, medication, and functional questions.

PROPOSED PROJECT

Objectives:

1) To describe the types of functional medication management problems rheumatology patients experience.

Rationale

- Patients with arthritis use medications for management of rheumatologic diagnoses as well as other comorbidities or self-care.
- Medications may be packaged with restrictive access or may require numerous steps with significant dexterity and fine motor skills (e.g. inhalers, eye drops, injections).

- Patients with rheumatologic conditions may experience functional limitations to properly use these medications.
- Further research is required to describe the breadth of functional medication management and to create a tool to help clinicians assess this in practice.

BACKGROUND:

Medication management is challenging for individuals with various forms of arthritis, including inflammatory arthritis (IA) because of limitation of handling the medication, reading the dosage or monitoring the therapy. A number of challenges need to be acknowledged when a patient takes their medication, such as difficulties opening packaging, administering injections, or following the sequencing for multiple medications. When managing chronic scheduled medication, poor adherence or improper administration may be problematic. The concept of functional medication management (FMM) has been described as the processes involved in using medications which includes obtaining, preparing, administering, and monitoring the medication. FMM is reported to be poorly documented in acute care older patients [Bolina 2016]. The principles of FMM apply not only to older adults, but to anyone who may be at risk of functional impairment. A screen of local practices in rheumatology in Edmonton indicate that assessment of FMM is not being conducted for IA patients.

The population with IA is made up mostly with patients who are diagnosed with rheumatoid arthritis (RA), which is up to 1% of the population [Helmick 2008, Lawrence 2008]. In 2016, 350 newly diagnosed and over 2000 follow-up patients from Edmonton and northern Alberta were seen by 10 rheumatologists in Edmonton. (Northern Alberta Retreat Presentation February 2017 Personal Correspondence). IA poses a significant burden on individuals [vanOnna 2016] and contributes to the development of a number of comorbidities, including cardiovascular, ophthalmic, psychiatric, musculoskeletal, infectious, and gastrointestinal complications [Bruce 2008, Dougados 2016, Charles-Schoeman 2012, Myasoedova 2010, Artifoni 2014, Gullick 2011, Ramos-Remus 2012]. The average patient with rheumatoid arthritis (RA) has 2 or more comorbidities [Michaud 2007]. These comorbidities often require treatment with oral medications or other devices (e.g. eye drops), leading to increased medication complexity and functional demand. The impact on functional ability is substantial, including pain, numbness, and hand dexterity [Ramos-Remus 2012, Scott 2007]. Underlying joint pain and deformity, visual deficits, or cognitive processes can impact the management of medication for IA.

Canadian Guidelines for IA include recommendations for early management with pharmacologic intervention to prevent disease progression, complications, and to improve patient function and quality of life [Bykerk 2012]. IA impacts not only joints, but internal organs, and can have debilitating complications leading to disability [Bykerk 2012]. Medications are used throughout the lifespan of a patient with IA. Some of these medications are complex medication devices and require significant effort for administration and monitoring. Surprisingly, little information is written about the management of medications, despite their complexity. The research related to concerns about medications in IA patients focuses on safety/adverse events rather than management or functional ability [Makol 2012]. More recent evidence has purported functional aspects of medication may play a role in self-discontinuation, poor adherence, or poor management [Betegnie 2016].

Patients prioritize disability and function in terms of their expectations for care of IA through the health care system [Hulen 2016]. Functional impairment can lead to difficulties with medication management for the patient, which can be attributed to several factors such as physical deficits, cognitive, or sensory (e.g. visual) changes. Because of the physical and sensory limitations that are seen with IA and associated comorbidities, management of medications and subsequent adherence may be affected [Betegnie 2016]. Although the medicinal products may be straightforward, oral tablets or capsules (for example a pain medicine or antihypertensive agent), an assortment of devices used, such as pill splitters, inhalers, dosettes or blister packages, injections, patches, glucose meters may be problematic. Not only is the physical management of the medications challenging, but the regimen complexity and underlying functional impairments from the IA may lead to poorer functional medication management.

