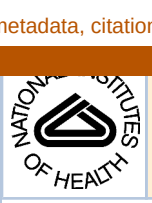

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The Quality of Medication Use in Older Adults: Methods of a Longitudinal Study

Mary T. Roth, PharmD, MHS[1], **Charity G. Moore, PhD, MSPH**[2], **Jena L. Ivey, PharmD**[3], **Denise A. Esserman, PhD**[4], **William H. Campbell, PhD**[5], and **Morris Weinberger, PhD**[6]

1*Division of Pharmaceutical Outcomes and Policy, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, NC*

2*Center for Research on Health Care Data Center, University of Pittsburgh, Pittsburgh, PA*

3*Division of Pharmacy Practice and Experiential Education, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, NC*

4*Division of General Medicine and Clinical Epidemiology, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC*

5*Dean Emeritus, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, NC*

6*Department of Health Policy and Administration, University of North Carolina at Chapel Hill, Chapel Hill, NC*

Abstract

Background—The quality of medication use in older adults is a recurring problem of substantial concern. Efforts to both measure and improve the quality of medication use often define quality too narrowly and fall short of addressing the complexity of an older adult's medication regimen.

Objective—In an effort to more comprehensively define the quality of medication use in older adults, we conducted a prospective cohort study to: 1) describe the quality of medication use in community-residing older adults at baseline, examining differences between Whites and African Americans; 2) examine the effect of race on medication-related problems[mtr1], and 3) assess the change in quality medication use between Whites and African Americans over time. This paper presents the research design and methods of this longitudinal study.

Methods—We interviewed 100 White and 100 African-American community-residing older adults three times over one year (baseline, 6, and 12 months). We oversampled African Americans so that we could estimate racial differences in the quality of medication use. We collected information on the quality of medication use, relying on a clinical pharmacist's assessment of quality and the Assessing Care of Vulnerable Elders (ACOVE) quality indicators. We also collected data on demographic characteristics, health literacy, functional status, and participant-reported drug therapy concerns.

Address correspondence to Dr. Mary T. Roth, Division of Pharmaceutical Outcomes and Policy, School of Pharmacy, CB# 7360, University of North Carolina at Chapel Hill, Chapel Hill, NC, 27599-7360. E-mail: E-mail: mroth@unc.edu. Telephone: 919-843-8083. Fax: 919-966-8486.

Results—Two hundred older adults were enrolled into the study and completed a baseline visit. Of the 200, 92% completed the 6-month visit (n=183) and 88% completed the 12-month visit (n=176). We present baseline demographic characteristics for the 200 older adults enrolled in the study.

Conclusion—This longitudinal study is an initial step toward developing more comprehensive, patient-centered measures and interventions to improve the quality of medication use in older adults.

Keywords

Quality; Medication; Elderly

Introduction

The Institute of Medicine (IOM) and other prominent organizations have recognized that medication-related problems plague our health care system.(1-3) Nowhere are medication problems more pronounced than in older adults.(4) The elderly are at an increased risk of developing medication-related problems due to their chronic disease burden, multiple prescribers, and concurrent medication use, which may compromise their health status, functional status, and quality of life.(5-7) The costs attributed to the use of potentially inappropriate medications in the elderly are projected to average $7.2 billion annually.(8) Moreover, the costs associated with drug-related morbidity and mortality are staggering, estimated in one study to be $177 billion annually, with nearly half ($80 billion) in ambulatory care.(9-11)

The IOM definition of quality care can be adapted to define quality medication use: "*the degree to which medication use for individuals and populations increases the likelihood of desired health outcomes and is consistent with current professional knowledge*."(12,13) Similarly, quality problems related to medication use can be classified broadly as: underuse (i.e., failure to provide a medication when it could have produced a favorable outcome for a patient); overuse (i.e., when a medication is provided under circumstances in which the potential for harm exceeds the possible benefit or when there is no clear benefit); and misuse (i.e., when an appropriate medication has been selected but a preventable problem occurs that precludes the patient from realizing the full potential benefit of the medication).

