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REVIEW, APPROVAL AND ACCEPTANCE

The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

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Polypharmacy Practice Inquiry Project

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August 2015

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Dedication

I want to dedicate my DNP program and project to my loving and supportive family that includes my husband, Dan Skinner, my sister, Stephanie George, and my parents, Dave and Pat George.

Acknowledgements

Thank you to my committee chair and members for assisting me in creating and perfecting my DNP project. I also want to acknowledge my colleagues at the University of Louisville who have supported me in my efforts to complete my pilot study and publish my findings: Dr. Lynne Hall, Dr. Sara Robertson, Dr. Whitney Nash, Dedra Hayden, and Diane Riff.

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DNP Practice Inquiry Project Overview

“The impending crisis, which has been foreseen for decades, is now upon us. The nation needs to act now to prepare the health care workforce to meet the care needs of older adults.” Institute of Medicine.

Given the rising tide of people over the age of 65, taking multiple medications or polypharmacy is becoming more prevalent in older adults. Unfortunately, there are many negative consequences associated with polypharmacy. Specifically, this burden has been associated with greater health care costs and an increased risk of adverse drug events, drug-interactions, medication non-adherence, reduced functional capacity and multiple geriatric syndromes including cognitive impairment. Cognitive impairment, seen with both delirium and dementia, has been associated with polypharmacy. Current medical practice guidelines often require multiple medications to treat each chronic disease state for optimal clinical benefit. Cognitive impairment can put a patient at risk for either under- or overtreatment due to their numerous chronic illnesses requiring treatment.

In Primary Care, the burden of polypharmacy can be daunting, especially when patient visit times are short and there are other issues to be addressed. There is a lack of an evidence-based, step-by-step protocol to address polypharmacy in Primary Care that can take the healthcare provider and patient through the medication list together, efficiently. If there was such an instrument, polypharmacy could be focused on and adverse reactions such as hospitalizations, falls, and cognitive impairment could be avoided. The purpose of this DNP project is to investigate the impact of polypharmacy on older adults and what is available in the literature to address this problem in primary care. Then implement a streamlined Polypharmacy Protocol in this type of setting to investigate its positive and negative attributes for future use to apply to the problem of polypharmacy.

Policy Analysis: Elder Financial Fraud and Polypharmacy

Abstract

While all types of elder abuse and neglect are serious problems affecting thousands of vulnerable elders, financial exploitation has especially serious implications for the victims' economic well-being and quality of life. Older adults living independently may suffer from mild cognitive impairment or take multiple drugs, known as polypharmacy, causing drug interactions that could lead to potential mental confusion. These cognitive deficits may frame an older adult to be taken advantage of unsuspectingly. Financial exploitation may deprive the victims of their life savings and assets and thus their economic foundation for independence. Current legislation focuses on identifying scams designed to strip seniors of their assets by helping seniors, their families, and caregivers identify and avoid fraud schemes. There is also regulations to improve the complaint system for seniors involved in fraud schemes and enhancing the monitoring of the types of schemes and number of seniors targeted. The *Seniors Fraud Protection Act of 2013* list of interventions includes: case management for frail, cognitively impaired elders; preventive educational programs; and ongoing collaboration among adult protective services, financial institutions, and law enforcement agencies. The purpose of this paper is to appraise current legislation in regards to financial and material exploitation of the elderly and the role polypharmacy plays with impairing cognition as a possible factor in this detrimental crime.

Statement of Issue

Financial or material exploitation is “the illegal or improper use of an elder's funds, property, or assets.” Examples include but are not limited to cashing checks without authorization or permission; forging an older person's signature; misusing or stealing an older person's money or possessions; coercing or deceiving an older person into signing a document (e.g., contracts or a will); and the improper use of conservatorship, guardianship, or power of attorney” (Administration on Aging, 1998). In the elderly, an increased number of medications can have a negative impact on orientation, memory and judgment leading to more cases of financial and material exploitation. Recreational drugs such as alcohol, as well as over-the-counter (OTC) and prescription medications, may cause a range of cognitive impairments from confusion to delirium, and may even mimic dementia (Rogers, Wiese, & Rabheru, 2008). Polypharmacy (defined as use of more than five drugs concurrently), is common among older adults, and increases the risk of adverse interactions that may interfere with cognition (Rogers et al., 2008). Age and disease-associated changes in brain neurochemistry combined with polypharmacy to treat multiple chronic diseases, can predispose an older adult to not recognize financial or material exploitation (Moore & O’Keeffe, 1999).

Background

Magnitude of issue

A Federal Reserve Survey of Consumer Finances for 2010 found that households with people 65 and older had approximately one-third of the wealth of the United States (Administration on Aging, 2010). Elder fraud is becoming more prevalent as the overall population ages and possibly suffers from cognitive impairment while taking multiple

medications to control chronic diseases. According to the Administration on Aging (2010), the older population is defined as those 65 or older, and there will be about 72.1 million Americans that meet this demographic by 2030, representing 19 %of the population. Nearly one-half (48%) of the victims of financial/material exploitation were 80 years of age and older, while another 28.7% were between 75 and 79 years of age (Administration on Aging, 2010). Next, elderly victims between 70 and 74 years of age and those between 65 and 69 accounted for 10.8% and 9.4%, respectively (Administration on Aging, 2010). Victims between 60 and 64 years old accounted for 3.1% of financial/material exploitation. Friends/neighbors (15%), hospitals (14.2%), and family members (14%) were the three most frequent reporters of substantiated financial/material exploitation (Administration on Aging, 2010). Elder fraud costs U.S. seniors \$3 billion a year, according to a report from Federal Trade Commission (Mushnick, 2013).

Psychological researchers suggests that age-related changes in memory, cognition, and emotion can make elderly Americans more vulnerable to fraud and leading to underreporting of victimization (Administration on Aging, 1998). Researchers have concluded that approximately 80 percent of elder abuse cases may go unreported (Curtis, 2006). In most cases, the reporting party is not the victim, but rather a family member, friend, caregiver, or advisor. There are a variety of reasons that elderly victims do not report abuse, including the following: a) belief that they are to blame, b) sense of shame or embarrassment, c) emotional or economic dependence on the abuser, d) fear of separation from home or family, e) fear of the criminal justice system, and f) lack of knowledge of their rights and alternatives available to them (Curtis, 2006). When crimes are not reported, victims may not receive supportive services and perpetrators are free to continue victimizing others (Curtis, 2006).

A study, published in the *Clinical Gerontologist*, entitled “Is psychological vulnerability related to the experience of fraud in older adults?” the authors reviewed financial exploitation of any kind within the older adult population (Lichtenberg, Stickney, & Paulson, 2013). The study included 4400 participants and highlighted prospective predictors of reported financial fraud victimization of older adults including those who are psychologically vulnerable (Lichtenberg et al., 2013). Those elders, who had the highest level of depression, more medications on their regimen, and perceived low social-status, were more vulnerable to experience financial fraud (Lichtenberg et al., 2013).

Financial exploitation is pervasive among all races, social economic status, and gender. Funds lost from exploitation that could be used to pay for basic needs such as housing, food, and medical care, effects every demographic. Financial/material exploitation was the third most frequent type of elder abuse behind neglect and emotional/psychological abuse involving 30.2% of the victims (Administration on Aging, 2010). Female elders were victims of financial/material exploitation somewhat more than their proportion of the elder population (63% vs. 57.6%), while male elders were victims of exploitation 37% of the time. The proportion of white victims of financial/material exploitation was 83% (Administration on Aging, 1998). Black elders comprised 15.4% of abuse victims of this type of elder maltreatment (Administration on Aging, 2010).

Historical health policy overview

It is only in recent decades that elder mistreatment as a social policy issue has moved to the forefront of health care and social services in the United States. The passage of Medicare, Medicaid, and the Older Americans Act legislation in the 1960s was a shift toward increased awareness to welfare issues impacting the elderly (Falk, Baigis, & Kopac, 2012). In 1974, Title

XX of the Social Security Act authorized the support of protective services to adults 18 years of age and older at all income levels who were suffering abuse, neglect, or exploitation. This legislation stimulated the creation of Adult Protective Services at the state level.

In 1987, the Administration on Aging, as part of the Department of Health and Human Services, established the Prevention of Elder Abuse, Neglect, and Exploitation program. Through the program, the Administration on Aging provides federal leadership in strengthening elder justice strategic planning and direction for programs, activities, and research related to elder abuse awareness and prevention. This program trains law enforcement officers, health care providers, and other professionals on how to recognize and respond to elder abuse; supports outreach and education campaigns to increase public awareness of elder abuse and how to prevent it; and supports the efforts of state and local elder abuse prevention coalitions and multidisciplinary teams. The situation improved in 2003 when Senator John Breaux introduced the Elder Justice Act in the U.S. Senate to highlight the human rights issue of freedom from abuse and exploitation (Falk, et al., 2012).

In March of 2010 the Elder Justice Act was passed as a law to authorize the expenditure of the federal funds to implement the law and provide benefits to elders nationwide. It is regarded as the most comprehensive bill ever passed to combat elder abuse, neglect, and exploitation (Falk, et al., 2012). The Elder Justice Act authorizes \$770 million in spending in the years 2010-2014. Of this total, approximately \$500 million has been earmarked for Adult Protective Services (APS) (Falk, et al., 2012). In May 2013, new legislation that assist the Elder Justice Act in combating elder financial fraud, is a bill entitled *The Senior Fraud Prevention Act*. It was introduced in the United States House of Representatives and Senate to focus attention on

monitoring the market for mail, television, Internet, and telemarketing fraud including recorded message telephone calls (robocalls) targeting seniors.

The *Senior Fraud Prevention Act of 2013* directs the Federal Trade Commission (FTC) to establish an office within the Bureau of Consumer Protection to advise the FTC on the prevention of fraud targeting seniors and to assist the FTC in monitoring the market for mail, television, Internet, and telemarketing fraud including recorded message telephone calls (robocalls) targeting seniors (House Bill 1953 Summary & Status, 2013). This will help protect seniors from fraud schemes by strengthening the complaint system to ensure complaints of fraud are handled quickly by the appropriate law enforcement agencies. The bill would also require the FTC, to coordinate with other agencies to monitor the market for fraud schemes targeting seniors. In addition, the bill would require the FTC to distribute information materials to seniors, their families, and their caregivers that explains the process for contacting law enforcement authorities in the event that a senior is targeted in a fraud scheme.

Conceptual Framework

In John Kingdon's *Agendas, Alternatives, and Public Policies* (2011) he states that there are three stages in the policymaking process: initiation, formulation and implementation. He devised a model that comprises three "streams" that flow individually but are important in the policymaking process. When two or three streams meet, a policy or bill will move forward. The three streams are: The recognition of something as a problem (problem stream); the identification of possible solutions (proposal stream); the necessary opportunities at the time of the item being added to public policy (political stream).

The *problem stream* involves persuading policy makers to pay attention to one problem over other problems. This is also known as agenda setting. Policy proposals will rise to the top of the agenda when the associated problem is recognized as important. This depends on how it is framed or brought to policy maker's attention. The *proposal stream* is the process by which policy proposals are generated, debated, revised, and put forth for consideration. For the policy proposal to be successful it must be perceived as feasible, compatible with policymaker's values, reasonable in cost, and appealing to the public (Kingdon, 2011). The *political stream* refers to the factors that influence agendas. This includes "swings of national mood, vagaries of public opinion, election results, changes of administration, shifts in partisan or ideological distributions in Congress, and interest group pressure campaigns" (p.87).

The Senior Fraud Prevention Act of 2013 aligns with Kingdon's Three Streams framework. There was recognition of the rising incidences of elder exploitation by the public but also by policy makers, thrusting this issue to the top of the agenda or *problem stream*. A bipartisan proposal was created, revised, and introduced by sponsors in both the Senate and House of Representatives. This indicates that the *Senior Fraud Prevention Act* flows into the *proposal stream* since it is feasible, compatible with the all of the policymaker's values, reasonable in cost, and appealing to the public (Kingdon, 2011). The factors that influence agendas of the *political stream* for this policy include interest groups campaigns to raise awareness of elder exploitation and fraud, public opinion on the topic, and the ideology of the congress men and women who put forth the *Senior Fraud Prevention Act*. Supporting *The Senior Fraud Prevention Act of 2013* with Kingdon's Three Streams framework demonstrates that there is a high probability of this policy moving forward through the political process and becoming law.

Discussion

The Senior Fraud Prevention Act of 2013 is an important policy and strategy to address the detrimental effects exploitation has on the elderly. Exploitation isolates the victim and promotes a sense of helplessness, hopelessness, and/or powerlessness. Early intervention and reporting can prevent devastating emotional and financial losses for older persons who have worked their entire lives to become financially independent. This policy will give seniors and their families the tools they need to avoid scams before they happen, and will also help make sure that when a complaint is filed, it gets into the right hands so it can be addressed swiftly and effectively. According to US Senators Amy Klobuchar and Susan Collins who introduced this policy, the bill would help protect seniors from fraud by establishing an advisory office within the Bureau of Consumer Protection (Klobuchar, 2013). The Bureau of Consumer Protection office would be responsible for increasing oversight, consumer education, and establishing a complaint tracking system focused on scams that target our seniors (Klobuchar, 2013).

In the article entitled *Financial exploitation of older persons: Policy issues and recommendations for addressing them* (2004), the authors address several policy issues and make recommendations for an effective public policy approach to combatting financial exploitation of elders. These recommendations are considered to be part of the plan to improve social service, legal and criminal justice systems' response to victims of financial exploitation (Rabiner, Brown, & O'Keeffe, 2004). The policy options include: understand risk factors for victimization; understand perpetrators of financial exploitation; accurate reporting of incidence and prevalence data; understand the full impact of financial exploitation; determine effectiveness of money management programs; key elements of successful prosecution of financial crimes;

reduce the misuse of powers of attorney; effectiveness of financial exploitation prevention messages; improve the process for appointing and monitoring guardians; establish restitution programs; and multidisciplinary training on financial exploitation (Rabiner, et al., 2004).