Underlying joint pain and deformity, visual deficits and limitations can impact the management of medication for IA. Our overarching goal is to optimize patient adherence to medication management of IA. This project builds upon earlier work in older adults in which we found that functional management of medications in acute care was not routinely recorded and no comprehensive evaluation was performed [Bolina 2016]. We feel that addressing this issue in individuals with IA is essential because adherence has been found to be low, but many studies focused on factors (e.g. literacy, carelessness) that did not include functional management of the medications [Quinlan 2013, Betegnie 2016]. While patients may intend to appropriately use a medication, the challenge of the delivery, packaging, or accessibility may play a role. Unfortunately, not being adherent to medication is associated with greater disease activity [Pasma 2015]. Persistence with DMARD medication in RA patients has been found to range from 30% to over 90%, due to a variety of factors [Blum 2011, van den Bemt 2012]. Beliefs about the medication and characteristics of the medication can impact adherence to treatment [Brandstetter 2016, Vangeli 2015]. Having a co-morbidity was also found to increase the risk of-treatment discontinuation and non-adherence [Chu 2015, Lopez-Gonzalez 2015]. This supports further work to investigate functional aspects of managing medications, impacting adherence.

The Guidelines focus on the breadth of patient care, from initial assessment, diagnosis, and ongoing management of both non-pharmacologic and pharmacologic strategies [Bykerk 2012]. A review of models of care has emphasized an interprofessional team-based approach to care for rheumatology patients [Speerin 2014]. This supports an approach to engage many team members, in clinic and in the community (e.g. pharmacists), in assessing activities relating to functional management of medications. The first point of contact for many IA patients is in the community pharmacy, where anti-inflammatory medications may be purchased. Patients view their information sources broadly, including the internet and support groups, but still rely primarily on health professionals, specifically doctors, pharmacists, and nurses [Quinlan 2013]. Within Alberta there is a provincial pharmacy services framework that reimburses pharmacists for an annual medication review and care plan. There is not a specific checklist or tool that pharmacists are required to use. However, a recent consensus statement includes several recommendations regarding comorbidities and management, including specific recommendations related to documenting medication and assessing polypharmacy [Loza 2015].

This project builds upon earlier work in older adults in which we found that functional management of medication in acute care was not routinely recorded and no comprehensive evaluation was performed [Bolina 2016]. It also builds on our recently completed scoping review [Abed 2019]. The scoping review aimed at identifying: 1. What types of functional difficulties

are described in the literature? 2. What assessment tools are available to measure functional medication management in older adults? 3. What areas of functional medication management are assessed by these tools? The scoping review found that there are several assessment tools described in the literature that aim at measuring the capacity of older adults to manage their medications at home, however, deficiencies in the assessment tools exist. As a consequence, none of the tools is currently being utilized in clinical practice. We feel that addressing this issue in individuals with IA is essential because medications are often given in more complex dosage formats (e.g. injections versus oral products), and adherence is a challenge for this population and the functional limitations associated with IA.

METHODS

Study design: A cross-sectional survey of 100 Patients attending the University of Alberta rheumatology outpatient clinic [Kaye Edmonton Rheumatology Clinic, Monday – Friday, from 08:00 – 16:00].

Inclusion: age 18 or older, able to communicate and read English, consenting

Questionnaire: The survey for people with IA will include experience with rheumatologic conditions (e.g. type, duration, diagnosis), and experiences and challenges with functional management of medications. The questionnaire we built contains 34 questions asking about demographics, medical history, medication assistance and medication management challenges. The questions design is a combination of multiple choice questions and checklists questions. Some of the questions were derived from the existing assessment tools found in the scoping review and modified accordingly and some questions were created by the research team.

Process: Patients will be asked to consent by the unit clerk at registration for their clinic appointments. Posters/notices will be given to patients when they register and informed by the unit clerk to see the research assistant if they would like to complete the survey while waiting for their appointment. Those subjects interested in participating will be directed to the location in the clinic where the research assistant (HA) will be available. The research assistant (HA) will ask if they would like to participate in a survey, by providing them with an information letter / consent form and answering any questions they may have. Upon written consent, the RA will then give the participant the survey and pen..

Should the participant have questions or require assistance completing the survey, the RA will be able to provide assistance. Upon completion of the survey, the participants will hand the survey back to the RA.

Analysis and Data: Data will be taken from the hard copy surveys and entered into an Excel database. Analysis will be descriptive. Cross tabs will be determined to look at explanatory variables as to who has difficulty and who does not.