Most efforts to measure and improve the quality of medication use target specific drugs, specific medication-related problems, or specific diseases, rather than the patient. These approaches too narrowly define the quality of medication use and cannot account for the complexity of an older adults' medication needs. For example, the Beers criteria, explicit criteria for identifying potentially inappropriate medications in the elderly, focus only on appropriate prescribing of select, high-risk medications in older adults. (14) Although important, the Beers criteria alone are insufficient to assess an individual's quality of medication use if the goal is to account for the unique medication needs of individual patients. The Medication Appropriateness Index (MAI) and the Assessing Care of Vulnerable Elders (ACOVE) quality indicators appear to be the most comprehensive measures of appropriate medication use, although they measure very different constructs of medication quality. (15, 16) The MAI assesses medication appropriateness for each medication a patient is taking, while the ACOVE quality indicators measure appropriateness of select medications and compliance with important medication-related processes of care that impact quality, such as appropriate medication documentation and medication monitoring. Neither instrument, however, accounts for both the unique medication needs of an individual and gaps in medication-related processes of care that often lead to medication-related problems. For this reason, we conducted an implicit review of the quality of medication use in older adults over time. This implicit assessment by a clinical pharmacist will allow us to obtain a more comprehensive assessment of quality

medication use that is unique to the medication needs of each individual patient. (17,18) The pharmacist's clinical assessment was guided by a list of potential medication-related problems, which was developed based on an extensive review of the literature. The list took into account the Beers criteria, important elements of medication appropriateness identified in the MAI, and processes of care such as medication access, documentation, and monitoring that have been shown to impact the quality of medication use. (14-16,19,20). The list of potential medication-related problems was developed with the goal of refining it based on our experience and study findings.

Although it is unknown what impact race may have on the quality of medication use, it has been suggested that racial differences exist in medication use and access to care. (21) For example, it is well documented that African American older adults have lower total drug spending, use fewer prescription medications, and have higher rates of nonadherence than Whites. (22,23) To further explore this potential relationship, we have oversampled race in our study to examine its effect on the quality of medication use in older adults.

Achieving quality medication use requires more than prescribing the right drug in the right dose to the right person—it will require measures and interventions that are tailored to the individual's needs and the multiple medications he/she is taking and address medication-related processes of care that enable quality medication use. In an effort to more comprehensively define the quality of medication use in older adults, we conducted a prospective cohort study to: 1) describe the quality of medication use in community-residing older adults at baseline, examining differences between Whites and African Americans; 2) examine the effect of race on medication-related problems, testing the hypothesis that race is an independent predictor of medication-related problems, and 3) assess the change in quality medication use between Whites and African Americans over time, testing the hypothesis that the number of medication-related problems will remain unchanged over the one year study. [MR2]This paper presents the research design and methods of this longitudinal study.

Subjects and Methods

Overview

We interviewed 100 White and 100 African-American older adults residing in the community three times (baseline, 6, and 12 months); we oversampled African Americans so that we could estimate racial differences in the quality of medication use. We collected information on the quality of medication use, relying on a clinical pharmacist's assessment of quality and an evaluation of quality medication use using the Assessing Care of Vulnerable Elders (ACOVE) quality indicators.(16) We also collected data on demographic characteristics, health literacy, functional status, and participant-reported drug therapy concerns. The study protocol was approved by the University of North Carolina at Chapel Hill School of Medicine Institutional Review Board.

Inclusion and Exclusion Criteria

Participants had to meet all of the following inclusion criteria: (a) age ≥ 60 years, (b) residing independently in the community setting; (c) taking ≥3 regularly-scheduled prescription and/or non-prescription medications (d) able to read and speak English, (e) willing to participate, as indicated by providing informed consent and HIPAA-compliant authorization for release of medical information. Participants were excluded if they had ≥3 errors on the cognitive screening instrument (24) or received clinical pharmacy services within the past 6 months.