The Senior Fraud Prevention Act 2013 is focusing on accurate reporting of the incidence of fraud in an effort to disseminate information to seniors, their families, and caregivers, on the most common fraud schemes. This information will go directly to the FTC where complaints will be directed to the Federal Bureau of Investigation, state attorney general's office, and law enforcement agencies for further investigation. This will allow for evaluation of effectiveness of financial exploitation prevention messages; help better understand risk factors for victimization; allow for accurate reporting of incidence and prevalence data; improve the process for appointing and monitoring guardians; and understand the full impact of financial exploitation.

Taking into consideration the recommendations outlined by Rabiner, Brown and O'Keeffe (2004), the following need to be implemented for legislation to be effective: better identification of perpetrators of financial exploitation; reduce the misuse of powers of attorney; improve the process for appointing and monitoring guardians; establish restitution programs; establish key elements of successful prosecution of financial crimes and multidisciplinary training on financial exploitation. Several national groups such as the National Council on Aging and AARP (American Association of Retired Persons) have published news releases and information on how to combat elder financial fraud. These types of news releases disseminate information to seniors, their caregivers, and families, on how to protect their loved ones from financial exploitation.

Possible implementation issues with the *Senior Fraud Prevention Act of 2013* include its vast outreach issues. Since the older adult population is continuously increasing in the United

States, discerning information about the latest financial fraud scams and victimization reports is going to take not only federal leadership but state and local agency leadership as well. Once this public policy is implemented, it must be reconciled with already existing policies regarding the issue of elder exploitation as highlighted in the historical context of this paper. Once this policy is approved into law, if it is dependent on a certain level of funding or participation, this will ultimately be the deciding factor in how far this policy will go towards battling the issue of financial exploitation. Also, for *the Senior Fraud Prevention Act of 2013* to succeed it must be supported publicly by local agencies that are a part of this fight to help seniors avoid exploitation.

Conclusion

Due to age and disease-related changes in the brain and how the brain manages medications, can cause drug interactions leading to potential mental confusion. Polypharmacy is common among older adults and increases the risk of adverse interactions that may interfere with cognition. These cognitive deficits may cause an older adult to be taken advantage of unsuspectingly. Financial exploitation is one type of elder abuse that affects thousands of vulnerable elders that can deprive the victims of their life savings and assets and thus their economic foundation for independence. The *Seniors Fraud Protection Act of 2013* is current legislation that focuses on fighting scams designed to strip seniors of their assets and prevent devastating emotional and financial losses for older persons who have worked their entire lives to become financially independent. This policy will give seniors and their families the tools they need to avoid scams and allow for proper follow-up when a complaint is filed, so it can be addressed effectively to prevent further exploitation to older adults.

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A Literature Review: Polypharmacy Protocol for Primary Care

Published in Geriatric Nursing Journal, June 2015

Abstract

Purpose: The purpose of this literature review is to critically evaluate published protocols on polypharmacy in adults ages 65 and older that are currently used in primary care settings that potentially lead to fewer adverse drug events.

Methods: A review of OVID, CINAHL, EBSCO, Cochrane Library, Medline, and PubMed databases was completed using the following key words: protocol, guideline, geriatrics, elderly, older adult, polypharmacy, and primary care. Inclusion criteria were: articles in medical, nursing, and pharmacology journals with an intervention, protocol, or guideline addressing polypharmacy that lead to fewer adverse drug events. Qualitative and quantitative studies were included. Exclusion criteria were: publications prior to the year 1992.

Results: A gap exists in the literature. No standardized protocol for addressing polypharmacy in the primary care setting was found. Mnemonics, algorithms, clinical practice guidelines, and clinical strategies for addressing polypharmacy in a variety of healthcare settings were interspersed throughout the literature. Several screening instruments for use in primary care to assess potentially inappropriate prescription of medications in the elderly, such as the Beers Criteria and the STOPP screening tool, were identified as well. However, these instruments were not included in a standardized protocol to manage polypharmacy in primary care.

Conclusion: Polypharmacy in older adults is a critical problem that may result in adverse drug events such as falls, hospitalizations, and increased expenditures for both the patient and the healthcare system. No standardized protocol to address polypharmacy was located in the literature. Given the growing population of elderly in this country and the high number of medications they consume, it is critical to focus on the utilization of a protocol to address polypharmacy in primary care and evaluate its effects on patient outcomes.

Introduction

There is a lack of consensus on the definition of polypharmacy among healthcare professionals. The two most common definitions are the use of potentially inappropriate drugs and the concurrent use of five or more medications including prescription and over-the-counter drugs (Bushardt, Massey, Simpson, Ariail, & Simpson, 2008). Polypharmacy is distinct from polymedicine, which is the use of many medications to treat multiple health problems (Michoki, 2001). The elderly, defined as those aged 65 years and older, have on average six co-morbid chronic conditions that require multidrug therapy to cure, slow progression, or reduce the symptoms of disease (Bushardt et al., 2008). Evidence based guidelines recommend several drugs in the treatment or prevention of a single medical condition such as in the case of diabetes mellitus or heart failure (Viktil, Blix, & Reikvam, 2008). The elderly tend to consume more over-the-counter (OTC) products than any other demographic group and account for 30% of OTC drug use in the U.S. (Francis, Barnett, & Denham, 2005; National Council on Patient Information and Education, 2010). Consequently, elderly patients likely take several medications, both prescription and OTC, concurrently. There is a multiplicative relationship between the number of medications and the number of drug-related problems that occur; with each additional medication, the number of adverse reactions rises exponentially (Zurakowski, 2009).

The U.S. Census Bureau projects that by the year 2020 there will be 55 million people over the age of 65; this group will represent 20% of the U.S population and consume 50% of healthcare costs (Vincent & Velkoff, 2010). Prescriptions for the elderly, account for 25% to 40% of all prescriptions written in the United States (Ferrario, 2008). Studies have found that a larger number of medications used by a patient leads to an increased risk of adverse drug

reactions and events, poorer patient compliance, and a larger economic burden (Bregnhøj, Thirstrup, Kristensen, Bjerrum, & Sonne, 2009). Other consequences of polypharmacy include: drug-drug interactions leading to hospitalization; change in functional status; cognitive impairment; urinary incontinence; and change in nutrition status (Maher, Hanlon, & Hajjar, 2014). Adverse drug reactions and other medication related problems such as falls and hospitalizations are associated with significant mortality; over 100,000 deaths occur annually in the U.S. due to medications at a cost of \$85 billion each year (Bilyeu, Gumm, Fitzgerald, Fox, & Selig, 2011). The relatively high rates of medication use by elderly in combination with the physiologic changes associated with aging such as decreased renal output, hepatic function, serum albumin levels, and total body water and lean body mass increase the prevalence of medication associated mortality (Bushardt et al., 2008).

Purpose

The use of medications is essential for treating chronic health conditions and maintaining quality of life. The use of potentially inappropriate medications is a known risk factor for adverse drug reactions in the elderly along with polypharmacy and inconsistent adherence to the drug regimen (Bilyeu et al., 2011). Inappropriate prescribing is an umbrella term for uncontrolled polypharmacy, under-prescribing, the prescription of medications that have more potential risk than benefit, and poor prescribing practices by healthcare providers that lead to adverse drug events (Penge & Crome, 2013). When a medication is used incorrectly or prescribed inappropriately, it can cause physical or psychological harm to a patient (Lam & Cheung, 2012). This can lead to increased healthcare utilization and expenditure. Appropriate prescribing by a healthcare provider is the fundamental first step in the proper use of a medication (Lam & Cheung, 2012). Evidence-based prescribing and following guideline directed therapy allows the

prescriber to be more confident and avoid adverse outcomes. However, if the medication has the potential for more risk than benefit to a patient or a safer, more effective alternative is available, this medication is considered inappropriately prescribed (Lam & Cheung, 2012).

Improving prescribing practices and decreasing adverse drug events in the elderly would have significant health and financial benefits. To produce these results, improved medication reconciliation and prescribing by the healthcare provider must be initiated to reduce the number of potentially inappropriate medications prescribed for elderly patients. The purpose of this literature review is to critically evaluate evidence based protocols on polypharmacy in elderly patients in the primary care.

Methods

Using the key words “protocol”, “guideline”, “geriatrics”, “elderly”, “older adult”, “polypharmacy”, and “primary care”, the OVID, CINAHL, EBSCO, Cochrane Library, Medline, and PubMed databases were searched. Articles published in the 15 year period from 1998 through 2013 was chosen for review of the most current state of the evidence. One article published in 1992 was included because it contained a well-documented and applied screening instrument for practice. Inclusion criteria were: articles in medical, nursing, and pharmacology journals with a protocol or clinical practice guideline or other clinical strategy for polypharmacy that led to fewer adverse drug events as the outcome variable. A clinical practice guideline is designed to support decision-making processes in patient care with content based on a systematic review of the clinical evidence. A protocol is viewed as more specific than a guideline, as it provides a comprehensive set of criteria outlining the management steps for a single clinical condition (Field & Lohr, 1992). Qualitative and quantitative studies were included. Sixteen articles met the criteria for inclusion in this review.

The articles were reviewed using the categories of: (a) Author (Date); (b) Type of Study; (c) Sample; (d) Purpose; (e) Findings; (f) Implications; (g) Evidence Level; and (h) Strength of Evidence. They were further grouped into subheadings of: Clinical Strategies, Algorithms, Acronyms, Guidelines, and Screening Instruments. The Hierarchy of Evidence Rating System used was the Strength of Recommendation Taxonomy (SORT) (Ebell et al., 2004). This system rates the evidence from Levels A to C, with Level A being consistent, good-quality patient-oriented evidence. Level B is inconsistent or limited-quality patient-oriented evidence, and Level C is consensus, disease-oriented evidence. The SORT system also is used to assess the quality of evidence of the studies where Level I is the highest and Level III is the lowest.

Results

The search yielded 16 articles that describe a broad range of approaches to address polypharmacy in the elderly including: screening instruments to reduce the prescription of inappropriate medications by healthcare professionals, expert clinical opinion strategies or recommendations, an algorithm for reducing or discontinuing medications, mnemonics for use by clinicians while reconciling a medication list, and clinical practice guidelines. Key findings from the articles are summarized in the following sections and in the Appendix.

Screening Instruments

Screening instruments in the literature can be applied in clinical practice to allow for closer monitoring of drug use, application of interventions to decrease adverse drug events in the elderly, and better patient outcomes. Four screening instruments were located in the literature: the American Geriatrics Society (2012) Beers Criteria; the Screening Tool of Older Person's Prescriptions (STOPP) (Gallagher, Ryan, Byrne, & O'Mahony, 2008); the Medication

Appropriateness Index (MAI) (Hanlon, Samsa, Weinberger, Uttech, Lewis, & Feussner. 1992); and the Hyperpharmacotherapy Assessment Tool (HAT) (Bushardt et al., 2008).

The American Geriatrics Society (2012) updated the 2001 Beers Criteria to: improve the selection of prescription drugs by clinicians and patients; evaluate patterns of drug use within populations; educate clinicians and patients on proper drug usage; and evaluate health-outcomes, quality of care, cost, and utilization data. This Systematic Review (Level I Evidence, SORT A) encompasses 53 medications or medication classes divided into three categories: potentially inappropriate medications and classes to avoid in older adults; potentially inappropriate medications and classes to avoid in older adults with certain diseases and syndromes that the drugs listed can exacerbate; and medications to be used with caution in older adults. Limitations of the Beer's Criteria are that it does not address potentially inappropriate medications (PIMs) commonly prescribed to older adults including drug-drug interactions, dosing of drugs in renal impairment, and therapeutic duplication (Penge & Crome, 2013). It also does not provide a list of alternative medications, requiring the provider to have patient specific judgment. According to Penge and Crome (2013), little evidence supports the use of the Beer's Criteria in terms of clinical outcomes and lack of significant associations between PIMs and adverse drug reactions.

Gallagher et al. (2008) developed the Screening Tool of Older Person's Prescriptions (STOPP) to incorporate potentially inappropriate medication use in the elderly, including drug-drug interactions and duplicate class prescribing, using a Delphi consensus technique with an 18-member expert panel (Level I evidence, SORT A). Sixty-five medications were identified and agreed upon by the expert panel and then recorded under physiologic systems (cardiovascular, central nervous, gastrointestinal, respiratory, musculoskeletal, urogenital, and endocrine).

Gallagher and O'Mahony (2008) conducted a cross-sectional study with 715 elderly patients

with consecutive acute hospital admissions to compare the performance of STOPP to the Beers Criteria in detecting potentially inappropriate medicines and adverse drug events. STOPP identified PIMs in 35% of patients compared with only 25% using the Beers Criteria. Also, the STOPP criteria PIMs, unlike Beers criteria PIMs, are significantly associated with avoidable adverse drug events (ADEs) in older people with acute illness that cause or contribute to urgent hospitalization (Hamilton, Gallagher, & O'Mahony, 2009). Previous studies had not demonstrated a consistent association between PIMs in older patients as defined by the Beers criteria and avoidable ADEs.

Hanlon et al. (1992) developed the Medication Appropriateness Index (MAI), a 10-component assessment tool, to assist physicians and pharmacists in assessing the appropriateness of a medications in elderly patients (Level I evidence, SORT A). The overall inter-rater agreement for the MAI was .88 and for medication inappropriateness was .95; the overall kappa was .83. The components include efficacy, drug dosage, interactions, cost, and duplications and provide a reliable method to assess drug therapy appropriateness. The MAI is not drug specific like the Beers or the STOPP criteria. The MAI requires clinical judgment on the part of the provider and incorporates explicit instructions to help standardize the process of medication reconciliation with a good inter-rater reliability (Penge & Crome, 2013).