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Appendix D: Rheumatology survey

Functional Medication Management in Rheumatology Patients at Kaye Edmonton Rheumatology Clinic Questionnaire

Stage 1-Demographics

1. Date of birth: ☐☐☐ ☐☐ ☐☐☐☐
   MM DD YYYY
2. Sex: ☐ Female ☐ Male ☐ Other

3. What is the highest level of education you have completed? (Select one only)
   ☐ Did not complete high school ☐ Completed high school
   ☐ College ☐ Apprenticeship ☐ University

4. What is your marital status?
   ☐ Married/Common-Law ☐ Divorced/Separated/Widowed ☐ Never married

5. What is your living arrangement?
   ☐ In own residence (e.g. Apartment/condo/duplex/home)
   ☐ In a supported living residence (e.g. Assisted living/Institution/Nursing home)

Stage 2 - Medical history

6. Do you have any of the following rheumatology conditions?
   ☐ Rheumatoid arthritis
   ☐ Osteoarthritis
   ☐ Psoriatic arthritis
   ☐ Systemic lupus erythematosus
   ☐ Gout
   ☐ Vasculitis
   ☐ Others, please specify _____

7. Do you have any of the following medical conditions that may interfere with medication management? (Check all that apply)

Nervous system conditions:
☐ Epilepsy (Seizure)
☐ Stroke
☐ Parkinson disease
☐ Alzheimer's disease
☐ Multiple sclerosis
☐ Essential tremor
☐ Others, please specify: _____

Eye conditions:
☐ Cataracts
☐ Glaucoma
☐ Dry eyes

Lung Conditions:
☐ Asthma
☐ COPD

Mental conditions:
☐ Anxiety
☐ Depression

8. Do you take any **prescription medications?**
   ☐ Yes ☐ No, if no go to question 10

9. If you take **prescription medications**, how many do you take?
   ☐ Less than 5 ☐ 5 or more

10. Do you take any **over the counter/non-prescription medications?**
    ☐Yes ☐No

11. Do you use any **herbal or natural health products**?
    ☐Yes ☐No

Stage 3- Medication assistance

12. Do you receive **assistance** with your medications?
    ☐ Yes, if yes go to question 14 ☐ No

13. If you do not receive assistance, do you **feel that you need assistance** with your medications?
    ☐ Yes ☐ No

14. If you receive assistance with your medications, who provides the assistance?
    ☐ Informal caregiver (partner/family member/friends)
    ☐ Formal caregiver (nurse/paid caregiver)
    ☐ Both formal and informal caregivers

15. If you receive assistance with your medications, what types of assistance is it? (Check all that apply)
    ☐ Ordering medication from a pharmacy
    ☐ Picking up medication from a pharmacy
    ☐ Organizing medication in a pillbox
    ☐ Reading prescription and warning labels
    ☐ Reminding you to take medications at proper times
    ☐ Opening packaging such as vials or blister packs
    ☐ Preparing medication (e.g. shaking an inhaler, drawing up an injection)
    ☐ Taking the medication (e.g. placing pill in the mouth, instilling eye drops, placing a topical patch, self-injecting)
    ☐ Observing the effects of medication (e.g. checking blood sugar or blood pressure)

Stage 4-Medication management challenges

16. Is it easy for you to remember **medication names?**

☐ Yes ☐ No

17. Is it easy for you to remember the **time to take your medications?**
☐ Yes ☐ No

18. Is it easy for you to remember the **purpose for taking your medication?**
☐ Yes ☐ No

19. Do you have difficulties **reading** any of the following: prescription labels, warning labels, information sheets?
☐ Yes ☐ No

20. Do you have difficulties **understanding prescription labels?**
☐ Yes ☐ No

21. Do you take any **medications by mouth?**
☐ Yes ☐ No, if no go to question 24

22. If you take oral medications, have you ever experienced difficulties with any of the following? (Check all that apply)

Opening safety cap vials	☐ Yes	☐ No	☐ Not applicable
Opening non-safety cap vials	☐ Yes	☐ No	☐ Not applicable
Opening blister packs	☐ Yes	☐ No	☐ Not applicable
Opening pill boxes	☐ Yes	☐ No	☐ Not applicable
Opening tablet blisters	☐ Yes	☐ No	☐ Not applicable
Breaking tablets into smaller doses	☐ Yes	☐ No	☐ Not applicable
Crushing tablets	☐ Yes	☐ No	☐ Not applicable
Swallowing tablets	☐ Yes	☐ No	☐ Not applicable
Removing tablets from vial	☐ Yes	☐ No	☐ Not applicable
Removing tablets from blister	☐ Yes	☐ No	☐ Not applicable
Filling a pillbox	☐ Yes	☐ No	☐ Not applicable