Study Setting

Participants were recruited from the Orange County Department on Aging Eldercare Program and two senior housing complexes. The Eldercare Program is staffed by licensed clinical social workers and an occupational therapist and provides case management to nearly 300 older persons residing independently in their own homes, apartments, or senior housing. Eldercare provides information and support to the individual and their caregivers to maximize the older persons' independence, enhance quality of life, and facilitate adjustment to age-related changes. The two senior housing complexes involved in the study are affiliated with the Eldercare program.

Participant Recruitment

Using the Eldercare Program contact list, the study pharmacist conducted a screening telephone call with each older adult to describe the study and invite them to participate in a baseline visit for verification of eligibility and enrollment of qualified individuals. All baseline study visits were scheduled within two weeks of the screening call. Individuals recruited from area senior housing complexes were volunteers who responded to posted flyers and advertisements about the study. This method of recruitment was used in addition to Eldercare to reach our anticipated enrollment goals. All participants were compensated $20 per visit for the baseline, 6-, and 12-month interviews (maximum $60).

Baseline Visit

For individuals expressing an interest in participating in the study, the pharmacist arranged a time to meet with the individual in their home to discuss the study, administer the 6-item cognitive screen, obtain informed consent and HIPAA-compliant authorization for release of medical information, verify eligibility, and enroll eligible individuals into the study. Cognitive status was assessed using a 6-item screen to identify older persons with probable cognitive impairment. (24) This screening test, which can be administered face-to-face in only 1-2 minutes, relies on a 3-item recall and a 3-item temporal orientation. Individuals with probable cognitive impairment (≥3 errors) were excluded; this cut-off previously demonstrated a sensitivity of 89% and specificity of 88% for a diagnosis of dementia, which is comparable to the Mini-Mental State Examination.(25)

Informed consent and authorization to release medical information were obtained on all individuals meeting eligibility criteria. The pharmacist then conducted the baseline interview. Measures (described below) included demographics, health literacy, functional status, drug therapy concerns, and clinical pharmacist assessment of quality medication use, including the ACOVE quality indicators. The data collection schedule for each instrument is presented in Table 1.

Health Literacy was assessed using the Short-Test of Functional Health Literacy in Adults (S-TOFHLA).(26) The S-TOFHLA measures a patient's ability to read and understand health-related material. It is comprised of 4 numeracy items and 2 prose passages (36 items) and takes about 12 minutes to administer. Scores range from 0 to 36 and are categorized as inadequate (0-16), marginal (17-22), or adequate health literacy (23-36). Patients with inadequate health literacy often misread simple materials, such as prescription bottles, appointment slips, or nutrition labels; persons with marginal health literacy frequently have trouble with more complex materials, such as an educational brochure or informed-consent document.(27,28)

Functional Status was assessed via self-report using an 8-item instrumental activities of daily living (IADL) scale.(29) This widely-used scale assesses complex self-maintenance skills in older adults, including the ability to use a telephone, shop, prepare food, complete housework, do laundry, utilize public transportation, administer medication, and handle financial

responsibilities. Each task is scored as 0 (independence), 1 (some assistance required), or 2 (complete dependence on others). Items are summed (maximum=16) to compute an IADL total score, with higher scores reflecting poorer functional status.

Drug Therapy Concerns contains 25 items related to patients' concerns in 5 areas: (1) perceived efficacy of therapy; (2) adverse drug reactions; (3) overmedication concerns; (4) adherence issues; and (5) knowledge. In initial research in the elderly, each subscale exhibited an acceptable level of reliability.(30) Validity of the subscales was demonstrated by correlations with a measure of overall medication satisfaction.