The Hyperpharmacotherapy Assessment Tool (HAT) was adapted from Bergman's Medication Management Guideline (2006) for residents in long-term care (Level III evidence, SORT C). Bushardt et al. (2008) designed the HAT to meet six goals to avoid polypharmacy: monitor number of medications; decrease inappropriate drug use; decrease inappropriate pharmacology; optimize dosing regimen; organize sources of medication; and educate the

patient. Additional research is needed to refine this instrument since it has not been validated in clinical practice.

Clinical Strategies

Clinical strategies and recommendations are available to enhance clinician and patient awareness of polypharmacy, to reduce its risks and drug costs. Three clinical strategies were identified in this review of the literature. They include a pharmacist directed education intervention program (Zarowitz, B.J., Stebelsky, L.A., Muma, B.K., Romain, T.M, & Peterson, E.L., 2005), nine key questions to address polypharmacy in the elderly (Bushardt, R. L. & Jones, K.W., 2005), and safe prescribing suggestions to avoid the pitfalls of polypharmacy (Zurakowski, T., 2009).

In a longitudinal, time series cohort study with two interventions separated by one year, five categories of high-risk drug combinations were identified to reduce polypharmacy in members of a managed care plan (Level II evidence, SORT A). Clinical pharmacists performed drug therapy reviews and provided education to physicians and patients about drug safety and ways to correct problems with polypharmacy (Zarowitz et al., 2005). This intervention reduced drug costs and number of prescriptions in patients at high risk for adverse drug events due to polypharmacy. The overall rate of polypharmacy events decreased from 29.01 to 9.43/1,000 patients (a 67.5% reduction) after the first intervention. After the second intervention, the overall rate decreased from 27.99 to 17.07/1,000 (a 39% reduction). The use of pharmacists to provide clinical information, decision support, patient self-management, and care delivery redesign solved some of the problems resulting from polypharmacy (Zarowitz et al., 2005).

Bushardt and Jones (2005) in an expert opinion article, outlined nine key questions to ask

during a primary care visit to address polypharmacy in the elderly and help patients avoid medication-related problems (Level III evidence, SORT C).

Table 1. Nine key questions to address polypharmacy in the elderly

- 1) Is each medication necessary?
 - 2) Is the drug contraindicated in the elderly?
 - 3) Are there duplicate medications?
 - 4) Is the patient taking the lowest effective dosage?
 - 5) Is the medication intended to treat the side effect of another medication?
 - 6) Can the drug regimen be simplified?
 - 7) Are there potential drug interactions?
 - 8) Is the patient adherent?
 - 9) Is the patient taking an OTC medication, herbal product, or another person's medication?
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To address the harm of polypharmacy in the elderly, Zurakowski (2009) provided a framework based on expert opinion for safe prescribing in the elderly to avoid medication related problems (Level III evidence, SORT C). The recommendations included: review the medication list at every visit; evaluate the patient's adherence; consider every new symptom or complaint as a possible drug-related problem and investigate it; use the Beers Criteria (2012) as a filter when considering a new medication and identify potentially inappropriate medications used in the elderly; ensure that each medication on the list has a clear indication; ask about the use of OTC products; "start low and go slow" when prescribing; and consult another healthcare professional such as pharmacist on a regular basis.

Algorithm

Algorithms are a streamlined method to approach a problem in the clinical setting. They have the potential to be an efficient and safe technique to reduce the adverse effects of multiple medications in elderly patients. Only one algorithm was found in the literature: the Good Palliative-Geriatric Practice algorithm (Garfinkel & Mangin, 2010).

Garfinkel and Mangin (2010) tested the feasibility of the Good Palliative-Geriatric Practice algorithm in a cohort study to improve drug therapy in community-dwelling elderly patients (Level II evidence, SORT A). This algorithm takes the healthcare provider through a series of yes and no stages to either stop a drug, shift to another drug, continue with the same drug, or reduce the dose of the current drug. Of the 70 elderly patients in the study, successful discontinuation of medications not immediately essential for life was achieved for 81% with no significant adverse events or deaths attributable to discontinuation. Also, 88% of patients reported global improvement in health.

Mnemonics

Several publications listed mnemonics as a pattern of letters or associations to assist healthcare providers in remembering strategies to reduce polypharmacy in the elderly. Four mnemonics were located in the literature: SAIL (Lee, 1998), AMROR (Haque, 2009), TIDE (Shah & Hajjar, 2012), and MASTER (Hoskins, 2011). The four mnemonics are listed in Table 2 but not in the Appendix since they are a technique that aids information retention and not studied extensively.

Table 2. Mnemonics to reduce polypharmacy in the elderly

SAIL (1998)

S simple; prescribing drugs that can be taken once a day or adding a combination pill when a

second pill must be added keeps a patient's drug regimen uncomplicated.

A adverse; the clinician must have knowledge of the adverse effects of all the drugs a patient is taking to avoid medication interactions

I indication; there must be a clear indication for each drug a patient is taking with a desired therapeutic goal in mind

L is for list; the patient's medication list must be accurate including OTC products, herbs, and alternative medications and correspond to their medical diagnoses.

ARMOR (2009)

A assess the individual for the total number of medications and for certain groups of medications that have potential for adverse outcomes in the older adult such as beta blockers, antipsychotics, and antidepressants

R review for possible drug-drug, drug-disease, and drug-body interactions

M minimize nonessential medications that lack a clear indication; the risks outweigh the benefits that could have a negative outcome on primary functions such as appetite, bladder/bowel, activity, and mood

O optimize by addressing duplication of drugs, adjustment of drugs for renal and hepatic function, reducing oral hypoglycemics, and monitoring anticoagulants and seizure medications carefully

R reassessment of the patient's vital signs, cognitive status, function, and medication compliance

TIDE (2012)

T time; allow sufficient time to address and discuss medication issues during each encounter

I individualize; apply pharmacokinetic and pharmacodynamics principles to regimens by adjusting doses for renal and hepatic impairment and starting medications at the lowest

effective dose

D drug interactions; consider potential drug-drug and drug-disease interactions

E educate; educate the patient and caregiver about non-pharmacological and pharmacologic treatments along with side effects and monitoring parameters

MASTER (2011)

M minimize drugs used

A alternatives that should always be considered, especially non-drug therapies

S start low and go slow

T titrate therapy, adjusting dose based on individual response

E educate the patient and family member with clear, written instructions

R review regularly

Clinical Practice Guidelines and Quality Indicators

Clinical practice guidelines are an evidence-based strategy to address a clinical issue such as polypharmacy. The aim of a guideline is to direct decisions and criteria regarding diagnosis, management, and treatment in specific areas of healthcare. Two guidelines met inclusion criteria for this review of the literature: Assessing Care of Vulnerable Elders (Wenger, Roth, & Shekelle, 2007) and Improving Medication Management for Older Adult Clients Residing in Long-term Care Facilities (Bergman, 2013).

Assessing Care of Vulnerable Elders (Wenger et al., 2007) is a set of evidence-based quality indicators designed to measure the quality of care of vulnerable adults in the United States (Level I evidence, SORT A). There are 26 conditions described to identify areas of care in need of improvement. This includes medications to avoid in the elderly along with domains of

care including screening and prevention, diagnosis and treatment, and follow-up. The quality indicators are not considered the same as practice guidelines. Rather they set a standard that if not met can identify poor-quality care and are processes of care that are amenable to direct action by providers. Practice guidelines, in contrast, strive to define optimal care in the context of complex medical decision-making. According to Penge and Crome (2013), the disadvantage of this quality indicators project was the lack of evidence of its validity in practice.

Improving Medication Management for Older Adult Clients Residing in Long-term Care Facilities (Bergman, 2013) is a guideline to maintain function, decrease polypharmacy, avert adverse drug reactions, and avoiding inappropriate prescribing by healthcare providers (Level I evidence, SORT A). The guideline identified individuals at risk for problems with medications as those who: self-treat, lack coordinated care, were recently discharged from the hospital, have impaired cognitive status, and were on complicated medication regimens. The goal is to provide long-term care residents with periodic reviews by both a clinician and a pharmacist to review medications for congruency with diagnoses, remove duplicate medications, assess renal function, and remove high-risk medications from the list when compared to the Beers Criteria (2012).

Discussion

The Beers Criteria, STOPP instrument, and MAI were developed and studied in clinical practice to reduce adverse drug events often found with the concurrent use of medications. Inappropriate prescribing can be detected using explicit (criterion-based) or implicit (judgment-based) prescribing indicators (Hamilton, et al, 2009). The Beers Criteria (2012) and STOPP (2008) are explicit or readily observable instruments that must be updated regularly to support new drugs on the market and evolving clinical practice. One of the most consistent findings is that the use of Non-steroidal Anti-inflammatory Drugs (NSAIDs) in the elderly is high-risk,

showing up on both “drugs-to-avoid” lists as well as drug-disease interactions with heart failure, chronic renal failure, and peptic ulcer disease. Also, both the Beers and STOPP criteria include tricyclic antidepressants as a class of drugs that can exacerbate a number of conditions including falls and cognitive impairment. The MAI (1992) is an implicit tool that is predominantly used as a research tool and requires clinical expertise to apply some of the criteria, resulting in variable inter-rater reliability (Hamilton, et al., 2009). However, each one of these screening instruments provides valuable evidence-based information about inappropriate medications in the elderly. The standards outlined in these instruments need to be assimilated into a step-by-step management protocol for a clinical condition such as polypharmacy.

A balance is required between over- and under-prescribing medications to elderly patients as outlined in each of the clinical strategies described in this literature review. Essential to avoiding polypharmacy and adverse drug events is to continual reappraisal of the patient’s medication regimen and their current clinical status, matching the medication regimen to the patient’s condition and goals of care, and weighing the potential risks/benefits of each medication. However, the clinical strategies lack a standardized approach for the healthcare provider to guide the tailoring of medication regimens to avoid polypharmacy.

Mnemonics and other memory aids can be helpful to busy healthcare providers in their daily work when trying to recall information that requires memorization. The mnemonics described above can assist in remembering the most important parameters when assessing a patient's drug therapy. The key factors in the use of mnemonics in medication selection emphasize that prescribers consider all possible pharmacotherapeutic alternatives and remind them to address issues such as contraindications and precautions. Combining each step of the mnemonic to include or exclude medications based on individual patient factors allows the

healthcare provider to arrive at the most suitable medication for the patient and avoid polypharmacy.

The movement towards evidence-based healthcare has generated the development of clinical practice guidelines and care indicators to address quality, consistency, and costs. Guidelines based on standardized practice are capable of supporting improvements in quality and consistency in healthcare and reduce inappropriate variation in practice (Field & Lohr, 1992). The drawback to clinical practice guidelines to address polypharmacy is that they do not account for patients having several medical diagnoses that require multiple medications. The goal of a healthcare provider reviewing a patient's medication list is to try and avoid adverse drug events and drug interactions, but also meet the targets set out by the clinical practice guidelines. However, the guideline may not take into consideration each patient's unique set of health priorities when addressing polypharmacy.

Conclusion

There is a need for a simple, time-efficient screening protocol that can be used routinely to guide prescribing practice and reduce the rate of adverse drug events in elderly patients in primary care settings. Protocols are designed in the healthcare system as a standardized way of performing a task that is repeatable and reproducible. The goals of protocols are to produce similar results, provide a consistent presentation of data and confidence in results, allow for efficient auditing procedures, and possibly prevents errors.

To address polypharmacy in primary care, such a protocol should be sensitive, specific, include commonly encountered adverse drug events, translate into positive clinical outcomes, and have good inter-rater reliability (Hamilton et al, 2009). This protocol should encompass the

recommendations highlighted in the articles reviewed in this manuscript. The strategies that are important to incorporate in the protocol are: (1) inquiring about the use of over-the-counter products; (2) whether or not the patient sees specialist(s) and/or has been recently discharged from the hospital; (3) if a medication has been recently added to the regimen to treat the side effect of another medication (the prescribing cascade); (4) are there any duplications of medications on the list; (5) is the patient consuming any high risk medications as identified by the American Geriatrics Society; (6) does each drug in the regimen have a clear indication; (7) does the patient exhibit any physiologic changes associated with aging that could potentially cause an adverse reaction; (8) and is the patient taking the lowest therapeutic dose of each medication. The development and use of a standardized protocol to address polypharmacy in the elderly population may lead to fewer adverse drug related events such as falls and hospitalizations, thus improving quality and reducing healthcare costs.