23. Do you use any of the following **medication management aids?** (Check all that apply)
☐ Prescription list ☐ Pill box or pill organizer
☐ Blister pack ☐ Calendar
☐ Pill splitter ☐ Alarm
☐ None

24. Do you use **eye drops?**
☐ Yes ☐ No, if no go to question 26

25. If you use eye drops, do you experience difficulties with any of the following? (Check all that apply)

Taking the lid off	☐ Yes	☐ No	☐ Not applicable
Holding the bottle or dispenser	☐ Yes	☐ No	☐ Not applicable
Squeezing the bottle	☐ Yes	☐ No	☐ Not applicable
Keeping hands steady	☐ Yes	☐ No	☐ Not applicable
Instilling correct number of drops	☐ Yes	☐ No	☐ Not applicable
Holding eyelids	☐ Yes	☐ No	☐ Not applicable

26. Do you use **an inhaler?**
    ☐Yes ☐No, if no got to question 28

27. If you use an inhaler, have you experienced any of the following difficulties? (Check all that apply)

Gripping the inhaler	☐ Yes	☐ No	☐ Not applicable
Opening cover of inhaler	☐ Yes	☐ No	☐ Not applicable
Shaking inhaler as needed	☐ Yes	☐ No	☐ Not applicable
Loading the capsule into the inhaler	☐Yes	☐ No	☐ Not applicable
Pressing to release the dose	☐ Yes	☐ No	☐ Not applicable
Twisting the inhaler	☐ Yes	☐ No	☐ Not applicable
Coordinating breath with dose release	☐ Yes	☐ No	☐ Not applicable
Closing the inhaler	☐Yes	☐ No	☐ Not applicable
Pressing perforation button (*Handihaler* ®)	☐ Yes	☐ No	☐ Not applicable

28. Do you use **an injection?**
    ☐ Yes ☐ No, if no go to question 30

29. If you use an injection, have you ever experienced any of the following difficulties? (Check all that apply)

Cleaning the injection area with alcohol swabs	☐ Yes	☐ No	☐ Not applicable
Gripping the injection device (e.g. a pen, syringe)	☐ Yes	☐ No	☐ Not applicable
Withdrawing medicine from vial to needle	☐ Yes	☐ No	☐ Not applicable
Depressing push-button/plunger	☐ Yes	☐ No	☐ Not applicable
Holding device stable when injecting	☐ Yes	☐ No	☐ Not applicable
Rotating the site of the injection	☐ Yes	☐ No	☐ Not applicable

30. Do you use any of the following? (Check all the apply)
    ☐ Creams or lotions
    ☐ Nasal sprays
    ☐ Patches
    ☐ Suppositories
    ☐ None of the above, if none of the above, go to question 32

31. If you use any of the forms listed in question 30, do you experience difficulty using any of them?
    ☐ Yes ☐ No

32. Are the challenges you noted above due to any of the following reasons?
    ☐ Vision problem
    ☐ Difficulty hearing
    ☐ Moving your hands (dexterity)
    ☐ Grip strength
    ☐ Pain
    ☐ Muscle weakness
    ☐ Joint stiffness
    ☐ Memory problems
    ☐ Anxiety
    ☐ Depression
    ☐ Others, please specify: _____

33. Who picks up your medication from the pharmacy?
    ☐ You
    ☐ Family member(s)
    ☐ Friend(s)
    ☐ Other caregiver(s)
    ☐ Delivery (by mail order or pharmacy service)

34. Overall, how would you rate your health?
    ☐ Excellent
    ☐ Very good
    ☐ Good
    ☐ Fair
    ☐ Poor

Additional comments (optional): _____
_____
_____
_____
_____

Form completed on ____ / ____ / _____
MM DD YYYY

Thank you for answering this questionnaire (Supervisor: Cheryl Sadowski and research assistant: Hadeel Abed)

Appendix E: Consent form

Information sheet

Title of Study: Assessment of functional medication management in rheumatology patients
Principal Investigator: Cheryl Sadowski Phone Number(s): 780-492-5078
Study Coordinator: Hadeel Abed

Why am I being asked to take part in this research study?