Clinical Pharmacist Assessment of Quality Medication Use—The pharmacist's assessment of quality medication use relied on a three-step implicit process. In contrast to an explicit review, which relies on predetermined criteria that are insensitive to the unique medication regimens of individual patients, an implicit review allows for the pharmacist to integrate all available information about a patient and arrive at an assessment of quality medication use. (17,18) Although judgments may be influenced by the pharmacist's experience, consistency, and attention to detail, an implicit review allows the pharmacist to make assessments of quality medication use that are patient-centered and account for an individuals' medication-related needs. Based on the results from our longitudinal study, we hope to develop a more structured implicit review process for use in subsequent studies. For purposes of this longitudinal study, the three-step implicit process involved: 1) a comprehensive medication review with the older adult, 2) a medical record review, and 3) formulation of an assessment of quality medication use. Each of these steps is described in greater detail.

The Comprehensive Medication Review: During the interview, the pharmacist recorded the following information: 1) medical conditions; 2) all medications, including prescription, over-the-counter, and complementary and alternative medications; 3) medication-taking behaviors; 4) medication allergies and adverse drug events; 5) method of payment for medications, including prescription drug insurance or assistance; 6) dispensing pharmacy; 7) use of medication adherence aids, including pill boxes, medication calendars or lists, and caregivers; 8) estimated out-of-pocket spending per month on medications; and 9) additional medication-related information provided by the individual. This information will be used in describing the population but is also critical in assessment of quality medication use.

The Medical Record Review: After completing the baseline visit, the pharmacist contacted the physician's office where the medical record was located, submitted documentation of participant consent to release information, and arranged a time to review the medical record at the office. During the medical record review, the pharmacist abstracted information on medications, medical conditions, laboratory values, physician assessment of the individual's medical conditions, hospitalizations, and any other information pertinent to assessing the individual's quality of medication use. Using the medical record, the pharmacist also completed an assessment of quality medication use by applying the Assessing Care of Vulnerable Elders (ACOVE-2) Quality Indicators.(31) The ACOVE Project, a collaboration between RAND Health and Pfizer, Inc., led to the development of the first quality-of-care assessment system for older persons (ACOVE), with a set of quality indicators specific to medication use.(16) The original set of ACOVE quality indicators was updated in 2001 (ACOVE-2); ACOVE-2 was the version used at all three visits for all participants throughout our longitudinal study. (31) ACOVE-2 consists of 39 quality indicators of medication use categorized in 4 domains: 1) prescribing indicated medications; 2) avoiding inappropriate medications; 3) education, continuity, and documentation; and 4) medication monitoring. Two of the 39 ACOVE-2 quality indicators were excluded from our study because they targeted hospitalized patients. The ACOVE indicators have excellent face validity due to the expert consensus process used in their development.

The Formulation of an Assessment of Quality Medication Use: The pharmacist has been trained extensively in assessing drug therapy in the older adult population. The pharmacist's evidence-based clinical assessment relied on data from the comprehensive medication review with the participant, the medical record review, and the published literature, including clinical practice guidelines and geriatric prescribing guidelines. The medication review provided an opportunity for the pharmacist to gather participant-reported information about current medication use, medical conditions, and other medication-related findings and inspect participant pill bottles. The medical record review provided information regarding medical history, medications, laboratory values, and other pertinent information that only the physician and other health care professionals can provide. Finally, the published literature, including clinical practice guidelines and geriatric prescribing guidelines, provided the pharmacist with evidence upon which to base clinical assessments.

In this study, the pharmacist's assessments were guided by a list of potential medication-related problems developed by study investigators following an extensive review of the literature.(14,15,19,31-36) The eight potential medication-related problems and their accompanying definitions are listed in Table 2. We provided the pharmacist with an open-ended selection in the event a potential medication-related problem was identified that could not be classified according to the list. In addition to identifying the type of medication-related problem, the pharmacist recorded a subcategory for each problem along with additional notes regarding the problem. A sample list of subcategories for each problem was available to the pharmacist with the option of also creating their own subcategory as needed. The list of potential medication-related problems was developed with the goal of refining it based on our experience and study findings. We used two methods to assess nonadherence: a clinical pharmacist assessment of adherence (i.e., adherent, nonadherent) for each medication a person was taking (Table 3) and a validated patient self-report measure.(37) Because no gold standard exists for measuring nonadherence, we relied on multiple methods of assessment.(38-40) Upon completion of the baseline visit, all baseline data was entered into the study database by the research assistant. (Figure 1)