Appendix

Table 3. Articles Reviewed in Order as Presented in the Text

Screening Instruments								
Author (Date)	Type	Sample	Purpose	Findings	Implications	Evidence Level	SORT Strength of Evidence Grade	Strengths and Weaknesses
American Geriatrics Society (2012)	Systematic Review	N/A	Update the previous Beers Criteria (2001) using a comprehensive, systematic review and grading of the evidence on drug-related problems and adverse drug events in older adults. The 11-member interdisciplinary expert panel reviewed 2,169 articles (446 systematic reviews or meta-analyses, 629 Randomized Control Trials, 1,094 observational	53 medications or medication classes encompass the updated 2012 AGS Beers Criteria and are divided into 3 categories: a) potentially inappropriate medications and classes to avoid in older adults; (b) potentially inappropriate	To improve the selection of prescription drugs by clinicians and patients, it is essential to evaluate patterns of drug use within populations, educate clinicians and patients on proper drug usage, and evaluate health-outcomes, quality of care, cost, and	Level I	A, based on consistent and good-quality patient-oriented evidence	Strengths: Evidence-based approach to identifying potentially harmful drugs in the elderly, streamlined into 3 tables for quick reference, and available in a pocket guide for clinicians to refer to while in

			studies, and 258 citations).	medications and classes to avoid in older adults with certain diseases and syndromes that the drugs listed can exacerbate; (c) medications to be used with caution in older adults.	utilization data.			practice (http://www.americangeriatrics.org/files/documents/beers/PocketCard.pdf) Weaknesses: does not address potential inappropriate medications (PIMs) that are common in aging including drug-drug interactions, dosing of drugs in renal impairment, and
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								therapeutic duplication; does not take the patients' views, wishes or adherence to treatment into consideration; time consuming to use in Primary Care with short visit times.
Gallagher, Ryan, Byrne, & O'Mahony, (2008)	Delphi consensus technique with an 18-member expert panel in geriatric medicine,	N/A	The STOPP list incorporates common instances of potentially inappropriate prescribing in older adults including drug-drug, drug-disease interactions, and drugs	65 medications were identified and agreed upon by the expert panel and then recorded under physiologic systems (cardiovascular,	Developed to address potentially inappropriate medication use in the elderly, especially with medications in use	Level I	A, based on consistent and good-quality patient-oriented evidence	Strengths: Identified potential inappropriate medications significantly more than the

	<p>clinical pharmacology, clinical pharmacy, old age psychiatry and primary care</p>		<p>which adversely affect older patients at risk for falls and duplicate drug class prescriptions. A Delphi consensus technique was used with an 18-member expert panel in geriatric medicine, clinical pharmacology, clinical pharmacy, gero-psychiatry, and primary care.</p>	<p>central nervous, gastrointestinal, respiratory, musculoskeletal, urogenital, and endocrine)</p>	<p>in Europe, including drug-drug interactions and duplicate class prescribing</p>			<p>Beers Criteria and significantly identified avoidable adverse drug reactions in older people that cause or contribute to urgent hospitalization. Weaknesses: Failure to capture use of nonprescription medications; does not take the patients' views, wishes or adherence to</p>
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								treatment into consideration; and time-consuming to use in Primary Care with short patient visits.
Hanlon, Samsa, Weinberger, Uttech, Lewis, & Feussner, (1992)	Pilot study	10 ambulatory, elderly male patients	Test reliability of a new tool to assist physicians and pharmacists in assessing the appropriateness of a medication for a given patient	Their overall inter-rater agreement for medication appropriateness index (MAI) was .88, and for medication inappropriateness was .95; the overall kappa was .83. Provides a reliable method to assess drug therapy	Clinicians rate 10 explicit criteria to determine whether a given medication is appropriate for an individual. The criteria are: indication, effectiveness, dosage, correct directions, practical directions, drug-drug	Level I	A, based on consistent and good-quality patient-oriented evidence	Strengths: Useful for detection of drug-related problems in geriatric patients admitted to the hospital from the community and reliable with a low inter-rater variability and

				appropriateness.	interactions, drug-disease interactions, duplication, duration and expense. Can be applicable as a quality care outcome measure in health services research and institutional quality assurance programs			positive correlation between high score and drug-related hospital admission. Weaknesses: Does not take under-prescribing into account and therefore does not cover all aspects of inappropriate prescribing; studied in the older adult in-patient population, not in
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								primary care setting; and does not take the patients' views, wishes or adherence to treatment into consideration.
Bushardt, Massey, Simpson, Ariail, & Simpson, (2008)	None	N/A	The Hyperpharmacotherapy Assessment Tool (HAT) was adapted from Bergman's Medication Management Guideline (2006) for residents in long-term care.	Has not been tested; Needs research to be conducted to refine instrument and establish reliability and validity.	6 goals for clinicians to avoid polypharmacy: monitor number of medications; decrease inappropriate drug use (drug-drug interactions, cost, diagnosis congruent with medication);	Level III	C, consensus, disease-oriented evidence, usual practice or expert opinion	Strengths: Well-organized instrument to be used in a primary care setting; does address patient adherence but does not take into account the patient's wishes or preferences.

					<p>decrease inappropriate pharmacology (duplications, OTC and herbal products); optimize dosing regimen (lowest effective dose and adherence); organize sources of medication (mail-order or multiple pharmacies); and patient education.</p>			<p>Weaknesses: Not studied in primary care setting, cannot draw conclusion about reliability and validity of the instrument.</p>
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Clinical Strategies								
Author (Date)	Type	Sample	Purpose	Findings	Implications	Evidence Level	SORT Strength of Evidence Grade	Strengths and Weaknesses
Zarowitz, Stebelsky, Muma, Romain, & Peterson, (2005)	Longitudinal, time series cohort study with two interventions, separated by one year based on five categories of high-risk drug combinations (polypharmacy events)	195,971 patients enrolled in a managed care plan	Objective: To enhance physician and patient awareness of polypharmacy; to decrease the risks, drug costs, and waste resulting from polypharmacy; and to make the business case for reducing misuse, overuse, and underuse of drugs by reducing polypharmacy.	Overall rate of polypharmacy events decreased from 29.01 to 9.43/1,000 patients (a 67.5% reduction) after first intervention. After second intervention, overall rate was 27.99 to 17.07/1,000 (a 39% reduction). (p=0.001) for all measures of polypharmacy.	With the use of pharmacists providing clinical information, decision support, patient self-management support, and care delivery redesign, some of the problems resulting from polypharmacy could be solved.	Level II	A, based on consistent and good-quality patient oriented evidence	Strengths: Reduced drug costs and number of prescriptions in patients at risk for polypharmacy; having a clinical pharmacist as part of the interdisciplinary team improved outcomes by providing decision support to providers and

								patient education/support. Weaknesses: Generalizability of the study's findings to primary care because clinical pharmacists not always available in primary care settings for consultation; expense to add pharmacist as a consultant to primary care; and despite the intervention with
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								increased awareness of polypharmacy, the physicians stated they would not change their prescribing habits.
Bushardt & Jones, (2005)	Expert opinion	N/A	Provide a systematic approach to assess and manage polypharmacy in the primary care visit	See text (Table 1) for the nine key questions	To reduce polypharmacy and help patients avoid medication-related problems.	Level III	C, consensus, disease-oriented evidence, usual practice or expert opinion	Strengths: Assessment system for the primary care visit based on various definitions of polypharmacy; streamlined effort to quickly assess medication lists of patients and ask important

								questions regarding medication use and adherence to avoid adverse drug reactions. Weaknesses: Not tested or data available to determine if the nine questions have improved outcomes in the primary care setting; does not list or advise the provider to follow-up if adjustments made
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								to patient's regimen.
Zurakowski, (2009)	Expert opinion	N/A	Provide safe prescribing tips for older adults for healthcare providers to weigh the risks and benefits of a medication	Recommendations: review the medication list at every visit; evaluate the patient's adherence; consider every new symptom or complaint as a possible drug-related problem and investigate it; use the Beers Criteria (2012) as a filter when	To reduce polypharmacy and help patients avoid medication-related problems	Level III	C, consensus, disease-oriented evidence, usual practice or expert opinion	Strengths: Resource for providers that highlights safe prescribing tips for older adults. Weaknesses: Not tested or data available for improved outcomes in the primary care setting; only refers to the Beers Criteria when reviewing a patient's

				considering a new medication and identify potentially inappropriate medications used in the elderly; ensure that each medication on the list has a clear indication; ask about the use of OTC products; “start low and go slow” when prescribing; and consult another healthcare professional such				medication list, does not refer to other screening instruments such as the STOPP criteria or MAI.
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				as pharmacist on a regular basis.				
Algorithm								
Author (Date)	Type	Sample	Purpose	Findings	Implications	Evidence Level	SORT Strength of Evidence Grade	Strengths and Weaknesses
Garfinkel & Mangin, (2010)	Cohort study	N=70 community dwelling older adults	Use of the Good Palliative-Geriatric Practice algorithm for drug discontinuation has been effective in nursing home setting. Will test feasibility in community dwelling older adults recording	The algorithm recommended discontinuation of 311 medications in 64 patients (58% of drugs). 81% successful discontinuation was achieved with 2%	It is feasible to decrease medication burden with the Good-Palliative Geriatric Practice algorithm. Clearly outpatient medication use	Level II	A, based on consistent and good-quality patient oriented evidence	Strengths: Evidence based developed algorithm that flows easily through a series of yes or no questions and when to stop or

			<p>rate of discontinuation, morbidity, mortality, and changes in health status.</p>	<p>restarted because of reoccurrence of disease. No significant events or deaths were attributed to discontinuation and 88% reported global improvement in health.</p>	<p>among older adults is a case where “less is more.”</p>			<p>continue a medication; use of algorithm improved the overall wellbeing of the patients participating in the study.</p> <p>Weaknesses: To date, only tested on patients in a long-term care setting and in community dwelling palliative care patients; challenging to apply to</p>
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								medication reviews with older adults who have multiple comorbidities that require multiple medications.
Clinical Practice Guidelines or Quality Indicators								
Author (Date)	Type	Sample	Purpose	Findings	Implications	Evidence Level	SORT Strength of Evidence Grade	Strengths and Weaknesses
Wenger, Roth, & Shekelle, (2007)	Evidence-based quality indicator guideline	N/A	Provide a measurement set to evaluate the care provided to vulnerable older persons at the level of the health system, health plan or medical group. The quality indicators are linked to scientific	Twenty-six conditions described using evidence-based quality indicators to identify areas of care in need of improvement to form the basis of interventions to	In regards to polypharmacy, the panel of experts said to avoid: drugs with strong anti-cholinergic properties; skeletal muscle relaxants; and high dose	Level I	A, based on consistent and good-quality patient oriented evidence	Strengths: Developed using high-quality evidence to form processes for community-dwelling elders at risk for functional decline rather

			evidence so that healthcare providers can enhance their practice.	improve care.	benzodiazepines. Along with recommending periodic drug regimen review and noting clear indications for each drug on the list.			than outcomes; the indicators cover the common geriatric syndromes; and the quality indicators take into account the patient's preferences. Weaknesses: Feasibility in primary care practice due to the indicators being designed to measure care at the level of the health system or
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								health plan, not an individual provider.
Bergman-Evans, (2013)	Evidence-based clinical guideline	N/A	To improve medication management practices by providers for older adults in the long-term care setting.	Individuals at risk for problems with medications were those who: self-treat, lack coordinated care, were recently discharged from the hospital, have impaired cognitive status, and were on complicated medication regimens.	Guideline implemented through use of Medication Management Outcomes Monitor with 4 outcomes: a) maintain function b) decrease polypharmacy c) avoid drug adverse events d) reduce inappropriate prescribing	Level I	A, based on consistent and good-quality patient oriented evidence	Strengths: Evidence-based medication management for complex patients with multiple medical conditions and medications; highlights periodically checking Creatinine Clearance and monitoring high risk drugs in older

								adults. Weaknesses: Only applies to long-term care population, not tested in primary care setting; polypharmacy defined as nine or more medications, a different definition than found in the literature.
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Pilot Study: Polypharmacy Protocol for Primary Care

Submitted for publication, Geriatric Nursing Journal August 2015

Abstract

Purpose: To develop and pilot an evidence-based protocol to address the problem of polypharmacy in older adult patients seen in a primary care setting. This protocol will optimize safe and effective medication prescribing and use, leading to improved patient care for the older adult patient and less adverse events from polypharmacy.

Methods: A cross-sectional pilot study was conducted to assess nurse practitioner implementation of the Polypharmacy Protocol to reduce polypharmacy and inappropriate prescribing in 20 patients, ages 60 years and older, seen in a primary care setting. A process evaluation survey, a satisfaction survey, and a fidelity assessment instrument were used to evaluate protocol implementation. Data from the evaluation and satisfaction surveys were analyzed using descriptive statistics. For the process evaluation and satisfaction surveys, summary scores were calculated.

Intervention: The Polypharmacy Protocol is an 8-step algorithm that systematically takes the healthcare provider and patient through pertinent questions while reviewing a patient's medication list to avoid polypharmacy and its adverse events.

Results: The mean score for the process evaluation was 3.08 (SD = .73) indicating that the protocol was "Just right" in terms of usefulness. The mean score for satisfaction was 4 (SD = 0) indicating that all Nurse Practitioners were very satisfied with the protocol. Qualitative feedback from the Nurse Practitioners also supported the benefits of using the protocol.

Conclusion: The Polypharmacy Protocol piloted in this study was demonstrated to be an efficient screening instrument that was feasible to use in primary care. In addition, the Nurse Practitioners were highly satisfied with it when they used it. The protocol can be used routinely to guide prescribing practice and reduce polypharmacy in older adult patients in primary care settings to improve quality of life and decrease unfavorable medication events such as falls and hospitalizations.

Introduction

Background and Significance

Older adult patients taking multiple medications is known as polypharmacy. The use of screening instruments designed to reconcile a patient's medication list for polypharmacy could reduce adverse drug reactions and duplication of medications. Ultimately, this could lead to an improvement in the older adult's quality of life and decrease unfavorable drug events such as falls and hospitalizations. The goal of this project was to develop an evidence-based protocol to address the problem of polypharmacy in older adult patients seen in primary care. This protocol will optimize safe and effective medication prescribing and use, leading to improved patient care for the older adult and fewer adverse events from polypharmacy.