You are being asked to be in this study because you may have a medical condition that may make it hard for you to take your medicine. For example, you may have problems such as opening a medicine bottle or reading a label. The purpose of this survey is to gather information about your health conditions, medicines, and any problems taking your medicines. The researchers hope to understand the types of problems with taking medicine and how medical conditions affect that. After the study is done, the University of Alberta requires that the data collected will be stored securely for a minimum of 5 years after the end of the study.
Before you make a decision, the research coordinator will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

What will I be asked to do?

- If you agree to take part in the study, you will be asked to check "Yes" at the end of this form.
- Next, you will be asked to fill out a questionnaire collecting information about your medical condition(s), medicines, difficulties with medicines and help received. Finally, you will hand it in to the research coordinator.
- The questionnaire may take about 10 minutes to complete.
- You do not have to answer any questions if you do not want to.
- If you have any questions at any point, you can ask the research coordinator.

What are the benefits and risks to me?

- Benefit: There is no direct personal benefits to the participants; however, this study may help participants identify problems with taking their medicine and discuss with a health professional in the future as needed.

- Risks: Taking time to fill out the questionnaire may cause physical or mental discomfort to some people. The research assistant will be present at the clinic to help clarify any part of the questionnaire.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study and then change your mind and wish to stop, you may do so at any time before handing the questionnaire to the research assistant; it will in no way affect the care or treatment that you are entitled to. Also, if you decide not to answer certain questions, you are free to do so.

Confidentiality

The questionnaires collected will be stored at the University of Alberta in locked research storage facilities. The information entered into the computer will not contain your name. The information will be analyzed on encrypted computers. Only the research team will have access to the information. Five years after the study ends the questionnaires will be shredded and the computer data deleted.

What if I have questions?

If you have any questions about the research now or later, please contact Cheryl Sadowski at (780-492-5078). If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study investigators.

Consent Form

Title of Study: Assessment of functional medication management in rheumatology patients
Principal Investigator(s): Cheryl Sadowski Phone Number(s): 780-492-5078
Study Coordinator: Hadeel Abed

	Yes	No
Do you understand that you have been asked to be in a research study?		
Have you read and received a copy of the attached Information Sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss this study?		
Do you understand that you are free to leave the study at any time without having to give a reason and without affecting your medical care you receive?		
Do you understand who will have access to your study records?		
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name _____		
Future Contact Do you agree to be contacted for follow-up or to facilitate future research?		
Use of my research information beyond this study Do you agree for your information to be securely stored at University electronic database to facilitate future reuse?		
Who explained this study to you? _____		

I agree to take part in this study:

Signature of Research Participant

_____

(Printed Name) _____

Date: _____

Signature of Witness (If needed)

_____

A witness signature is only required if the participant is unable to read the consent for themselves. If so, an impartial witness (i.e. not associated with the study team) must be present during the entire informed consent discussion and is witnessing that the participant understood what was discussed and the signature process.

Appendix F: Ethics approval

EDMONTON ZONE
ADMINISTRATIVE APPROVAL FOR CLINICAL RESEARCH

All clinical research being conducted within the Edmonton Zone requires operational approval to access AHS areas and ethics approval by a recognized Alberta Research Ethics Board.
Other related documents may be required depending on the scope of the study.
Research in the Edmonton Zone cannot begin until Administrative Approval has been issued.

Protocol Title: Functional Medication Management in Rheumatology Patients at Kaye Edmonton Rheumatology Clinic Questionnaire

Principal Investigator:
Cheryl Sadowski
Medicine & Dentistry
Pharmacology

Funding Agency: No Funding Agency
Funding Type: Investigator-Initiated/No Funding
Overhead Rate: 0%

Related Documents:	ID#	Status	Effective
Research Ethics:	Pro00088738	Approved	Mar 12, 2019
AHS Data Disclosure Agreement:	RA90600	Not Required	

AHS Operational Approval: The following AHS areas have agreed to support your research. To gain access, you must have Edmonton Zone Administrative Approval.