The study pharmacist did not intervene on any potential medication-related problem at any point throughout the study unless deemed to be life-threatening. In addition, the pharmacist only responded to participant questions regarding their medications when asked. Pharmacist responses to participant inquiries were considered standard of care and only occurred if the participant posed a question. The study team developed guidelines for addressing life-threatening medication-related problems during the study, which were presented to the IRB, refined based on feedback, and approved as part of the study protocol. The guidelines stated that if a life-threatening medication-related problem was detected during the in-home interview and the medication-related problem warranted immediate attention, clinical judgment would be exercised by the pharmacist in determining when to call 911 versus contacting the study physician and principal investigator to discuss the most appropriate action to be taken. All of this occurred while the study pharmacist was present in the home with the participant. If a medication-related problem was identified after the pharmacist had left the participant's home (i.e., through medical record review) and thought to be of a serious nature, the same procedure for contacting the study physician and principal investigator was followed. In addition, the study pharmacist contacted the participant's primary physician, as necessary, to have the individual's medications modified accordingly. The IRB-approved guidelines included in our study protocol provided examples of medication-related problems considered life-threatening.

Examples of medication-related problems considered life-threatening and, therefore, warranting intervention

- Medications that are absolutely contraindicated in a participant based on prescribing guidelines (e.g., metformin in severe renal failure).
- Medical conditions that warrant immediate attention and intervention based on medical care standards (e.g., the participant with severe chest pain or shortness of breath who needs to seek immediate medical help; hypertensive urgencies and hypertensive emergencies as defined in the The Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7).
- Adverse drug events that are causing the participant immediate and life-threatening harm (e.g., a beta blocker that is contributing to a significant drop in heart rate and causing severe dizziness and lightheadedness)
- Nonadherence to a medication that could be considered life-threatening (e.g., nonadherence to warfarin in a participant with deep vein thrombosis)

Examples of medication-related problems not considered life-threatening and, therefore, not warranting intervention

- Drugs that are potentially inappropriate in the elderly, but not absolutely contraindicated (e.g., benzodiazepines, propoxyphene)
- Medical conditions that are undertreated (e.g., hypertension, hyperlipidemia, diabetes), in that blood pressure, lipids, and blood sugars are not at goal, but also are not causing immediate, life-threatening complications.
- Nonadherence with a medication regimen that is not immediately life threatening (e.g., nonadherence to an antihypertensive or nonadherence to a diabetes medication that is causing blood pressure or blood sugars to be poorly controlled, but at a level that does not warrant immediate attention.)

Based on time spent by the pharmacist in subject recruitment, enrollment, and follow-up in addition to her other responsibilities outside of the study, it was determined, within several months of starting the study, that a second study pharmacist would be needed to meet our projected enrollment numbers and complete the study in a timely manner. The second pharmacist joined the study team in October 2005, participated in education and training regarding the study, and enrolled her first participant in December 2005.

To assess inter-rater reliability, the second clinical pharmacist conducted an independent assessment of quality medication use on a random sample of participants seen by the primary study pharmacist (n=20). To determine physician agreement with the clinical assessments, a physician reviewed the assessments of quality medication use made by the clinical pharmacist for the random sample of 20, indicating whether the assessments appear valid and warrant attention.

Six- and Twelve- Month Visits

We conducted 6- and 12-month interviews and medical record reviews with all participants using virtually the same measures as at baseline (Table 1). All follow-up visits had to be scheduled within 6-weeks preceding or following the expected 6- and 12-month visit. In completing the assessments of quality medication use at 6 and 12 months, the pharmacist conducting the assessment did not refer to her previous assessments of quality medication use.