Older adult patients often take multiple medications for many health conditions which results in polypharmacy. There is a lack of consensus on the definition of polypharmacy. The most common definitions are "the use of potentially inappropriate drugs" and "the concurrent use of five or more medications" including prescription and over the counter drugs (Bushardt, Massey, Simpson, Ariail, & Simpson, 2008). The average older adult, defined as those aged 65 and older, has six chronic conditions that require multidrug therapy to cure, slow progression, or reduce the symptoms of disease (Bushardt et al., 2008). Evidence based guidelines recommend several drugs in the treatment or prevention of a single medical condition such as in the case of diabetes mellitus or heart failure (Viktil, Blix, & Reikvam, 2008). Also, older adults tend to consume more over the counter products than any other demographic group, accounting for 30% of over the counter use in the U.S. (Francis, Barnett, & Denham, 2005; National Council on Patient Information and Education, 2010). Consequently, this leads to the older adult patient concurrently taking several medications, both prescription and over the counter. The relationship

between the number of medications and the number of drug-related problems is linear, meaning with each additional medication, the number of adverse reactions rises exponentially (Zurakowski, 2009).

The U.S. Census Bureau projects that by the year 2020 there will be 55 million people over age 65 which will represent 20% of the U.S population and who will account for 50% of healthcare costs (Vincent & Velkoff, 2010). Prescriptions for the older adults, those age 65 years and older, account for 25% to 40% of all prescriptions written in the United States (Ferrario, 2008). The increased number of medications used by a patient leads to an increased risk of adverse drug reactions and events, poorer patient compliance, and a larger economic burden (Bregnhøj, Thirstrup, Kristensen, Bjerrum, & Sonne, 2009). Adverse drug reactions and other medication related problems such as falls and hospitalizations are associated with significant mortality. Medications are associated with more than 100,000 deaths occur annually in the United States at a cost of \$85 billion each year (Bilyeu, Gumm, Fitzgerald, Fox, & Selig, 2011). The relatively high rates of medication use by older adults--in combination with the physiologic changes associated with aging such as decreased renal elimination, hepatic function, serum albumin levels, total body water, and lean body mass--increase the prevalence of medication associated mortality (Bushardt et al., 2008).

Patients over the age of 65 years see an average of seven healthcare providers (Antimisiaris & Cheek, 2014). For older adults living with five or more chronic conditions this number rises to 14 different healthcare providers, averaging over 40 office visits in one year (Berenson, 2010). The utilization of specialist healthcare providers and the lack of communication between multiple clinicians contributes to polypharmacy in the older adult population (Riker & Setter, 2012). With an older adult patient visiting multiple healthcare

providers and receiving several prescriptions, the patient is at risk for drug-drug and drug-disease interactions along with side effects from each medication. Often times, the older adult patient can be subjected to a phenomenon known as the “prescribing cascade” where a medication is added to treat the side effect of another medication (Riker & Setter, 2012). This can happen when it is not recognized that the initial medication is causing a side effect and the side effect is viewed as a new symptom or disease and is therefore treated. Bootman, Harrision, and Cox (1997) reported that for every \$1 spent on medications, \$1.33 was spent on treating drug-related problems, highlighting the significant problems and expenses polypharmacy can cause an older adult.

The use of medications has become essential for treating health conditions and maintaining quality of life. When a medication is used incorrectly or prescribed inappropriately, it can cause physical or psychological harm to a patient (Lam & Cheung, 2012). Inappropriate prescribing is a blanket term for unregulated polypharmacy, under-prescribing, the prescription of medications that have more potential risk than benefit, and poor prescribing practices by healthcare providers that lead to adverse drug events (Penge & Crome, 2013). Inappropriate prescribing can lead to increased healthcare utilization and expenditures. Appropriate prescribing by a healthcare provider is the fundamental first step in the proper use of a medication (Lam & Cheung, 2012).

Assessing and managing polypharmacy along with insuring appropriate prescribing in the older adult patient can be overwhelming without a systematic approach. With the use of a polypharmacy protocol, the healthcare provider will be able to evaluate a patient’s medication list and make appropriate changes to decrease polypharmacy and its adverse events thus improving quality of care and enhancing safe prescribing practices. The purpose of this pilot study was to test an evidence-based research protocol to address polypharmacy in the primary

care setting. This included assessing its feasibility to gauge whether or not it is realistic for use in the primary care setting.

Objectives

The objectives of this study were to:

1. Conduct a medication review with the Polypharmacy Protocol to modify the patients' regimen, where indicated, to reduce polypharmacy.
2. Assess nurse practitioners' prescribing habits to identify inappropriate prescription of medications to older adults that may lead to adverse events.
3. Evaluate the implementation of the Polypharmacy Protocol with a process evaluation survey, a satisfaction survey, and a fidelity assessment instrument (i.e., the extent to which delivery of the intervention adhered to the protocol).

Review of Literature

Using the key words “protocol,” “guideline,” “geriatrics,” “elderly,” “older adult,” “polypharmacy,” and “primary care,” the OVID, CINAHL, EBSCO, Cochrane Library, MEDLINE, and PubMed databases were searched. Inclusion criteria were: articles in medical, nursing, and pharmacology journals with a protocol or clinical practice guideline or other clinical strategy for polypharmacy that led to fewer adverse drug events as the outcome variable. A clinical practice guideline is designed to support decision-making processes in patient care with content based on a systematic review of the clinical evidence. A protocol is viewed as more specific than a guideline, as it provides a comprehensive set of criteria outlining the management steps for a single clinical condition (Field & Lohr, 1992). Qualitative and quantitative studies were included. Articles published in the 15-year period from 1998 through 2013 were chosen for

review of the most current state of the evidence. One article published in 1992 was included because it contained a documented screening instrument for practice.

Sixteen articles met the criteria for inclusion in this review. The articles described a broad range of approaches to address polypharmacy in the older adult including: screening instruments to reduce the prescription of inappropriate medications by healthcare professionals, expert clinical opinion strategies or recommendations, an algorithm for reducing or discontinuing medications, mnemonics for use by clinicians while reconciling a medication list, and clinical practice guidelines. The articles were reviewed using the categories of: (a) author (date); (b) type of study; (c) sample; (d) purpose; (e) findings; (f) implications; (g) evidence level; and (h) strength of evidence. They were further grouped into subheadings of: Clinical Strategies, Algorithms, Acronyms, Guidelines, and Screening Instruments. The Hierarchy of Evidence Rating System used was the Strength of Recommendation Taxonomy (SORT) (Ebell et al., 2004). This system rates the evidence from Levels A to C, with Level A being consistent, good-quality patient-oriented evidence. Level B is inconsistent or limited-quality patient-oriented evidence, and Level C is consensus, disease-oriented evidence. The SORT system also is used to assess the quality of evidence of the studies where Level I is the highest and Level III is the lowest. Key findings from the articles are summarized in the manuscript, *A Literature Review: Polypharmacy Protocol for Primary Care*, published in *Geriatric Nursing* (Skinner, 2015).

Methods

Design

A cross-sectional pilot study was conducted between April and July 2015 to assess nurse practitioner implementation of the polypharmacy protocol to reduce polypharmacy and

inappropriate prescribing in older adults, age 60 years and older, seen in a primary care setting.

Setting

The pilot study was conducted at a primary care clinic in Louisville, KY. The Kentucky Racing Health Service Center (KRHSC) is an independent clinic not affiliated with a specific medical system. The clinic provides health care services for the uninsured, migrant workers that look after and train thoroughbred horses at Churchill Downs. At the KRHSC, there are three exam rooms complete with computers for documentation and equipment to complete physical exams. Staff and personnel include four Nurse Practitioners and a Spanish interpreter. The four Nurse Practitioners have 2-10 years of experience as Primary Care Providers. The Spanish interpreters are either from Hispanic backgrounds or are Foreign Language graduates in Spanish. All are fluent in both English and Spanish and are always on site during clinic hours. The clinic offers full primary care services including prescriptions, lab work, diagnostic testing, and referrals to specialists when needed.

Sample

There were two study samples, (1) the patients who meet the age and polypharmacy criteria and (2) the Nurse Practitioners. The data on the purposive sample of patients were collected. Four Nurse Practitioners in the primary care clinic piloted the Polypharmacy Protocol on five patients each for a total of 20 patients who used five or more medications per day. Male and female adult patients age 60 years and older were included. The lower boundary of 60 years of age was set due to the large number of adult patients in the primary care clinic who consume greater than five medications daily and could benefit from participating in this pilot study. The primary care clinic predominately serves a Hispanic population in Louisville, KY, but African American and Caucasian patients were seen as well. Patients at this clinic have a variety of

common chronic diseases such as hypertension, dyslipidemia, type 2 diabetes, and chronic obstructive pulmonary disease that require treatment with multiple medications.

Inclusion criteria for the patients were: The use of five or more medications per day and age 60 years or older. Exclusion criteria for the patients were: Any patient who had moderate to severe cognitive impairment (dementia). Cognition was evaluated by the Principal Investigator with the Mini-Cog screening instrument (see Appendices) prior to using the polypharmacy protocol. There are three parts to the Mini-Cog that are totaled. A score of 0-2 indicates a positive screen for dementia, while a score of 3-5 is a negative screen for dementia. The Mini-Cog (Borson, Scanlan, Brush, Vitaliano, & Dokmak, 2000) was developed as a brief screening tool to differentiate patients with dementia from those without dementia. It takes approximately three minutes to administer. The Clock Drawing Test (CDT) component of the Mini-Cog allows clinicians to quickly assess numerous cognitive domains including cognitive function, memory, language comprehension, visual-motor skills, and executive function and provides a visible record of both normal and impaired performance that can be tracked over time. Depending on the prevalence of dementia in the target population, the Mini-Cog has sensitivity ranging from 76%-99%, and specificity ranging from 89%-93% with a 95% confidence interval. This tool has strong predictive value in multiple clinical settings (Borson et al., 2003). A score of 3-5 out of 5 is a negative screen for dementia (Borson et al., 2006), whereas a score of 0-2 out of 5 indicates mild cognitive impairment (McCarten et al., 2012).

The Mini-Cog has been shown to identify early dementia in nonnative and non-English speakers as well as in native English speakers (Doerfing, 2007). Borson et al. (2000) conducted additional testing to examine the tool's accuracy in a "community sample of culturally,

linguistically, and educationally heterogeneous older adults" ($N = 249$). Researchers tested 129 subjects who met the clinical criteria for probable dementia based on interviews and 120 subjects who had no history of cognitive impairment. There were 124 non-English speakers in the sample. The sample was 22% African American, 48% Asian American, 17% Hispanic, 7% white non-Hispanic, and 6% Native American and other. The Mini-Cog was compared with the MMSE and the Cognitive Abilities Screening Instrument (CASI). The Mini-Cog correctly identified 96% of subjects--more than either of the other tools. It also had the highest sensitivity at 99% ($P < 0.001$). The researchers noted that the Mini-Cog's diagnostic value was not influenced by education or language (Borson et al., 2000). The Mini-Cog has been tested in multiethnic and multilingual populations without being formally translated (Borson et al., 2000).

Inclusion criteria for the Nurse Practitioners were: hold a Master of Science in Nursing or Doctorate in Nursing Practice and licensed as an Advanced Practice Registered Nurse (APRN) in the state of Kentucky. Those who practiced at the clinic less than 8 hours per week were excluded. The four Nurse Practitioners were approached about participation in this pilot study. All agreed to participate after the purpose of the pilot study was described.

Measures

The Polypharmacy Protocol implementation in the community primary care clinic was evaluated. This included formative and summative questions as part of a process evaluation to determine if the protocol changed the nurse practitioner's review of the patient's medication list to reduce polypharmacy and improved their prescribing habits with older adult patients. The purpose of this process evaluation was to determine if the Polypharmacy Protocol assisted the Nurse Practitioners in identifying polypharmacy and potential adverse events. The Nurse

Practitioners also evaluated their satisfaction with the protocol. The four Nurse Practitioners in the primary care clinic were asked to complete the process evaluation instrument and satisfaction survey after using the protocol with five patients apiece.

Specifically, three questions were asked:

1. Is the Polypharmacy Protocol **feasible** to use in your primary care practice with older adults? Feedback was requested with any negative responses (not nearly enough, not quite enough) as to why the protocol is not feasible for the primary care setting.
2. How do you rate your **satisfaction** with the Polypharmacy Protocol? Recommendations or suggestions for improvement for future use were requested.
3. How much **time** did it take to administer the protocol? Time can be a factor in how well the protocol was adopted and recommendations were requested on how to make the protocol efficient in a timely manner for future use.

The process evaluation survey outlined in the Appendices was a new instrument created specifically for the Polypharmacy Protocol pilot study. Two PhD prepared nurse researchers with expertise in survey development and epidemiology reviewed the survey. To improve the validity of the protocol, the Principal Investigator was present for each patient visit to ensure the Nurse Practitioners consistently administered the Polypharmacy Protocol. Once the pilot study was completed, each of the Nurse Practitioners were asked for feedback to identify ambiguities and difficult questions along with recording the time taken to complete the protocol.

Once the medication review with the Polypharmacy Protocol was completed for all 20 patients, the Nurse Practitioners completed the two surveys. The first survey provided ordinal level data using a Likert scale for feedback on protocol implementation along with

recommendations for improvement for future use. The second survey provided ordinal level data on their contentment or satisfaction with the protocol using a Likert scale. The Principal Investigator used the fidelity assessment instrument created specifically for this pilot study during chart audits after implementation of the Polypharmacy Protocol to assess the extent to which delivery by the Nurse Practitioners adhered to the originally developed protocol. The fidelity assessment determined if adjustments to a patient's medication regimen were made by the Nurse Practitioner to avoid polypharmacy. Examples of questions included in the fidelity instrument were: inquiring about OTC medications, if any new medications had been added by a specialist or to treat another symptom of a disease, and to remove or decrease the dose of any high-risk medications that have been deemed by the American Geriatrics Society as having the most adverse effects.