46137: Kaye Edmonton Clinic - Rheumatology

Edmonton Zone Administrative Approval for Project (PRJ) #36187

Approved: Mar 14, 2019
Approved By: Ron Welch
Director of Operations, NACTRC

Appendix G: Supplementary rheumatology results

Table 1: Age groups

Age group	n	Percent
45 or less	20	20
46-64	50	50
65 or older	30	30

Table 2: Three different age groups* functional challenges crosstabs

Functional challenges (n)	Age groups (n)		
	45 or less (20)	46-64 (50)	65 or older (30)
Vision problem	0	6	11
Difficulty hearing	0	1	5
Dexterity	2	17	11
Grip strength	4	21	16
Pain	6	17	17
Muscle weakness	2	12	8
Joint stiffness	6	20	17
Memory problems	1	4	7
Anxiety	2	3	6
Depression	0	1	4
Others	1	1	1

Table 3: Rheumatology conditions* functional challenges cross tabs

Functional challenges (n)	Rheumatology conditions						
	Rheumatoid arthritis (51)	Osteoarthritis (21)	Psoriatic arthritis (10)	Gout (8)	Vasculitis (6)	Systemic lupus Erythematosus (4)	Others (29)
Vision problem	12	6	1	3	1	0	4
Difficulty hearing	5	2	1	0	0	0	2
Dexterity	20	11	1	2	4	0	7
Grip strength	24	11	4	3	4	1	11
Pain	23	14	4	2	2	2	15

Muscle weakness	12	9	3	1	1	0	7
Joint stiffness	28	12	4	3	0	2	12
Memory problems	8	4	1	0	0	1	5
Anxiety	5	5	1	0	1	0	7
Depression	1	3	0	0	0	0	4
Others	1	1	0	0	0	0	2

Table 4: Sum number of challenges per person per device

Sum number of challenges per person	Frequency of people
Oral medications (out of 11)	
0	29
1	19
2	20
3	11
4	7
5	5
6	3
7	1
8	1
9	1
***Eye drops (*out of 6)**	
0	18
1	7
2	3
3	3
4	2
6	2
Inhalers (out of 9)	
0	16
1	6
2	1
3	2
4	1
Injection (out of 6)	
0	25
1	3

2 3 4 5 6	9 4 1 1 1

Table 5: Cross tabs of challenges with different dosage forms and different IA.

Challenges with different dosage forms	People with challenges n (%)	RA (n)	OA (n)	Other IA (n)
Oral medications	69 (70%)	36	15	29
Ophthalmic	18 (50%)	10	8	9
Inhaler use	10 (38%)	2	2	8
Injections	19 (43%)	13	4	6
Other formulation	5 (6%)	3	2	2

Table 6: Cross tabs of comorbidities and different types of IA

Comorbidities	RA (n)	OA (n)	Other IA (n)
Nervous system	6	4	4
Eye conditions	22	10	15
Lung conditions	11	3	13
Mental conditions	10	7	16
Others	6	2	7

Table 7: Cross tabs for challenges with different medication forms and comorbidities

Comorbidities	Oral medication (n)	Ophthalmic (n)	Inhaler use (n)	Injections (n)	Others (n)
Nervous system	7	4	1	3	1
Eye conditions	25	11	2	10	2
Lung conditions	22	9	7	4	3
Mental conditions	20	6	5	5	1
Others	7	1	1	1	0

Table 8: Cross tabs based on sex (men=24).

Type of arthritis	RA	12
	OA	2
	Other IA	12
Difficulty with different formulation	Oral	11
	Ophthalmic	2
	Inhaler	1
	Injection	2
	Other formulation	2
Marital status	Married/Common-law	21
	Divorced/separated/widowed	3
	Never married	0
Receiving assistance	Yes	6
	No	18
Types of challenges	Ordering medication	1
	Picking up medications	0
	Organizing medication	2
	Reading Rx labels	0
	Reminding you to take medication	1
	Opening packaging	3
	Preparing medication	2
	Taking medication	4
	Observing effect of the medication	0

Table 9: Comparison of participant difficulty with different dosage forms according to their age

Age		F	Mean	Sd	t	df	p
Challenges with oral medication	Yes	69	57.6	14.0	0.918	96	0.361
	No	29	54.8	13.6			
Challenges with eye drops	Yes	18	61.0	9.9	0.612	34	0.545
	No	18	58.4	15.1			
Challenges with inhaler	Yes	10	60.0	8.8	-0.119	24	0.906
	No	16	60.5	11.9			
Challenges with injection	Yes	19	54.4	14.6	-0.760	42	0.451
	No	25	57.7	14.3			

Table 10: Comparison of different IA according to their age

Age		F	Mean	Sd	t	df	p
RA	Yes	52	59.4	14.3	1.927	98	0.057
	No	48	54.2	12.7			
OA	Yes	21	65.4	11.7	3.317	98	0.001
	No	79	54.6	13.5			
IA	Yes	45	55.9	12.4	-0.642	98	0.522
	No	55	57.7	14.9			