The Appendices contain the instruments used in the pilot study. Table 1 describes the Process Evaluation instrument used by the Nurse Practitioners after implementation of the Polypharmacy Protocol. Table 2 outlines the survey that assessed the Nurse Practitioners' satisfaction in using the Polypharmacy Protocol. Four questions were adapted from the Client Satisfaction Questionnaire CSQ-8 (Attkisson, & Zwick, 1982). The CSQ-8 is a reliable and valid measure of client satisfaction with services or programs; Cronbach's alpha was .93 (Attkisson, & Zwick, 1982). Table 3 provides three questions that were part of the fidelity assessment instrument. Table 4 includes the measures.

Intervention Protocol

The Polypharmacy Protocol is an 8-step algorithm based on the review of the literature findings (see Skinner, 2015). The pertinent conclusions from the review of literature were placed

into the algorithm to systematically take the Nurse Practitioner and patient through pertinent questions while reviewing the patient's medication list to avoid polypharmacy and its adverse events. The questions included: (1) inquiring about the use of over the counter products; (2) whether or not the patient sees a specialist or specialists and/or has been recently discharged from the hospital; (3) if a medication has been recently added to the regimen to treat the side effect of another medication (the prescribing cascade); (4) are there any duplications of medications on the list; (5) is the patient consuming any high risk medications as identified by the American Geriatrics Society; (6) does each drug in the regimen have a clear indication; (7) does the patient exhibit any physiologic changes associated with aging that could potentially cause an adverse reaction; (8) and is the patient taking the lowest therapeutic dose of each medication. Each step in the protocol has a clear path based on the patient's yes or no response, including what to do if a medication is discontinued from the list with consulting the specialist, monitoring the patient, and reassessing the patient with a follow-up visit. The Polypharmacy Protocol for Primary Care can be found in the Appendices.

Procedure

The proposal was approved in March 2015 by the University of Kentucky Medical Institutional Review Board. The Principal Investigator obtained written informed consent from the four Nurse Practitioners who agreed to use the Polypharmacy Protocol with five patients each. No cold calls or direct mailings were conducted to recruit patients. During a scheduled office visit, the patients who met screening eligibility were approached by the Principal Investigator about the pilot study. In order to avoid coercion, the patients were assured that their participation was voluntary and they would not suffer negative consequences involving their continued care at the clinic if they chose not to participate. If they chose to participate, they

could stop at any time during the study and still keep the benefits and rights they had before volunteering. If the patient agreed to participate, the Principal Investigator obtained written informed consent in their native language (Spanish or English).

After the consent form was signed in their native language, the Principal Investigator completed the Mini-Cog instrument to assess for cognitive impairment. Every patient scored between 3-5, indicating a negative outcome for cognitive impairment based on recalling three objects and drawing the face of a clock appropriately.

Once consent was obtained and the Mini-Cog was completed, each patient was randomly seen by one of the four Nurse Practitioners in the clinic. The patients were requested to bring in their home medication list and/or bottles with them to their next scheduled office visit. At that visit, the Nurse Practitioner: (1) used the protocol to review the patient's medication list; (2) made appropriate adjustments to reduce the adverse effects of polypharmacy; and (3) assessed their own prescribing habits for inappropriate medications. If needed, in order to ensure the medication information obtained from the patient was accurate, the nurse practitioner contacted the pharmacy where the medications were filled to verify medication the name, dosage, and last time the medication was filled by the patient.

Privacy of the patients was insured with no use of patient identifiers. Each patient who agreed to participate and signed an informed consent form was assigned a study number that correlates with the Nurse Practitioner who saw the patient. For example, NP #1's five patients were coded as: NP1-1, NP1-2, NP1-3, NP1-4, and NP1-5. This numbering system continued for each of the four Nurse Practitioners and their five patients apiece. After the Principal Investigator obtained informed consent from the patients, the consent forms were locked in a file cabinet in a secure location at the primary care clinic.

Privacy of the four Nurse Practitioners was insured with no identifiers such as name or license number on the two surveys they completed after using the Polypharmacy Protocol with their five patients. The Nurse Practitioners' informed consent forms were locked in a file cabinet in a secure location at the primary care clinic. The Nurse Practitioners completed the two surveys after completing the Polypharmacy Protocol with their fifth patient. The Principal Investigator completed chart audits after implementation of the Polypharmacy Protocol to assess for fidelity or the extent to which delivery of the Polypharmacy Protocol by the Nurse Practitioners adhered to the originally developed protocol. Data were analyzed using descriptive statistics including frequency distributions, measures of central tendency (mean, median and/or mode) for the 4-point Likert scales. For the process evaluation, summary scores for all of the questions on the survey were derived and means were calculated.

Results

Demographic information for the 20 patients who participated in the pilot study included: five African Americans, four Caucasians, and 11 Hispanics. The male to female ratio was 14:6 with the male age range between 60-71 and the female age range between 60-66. Each patient had a minimum of five medications while the highest number found on a regimen was seven prescription medications. One patient had a total of 10 medications, four prescribed and six OTC products including vitamins and herbal preparations. The most commonly prescribed medications found during the pilot study included ACE-inhibitors and Calcium Channel Blockers for hypertension, Metformin for treatment of type 2 diabetes, and the family of cholesterol drugs known as the statins. The most common OTC medications found during the pilot study were NSAIDs (Ibuprofen, Naproxen, and Tylenol), Calcium plus Vitamin D along with antacids such as omeprazole.

The Nurse Practitioners used all eight steps of the Polypharmacy Protocol correctly when reviewing the patient’s medication list. Table 1 describes the changes made to the patient’s medication regimen by the Nurse Practitioners using the protocol. This information was collected during the chart audits using the fidelity instrument, post-implementation of the protocol.

Table 1. Fidelity Instrument for the Polypharmacy Protocol Pilot Study Results

Question	Change
Were OTC medications added to the med list?	OTC products such as Multi-vitamins and Tylenol were added to 3 out of 20 charts
Was a note made about specialist or recent discharge from hospital with changes to med list?	Medication lists were updated based on a patient’s recent discharge from the hospital for 2 patients
Was the medication list reviewed and adjusted for: Prescribing cascade?	No adjustments were made for problems related to the Prescribing Cascade as no issues were identified.
Was the medication list reviewed and adjusted for: Duplications?	Duplicate medications were removed from 2 patients’ medication lists
Was the medication list reviewed and adjusted for: High-risk medications from Table 2?	All patient lists were compared with the high-risk medications from Table 2 leading to removal of NSAIDs from 2 patients’ lists and switching 1 patient’s glyburide to another diabetic medication.
Was the medication list reviewed and adjusted for: Matched medication with diagnosis?	All patient medications were matched with an appropriate diagnosis.
Was the medication list reviewed and adjusted for: Note any physiologic changes in the patient?	Each patient either had recent or was asked to have blood work drawn to look for renal, liver and protein changes that could affect the pharmacokinetics
Was the medication list reviewed and adjusted for: Decrease dose to lowest effective dose?	3 patient medications were decreased to the lowest effective dose and monitored closely (Ambien, Ultram, Glipizide)

Results for each survey item on the process evaluation are listed in Table 2. For Nurse Practitioner satisfaction, summary scores for the four questions adapted from the CSQ-8 were calculated and had a mean of 4 (SD = 0.0) indicating there was perfect agreement across all four Nurse Practitioners in terms of high satisfaction with the protocol. Results for each item on the satisfaction survey are listed in Table 3. Qualitative feedback from the Nurse Practitioners on the use of the Polypharmacy Protocol is summarized in Table 4.

Table 2. Mean and Standard Deviation for Process Evaluation Items (*N* = 4)

Item	Mean	Standard Deviation
Does the protocol include enough background information about the problem of polypharmacy and inappropriate prescribing?	3	0.0
Does the protocol allow the APRN freedom to individualize the protocol for each patient's medication list review?	3.25	0.5
Is the protocol feasible/appropriate for an APRN in this practice setting?	3	0.0
Does the protocol provide the minimum standard of care for the clinical problem of polypharmacy?	3	0.0
Does the protocol provide the minimum standard of care for addressing inappropriate prescribing in the older adult population?	3	0.0
How much time did it take to administer the protocol?	3.25	0.96

Table 3. Mean and Standard Deviation for Satisfaction Items ($N = 4$)

Item	Mean	Standard Deviation
How would you rate the quality of the Polypharmacy Protocol?	4	0.0
To what extent did the Polypharmacy Protocol meet the needs of your practice setting?	4	0.0
Did the Polypharmacy Protocol help you address the problem of polypharmacy and inappropriate prescribing in your practice setting?	4	0.0
Overall, how satisfied are you with the Polypharmacy Protocol in addressing polypharmacy and inappropriate prescribing in your practice setting?	4	0.0

Table 4. Qualitative feedback from the Nurse Practitioners on the use of the Polypharmacy Protocol ($N = 4$)

1. Do you feel that the protocol made you more aware of the problem of polypharmacy and its problems?

- It simplified the Beers criteria
- Having an algorithm really helped streamline the medication review
- The protocol re-emphasized potential drug-drug interactions

2. Do you feel that the protocol modified your prescribing habits to avoid inappropriate prescribing in older adults?

- It made me more aware of the over-the-counter interactions
- Made me more aware of problem drugs
- Helped to remind me to ask about over-the-counter medications at every visit
- Helped me to identify drug side effects

3. What are the best features of the protocol?

- Ease of use
 - Protocol is clear
 - The flow of the algorithm with tables to guide your interview
 - Provided a defined process to logically assess a patient's medication list
-

4. What are the worst features of the protocol?

- Trying to explain to the patient your reason for doing the protocol as part of their visit
- None

5. Please list any suggestions you have to improve or change the protocol for use in practice.

- Needs medication reconciliation as part of Step 1
 - Ask about adherence to medications in Step 1
 - Change Step 2 to specialist or other provider who has prescribed medications
 - Add Emergency Room and Urgent Care to Step 2
 - Quantify the term recently in Step 3 as last month/week, since last visit, etc.
 - Define the term prescribing cascade in Step 4 because not all providers are aware of this phrase
 - Consider adding to Step 8 titration of medication to most effective dose (as in the case of titration of medications to therapeutic dose for medications such as Beta Blockers and ACE-inhibitors for Heart Failure patients)
 - Consider adding a Step that asks about the patient's wishes or preferences
 - Consider adding a Step that takes cost of medication into account
-

Discussion

The Polypharmacy Protocol is feasible for use in the primary care practice with older adults and received high satisfaction ratings from the Nurse Practitioners. However, time was an implementation factor with varying ranges reported by the Nurse Practitioners. Time is an important element to consider when initiating a protocol especially in the primary care setting where patient visit times can be brief and other issues may take precedence. If the Polypharmacy Protocol became part of an Electronic Medical Record (EMR) a provider could simply scroll through the algorithm as he or she reviews a patient's medication list, checking yes or no boxes, leading to a quicker review process. Goals for the future with the Polypharmacy Protocol include investigating software to incorporate it into an EMR or an application for a smart phone.

The qualitative responses from the pilot study participants yielded the most valuable findings. Based on the Nurse Practitioner's responses to both surveys, the Polypharmacy Protocol was reviewed to either discard or revise all unnecessary or ambiguous questions and assess whether each question gave an adequate range of responses to establish replies from patients that can be interpreted in terms of the information that is necessary to reduce polypharmacy. Revisions to the Polypharmacy Protocol based on the feedback will include: verifying that what is in the chart is what the patient is currently taking and inquiring about medication adherence in Step 1; adding other providers who have prescribed medications along with recent Emergency Room or Urgent Care visit to Step 2; quantifying the term "recently" in Step 3 to reflect time since the patient's last visit in the primary care office or clinic; define the term "prescribing cascade" in Step 4 as a recently prescribed medication is causing a side effect and the side effect is viewed as a new symptom and therefore treated; supplement Step 8, to include therapeutic doses for specific disease states; adding a step that prompts the provider to ask about the patient's preferences or wishes regarding their medication regimen; and inserting a final step that features inquiring about the cost of medications for the patient.

Limitations

Pilot studies are exploratory trials limited in size and scope that give insight into research protocols, medications, or medical devices but cannot provide definitive support for specific systematic or therapeutic claims (Polit et al., 2001). Individual small-sized studies include assessing feasibility, determining potential harm, validating a method for determining an outcome measure, and evaluating the organization of the pilot study performance (Loscalzo, 2009). However, there are associated disadvantages or limitations of pilot studies. The feasibility

and acceptability may be misleading if the size is small leading to inadequate power to detect harm or other problems (Loscalzo, 2009). Further, a study can only examine feasibility of the patient type included in the study making generalizability of the results difficult beyond the inclusion and exclusion criteria of the pilot (Loscalzo, 2009). This was the case with the Polypharmacy Protocol Pilot Study; it was tested in a single setting with a small number of patients and healthcare providers.

A pilot study is not a hypothesis testing study and therefore safety and efficacy are not evaluated (Leon, Davis, & Kraemer, 2011). However, a pilot study can be clinically meaningful if it requires contributions from clinicians who treat the patient population of interest (Leon et al., 2011). The Polypharmacy Protocol pilot study was conducted with the goal of seeking the input of healthcare providers wanting to improve their practice by avoiding polypharmacy in their older adult patients. To ensure that the interpretation of a pilot study is reliable, it must be approached rigorously and with the same level of scrutiny as other trials (Loscalzo, 2009). The outcomes for the Polypharmacy Protocol pilot study were outlined practically to avoid misinterpretation of the results.

Additional limitations specific to this pilot study include the highly motivated Nurse Practitioners who wanted to see the protocol be successful, the demographics of the patient population and the nature of the clinic. The KRHSC fulfills a need in the community for the migrant workers in the thoroughbred racing industry who typically only seek care while in Louisville, KY. Also, there are differences in the prescribing habits of the providers. Due to not billing insurance companies or having access to samples of medications from drug companies, the providers primarily prescribe from the generic \$4 or \$10 medication lists available from local

retailers. These types of prescribing habits may not be generalizable to the primary care clinics in other areas of the United States.

In summary, pilot studies are a necessary first step in exploring new interventions, such as a protocol, that are designed to inform the healthcare community of its feasibility. Once completed, the intervention can be modified for a larger trial to evaluate its safety and efficacy. After revisions are completed on the Polypharmacy Protocol, the next step will be to test it in a larger setting such as several community primary care clinics that care for a variety of older adult patients.

Conclusion

There is a need for a simple, time-efficient screening protocol that can be used routinely to guide prescribing practice and reduce polypharmacy in older adult patients in primary care settings. Protocols are designed as a standardized way of performing a task that is repeatable and reproducible. The goals of protocols were to produce similar results, provide a consistent presentation of data and confidence in results, allow for efficient auditing procedures, and possibly prevents errors (Loscalzo, 2009). To address polypharmacy in primary care, such a protocol should be sensitive, specific, include commonly encountered adverse drug events, translate into positive clinical outcomes, and have good inter-rater reliability (Hamilton et al., 2009). The Polypharmacy Protocol piloted in this study encompasses these attributes and provides a strategy that can be incorporated into practice to reduce adverse drug reactions, improve an older adult's quality of life, and decrease unfavorable events such as falls and hospitalizations.

Appendix

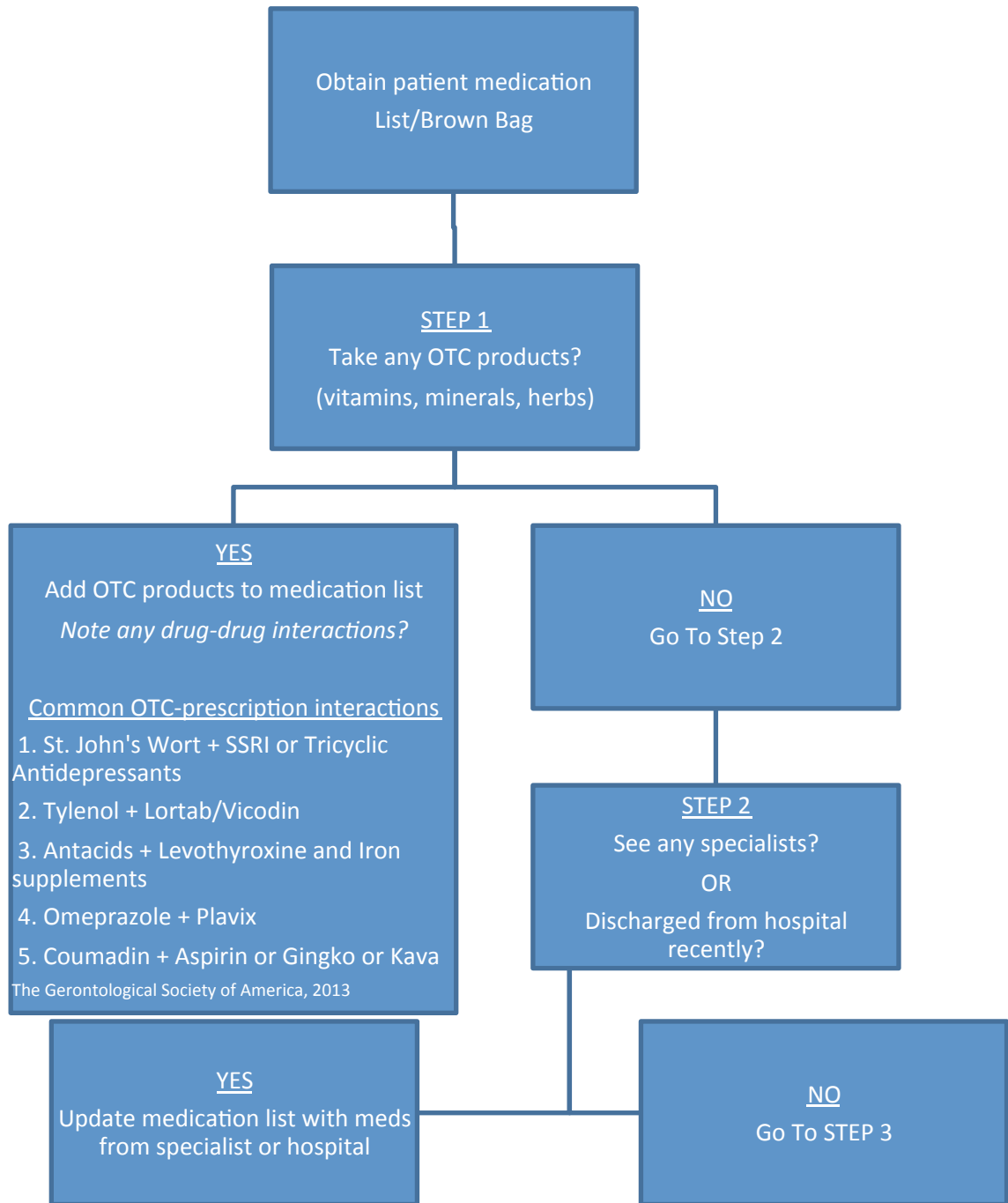
Figure 1. Polypharmacy Protocol for Primary Care

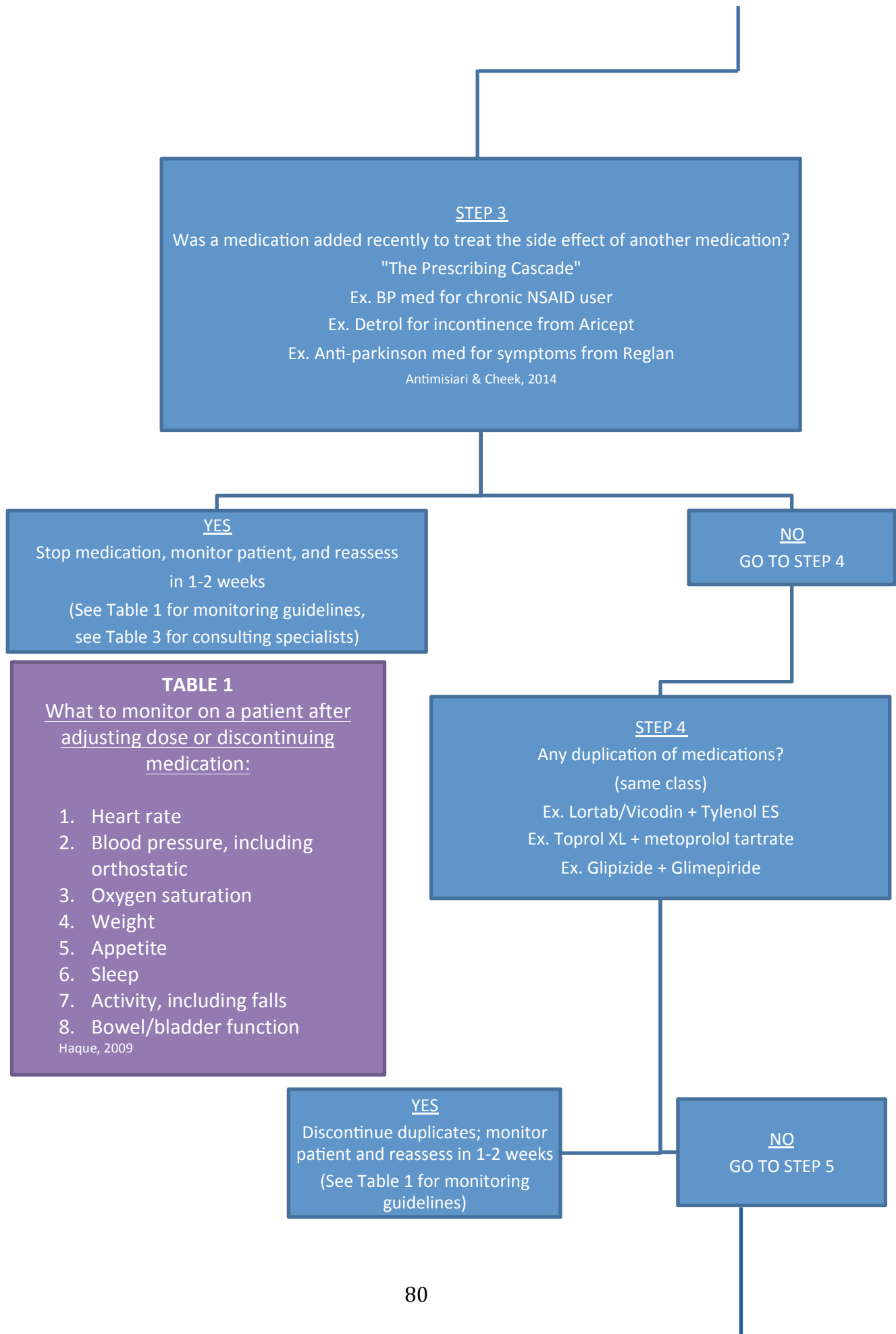
Purpose: To address the problem of polypharmacy and inappropriate prescribing in older adult patients (age 60 and older) seen in a primary care setting. This protocol will provide a systematic approach for the healthcare provider to evaluate a patient's medication list and make appropriate changes to decrease polypharmacy. It will also optimize safe and effective medication prescribing by the healthcare provider leading to improved patient care for the older adult and less adverse drug events.

Definitions:

- *Polypharmacy*—"the use of potentially inappropriate drugs" and "the concurrent use of five or more medications" including prescription and over the counter drugs
- *Inappropriate Prescribing in Older Adults*--unregulated polypharmacy, the prescription of medications that have more potential risk than benefit, and poor prescribing practices by healthcare providers that lead to adverse drug events.

Polypharmacy Protocol for Primary Care





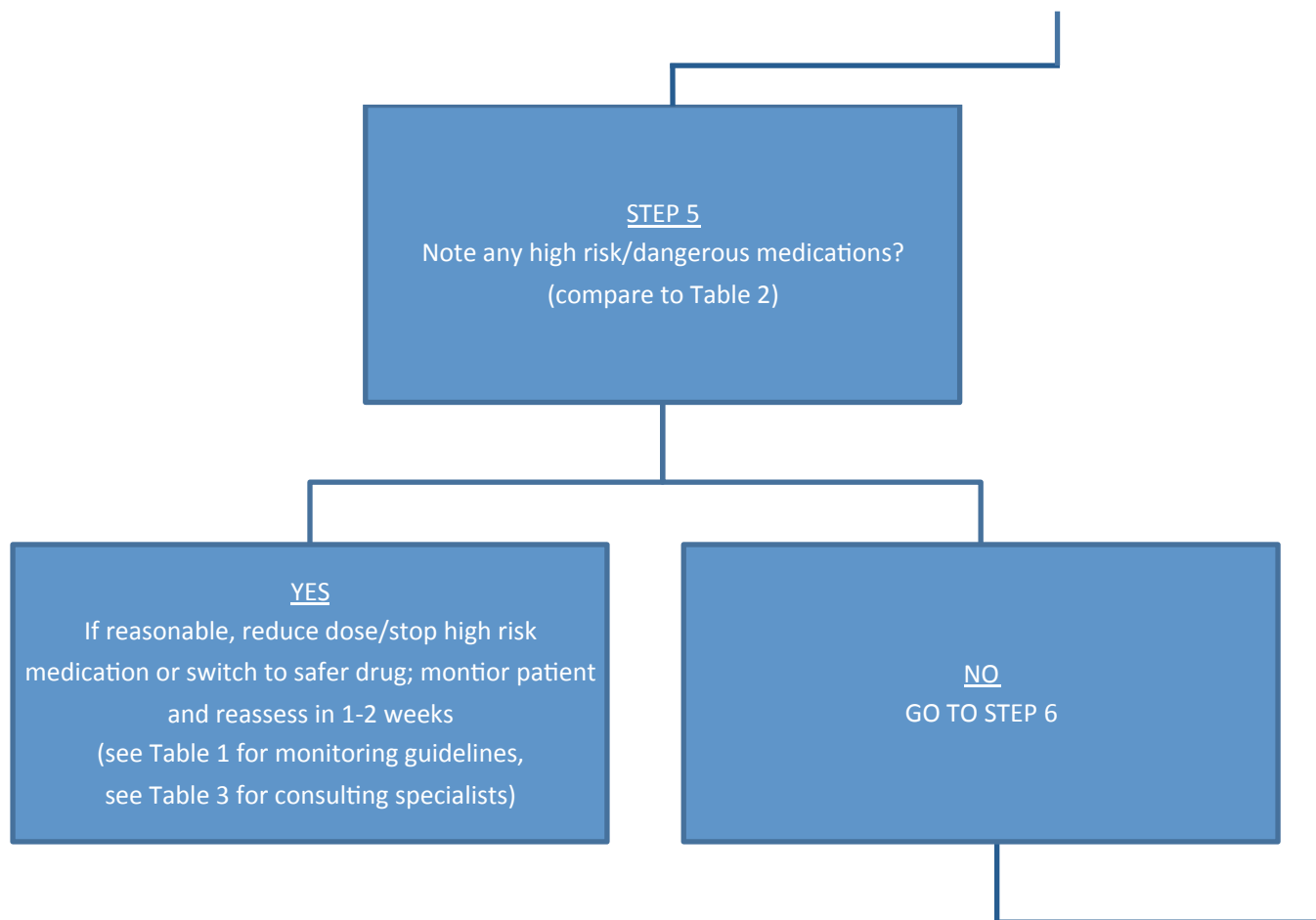


TABLE 2
10 Medications to Avoid or Use Caution in Older Adults

1. NSAIDs
 - Especially with blood thinners, such as Coumadin
2. Lanoxin (digoxin)
3. Sulfonylureas (Glyburide, chlorpropamide)
4. Muscle Relaxants (Flexeril, Robaxin, Soma)
5. Anxiety/Insomnia (Valium, Xanax, Librium, Sonata, Ambien)
6. Anticholinergic Drugs (Amitriptyline, Bentyl, oxybutynin)
7. Demerol
8. OTC Drugs (Benadryl, chlorpheniramine, Tylenol PM)
9. Antipsychotics (Haldol, Risperdal, Seroquel)
10. Estrogen pills/patches

American Geriatrics Society, 2012

*****Please note: If discontinuing a psychoactive drug (antidepressant, antipsychotic, neuralgia medications, pain medications, and anticonvulsants) taper the dose to avoid adverse withdrawal effects.**

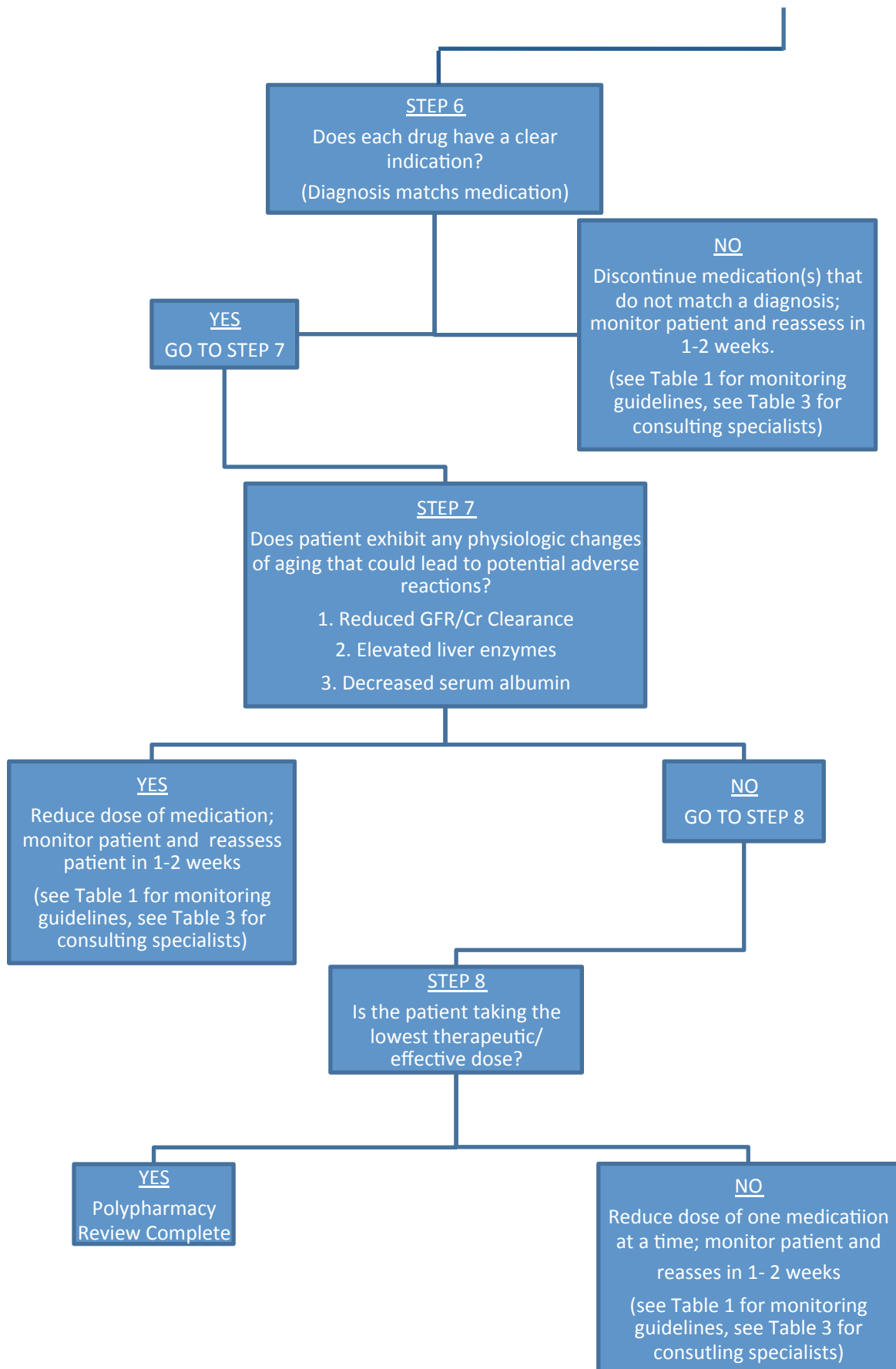


Table 3

When to consult specialists regarding withdrawal of medications:

1. ACE inhibitors for HF
2. Diuretics for HF
3. Essential hormones (long-term corticosteroids, levothyroxine)
4. Antipsychotics, mood stabilizing drugs
5. Anticonvulsants for seizures
6. Parkinson's medications
7. Disease modifying anti-rheumatic drugs
8. Longstanding benzodiazepines and opiates

CNA, 2013

Figure 2. The Mini Cog

Administration:

1. Instruct the patient to listen carefully to and remember 3 unrelated words and then to repeat the words. The same 3 words may be repeated to the patient up to 3 tries to register all 3 words.
2. Instruct the patient to draw the face of a clock, either on a blank sheet of paper or on a sheet with the clock circle already drawn on the page. After the patient puts the numbers on the clock face, ask him or her to draw the hands of the clock to read a specific time. The time 11:10 has demonstrated increased sensitivity.
3. Ask the patient to repeat the 3 previously stated words.

Scoring: (Out of total of 5 points)

- Give 1 point for each recalled word after the CDT distractor. Recall is scored 0-3.
- The CDT distractor is scored 2 if normal and 0 if abnormal.
(Note: The CDT is considered normal if all numbers are present in the correct sequence and position, and the hands readably display the requested time. Length of hands is not considered in the score.)

Interpretation of Results:

0-2: Positive screen for dementia

3-5: Negative screen for dementia

Sources:

Borson, S., Scanlan, J., Brush, M., Vitallano, P., & Dokmak, A. (2000). The Mini-Cog: A cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. *International Journal of Geriatric Psychiatry*, 15(11), 1021-1027.

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Table 1. Process Evaluation

Question				
Does the protocol include enough background information about the problem of polypharmacy and inappropriate prescribing?	Not nearly enough 1	Not quite enough 2	Just right 3	More than enough 4
Does the protocol allow the APRN freedom to individualize the protocol for each patient's medication list review?	Not nearly enough 1	Not quite enough 2	Just right 3	More than enough 4
Is the protocol feasible/appropriate for an APRN in this practice setting?	Not nearly enough 1 Why not?	Not quite enough 2 Why not?	Just right 3	More than enough 4
Does the protocol provide the minimum standard of care for the clinical problem of polypharmacy?	Not nearly enough 1	Not quite enough 2	Just right 3	More than enough 4
Does the protocol provide the minimum standard of care for addressing inappropriate prescribing in the older adult population?	Not nearly enough 1	Not quite enough 2	Just right 3	More than enough 4
How much time did it take to administer the protocol? (circle one)	25-30 minutes 1	20-25 minutes 2	15-20 minutes 3	10-15 minutes 4
<u>Feedback:</u> Do you feel that the protocol made you more aware of the problem of polypharmacy and its complications?	Yes or No Why or Why not?			
<u>Feedback:</u> Do you feel that the protocol modified your prescribing habits to avoid inappropriate prescribing in older adults?	Yes or No	Why or why not?		

<u>Feedback:</u> What are the best features of the protocol?	
<u>Feedback:</u> What are the worst features of the protocol?	
<u>Feedback:</u> Please list any suggestions you have to improve or change the protocol for use in practice.	

Adapted from: Paul, S. (1999). Developing practice protocols for advanced practice nursing. *AACN Clinical Issues*, 10(3), 343-55.

Table 2. Nurse Practitioner Satisfaction with the Polypharmacy Protocol Implementation Survey

Question				
How would you rate the quality of the Polypharmacy Protocol?	Poor 1	Fair 2	Good 3	Excellent 4
To what extent did the Polypharmacy Protocol meet the needs of your practice setting?	None of my needs have been met 1	Only a few of my needs have been met 2	Most of my needs have been met 3	Almost all of my needs have been met 4
Did the Polypharmacy Protocol help you address the problem of polypharmacy and inappropriate prescribing in your practice setting?	Didn't help 1	Helped some 2	Helped a good bit 3	Helped a great deal 4
Overall, how satisfied are you with the Polypharmacy Protocol in addressing polypharmacy and inappropriate prescribing in your practice setting?	Very dissatisfied 1	Dissatisfied 2	Mostly satisfied 3	Very satisfied 4

Adapted from: Client Satisfaction Questionnaire (CSQ-8). (Attkisson, & Zwick, 1982).

Table 3. Fidelity Instrument for the Polypharmacy Protocol Pilot Study

1. Are the Nurse Practitioners using the Polypharmacy Protocol correctly when reviewing the patient's medication list?

Circle the appropriate percentage:

- 100% of the time (used all 8 steps of the protocol)
- 88% of the time (used 7 steps of the protocol)
- 75% of the time (used 6 steps of the protocol)
- 63% of the time (used 5 steps of the protocol)
- 50% of the time (used 4 steps of the protocol)
- 38% of the time (used 3 steps of the protocol)
- 25% of the time (used 2 steps of the protocol)
- 13% of the time (used 1 step of the protocol)

2. What types of adjustments were made by the Nurse Practitioners to the patient's medication list to reduce polypharmacy while using the protocol?

Check Yes or No

Question	Yes	No
Were OTC medications added to the med list?		
Was a note made about specialist or recent discharge from hospital with changes to med list?		
Was the medication list reviewed and adjusted for: Prescribing cascade?		
Was the medication list reviewed and adjusted for: Duplications?		
Was the medication list reviewed and adjusted for: High-risk medications from Table 2?		
Was the medication list reviewed and adjusted for: Matched medication with diagnosis?		
Was the medication list reviewed and adjusted for: Note any physiologic changes in the patient?		
Was the medication list reviewed and adjusted for: Decrease dose to lowest effective dose?		

3. Did the Nurse Practitioners modify their prescribing habits with the older adults while using the protocol?

Check Yes or No

Question	Yes	No
Did the nurse practitioners state in the survey that it helped with awareness of the problem of polypharmacy?		
Did the nurse practitioners state in the survey that it helped modify their prescribing habits to avoid inappropriate prescribing in older adults?		

Table 4. Table of Study Measures

Variable Name	Measure	Level of measure	Time of measurement
OUTCOME VARIABLE (Nurse Practitioner Process Evaluation)			
Does the protocol include enough background information about the problem of polypharmacy and inappropriate prescribing?	4-point Likert scale with following choices: Not nearly enough, Not quite enough, Just right, More than enough.	Ordinal	Survey, post-implementation of protocol
Does the protocol allow the APRN freedom to individualize the protocol for each patient's medication list review?	4-point Likert scale with following choices: Not nearly enough, Not quite enough, Just right, More than enough.	Ordinal	Survey, post-implementation of protocol
Is the protocol feasible/appropriate for and APRN in this practice setting?	4-point Likert scale with following choices: Not nearly enough, Not quite enough, Just right, More than enough.	Ordinal	Survey, post-implementation of protocol
Does the protocol provide the minimum standard of care for the clinical problem of polypharmacy?	4-point Likert scale with following choices: Not nearly enough, Not quite enough, Just right, More than enough.	Ordinal	Survey, post-implementation of protocol
Does the protocol provide the minimum standard of care for addressing inappropriate prescribing in the older adult population?	4-point Likert scale with following choices: Not nearly enough, Not quite enough, Just right, More than enough.	Ordinal	Survey, post-implementation of protocol
How much time did it take to administer the protocol?	Intervals of time: Less than 10 minutes, 10-15 minutes, 15-20 minutes, 20-25 minutes, 25-30 minutes	Ratio	Survey, post-implementation of protocol
OUTCOME VARIABLE (Nurse Practitioner Satisfaction)			
How would you rate the quality of the Polypharmacy Protocol?	4-point Likert scale with following choices: Poor, Fair, Good, Excellent	Ordinal	Survey, post-implementation of protocol
To what extent did the Polypharmacy Protocol meet the needs of your practice setting?	4-point Likert scale with following choices: None of my needs have been met, Only a few of my needs have been met, Most of my needs have been met, Almost all of my needs have been met	Ordinal	Survey, post-implementation of protocol

Did the Polypharmacy Protocol help you address the problem of polypharmacy and inappropriate prescribing in your practice setting?	4-point Likert scale with following choices: Didn't help, Helped some, Helped a good bit, Helped a great deal	Ordinal	Survey, post-implementation of protocol
Overall, how satisfied are you with the Polypharmacy Protocol in addressing polypharmacy and inappropriate prescribing in your practice setting?	4-point Likert scale with following choices: Very dissatisfied, Dissatisfied, Mostly satisfied, Very satisfied	Ordinal	Survey, post-implementation of protocol

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DNP Practice Inquiry Project Conclusion

Polypharmacy is common among older adults and increases the risk of adverse interactions that may interfere with cognition and cause other adverse events. To avoid this, the protocol piloted for the DNP project in a primary care setting has been found to address polypharmacy both simply and efficiently. The Polypharmacy Protocol screening instrument can be used routinely to guide prescribing practice and reduce polypharmacy in older adult patients. It also provides a strategy that can be incorporated into practice to reduce adverse drug reactions, improve an older adult's quality of life, and decrease unfavorable events such as falls, hospitalizations, and changes in cognition.