We assessed health care utilization during the study year at the 12-month visit. Specifically, the pharmacist elicited from the participant information regarding visits over the previous year to urgent care and the emergency room as well as admissions to a hospital, assisted living facility, and long-term care facility. This information was verified by the pharmacist through medical record review. The pharmacist also asked about falls during the past year. All data were entered into the database by the research assistant; we re-entered baseline, 6-, and 12-month data for a random sample of 20% of the participants to insure accuracy of data entry.

Sample Size and Planned Statistical Analyses

The sample size estimation for our study was based on confidence interval widths and detecting meaningful differences between Whites and African Americans in the proportion of individuals with at least one medication-related problem at baseline. A sample size of 100 per group met the conservative $np \geq 10$ or $n(1-p) \geq 10$ "sufficiently large" criterion where n=sample size and p=prevalence of at least one medication-related problem allowing the use of the normal distribution for calculation of confidence intervals.(41) This sample size resulted in 95% confidence interval half-widths of 6%-10% for prevalences ranging from 10%-90% and provided 80% power to detect absolute differences of at least 14%-21% between Whites and African Americans depending on the prevalences in the two groups (α=0.05). Using the number of medication-related problems and a Poisson regression power analysis, we would have 80% power to detect a difference of at least 17% in the rate of medication-related problems between Whites and African Americans assuming the average number of medication-related problems in Whites was 6 (α=0.05).(42,43)

Analyses

In this paper, we present demographic and baseline characteristics of our sample. However, we have outlined our planned analyses for subsequent papers. For our first objective, we will describe the quality of medication use among White and African American community dwelling older adults. This begins with descriptive statistics within each race group as well as comparisons between the races. Our primary variable of interest, medication-related problems, will be analyzed as both categorical variables (present or not by type) and as count data (total number of problems). Chi-square tests for independence and count data regression models will be used to compare these outcomes between White and African American older adults. Associations between other variables such as health literacy and functional status with medication-related problems will be investigated using correlations and regression models that are appropriate for the distributions of the variables being compared (e.g., continuous normal, discrete ordinal, binary data). These analyses will be conducted within each race group then combined if the relationship is found to be consistent by testing interaction terms in multivariable models.

Second, we will test the hypothesis that race *is an independent predictor of number of* medication-related problems, *controlling for factors such as age, number of medications, health literacy, functional status and drug therapy concerns*. We will also evaluate the quality of medication use using the set of explicit quality indicators developed in the ACOVE project.(31) We will analyze the data in a similar way to the work of Higashi et al.(4) Quality scores are calculated as the proportion of eligible patients who receive indicated care. This is reported as pass rates for each quality indicator for which an individual was eligible. The indicators are classified in 4 domains, with overall pass rates for each domain calculated and compared.

Our final goal is to assess the change in quality medication use over time. To do so, the prevalence and number of medication-related problems in total and by type will be reported at each time point (6 and 12 months). We also plan to estimate the incidence of new medication-related problems (overall and by type) at 6 months and 12 months by tracking the number of

new medication-related problems that have occurred since the last assessment as well as the persistence of problems (i.e., problems present at baseline or 6 months that remain unresolved at 6 or 12 months, respectively). We will test the following hypothesis: *the number of medication-related problems will remain unchanged over the one year study, specifically 6 months compared to baseline and 12 months compared to baseline*. The goal of the longitudinal analysis is to assess the stability (or change) in quality medication use over time and any factors that are associated with worsening of medication-related problems. We will use mixed model methodology to look at the effect of time (baseline, 6 and 12 months), type of problem, and any covariates that are found to be significant in predicting medication-related problems at baseline. Mixed models account for the intra-person correlation of data from the multiple time points and allow estimation of the variability of change over time across individuals. Knowing the stability of medication-related problems (or lack thereof) and important risk factors of instability will be critical for planning intervention trials designed to improve the quality of medication use in older adults.

Results

Progress to Date

The first participant was enrolled in April 2005, and we completed enrollment in August 2006. A total of 435 older adults were recruited for participation in the study to reach an enrollment of 200 older adults (100 Whites, 100 African Americans) (Figure 2). All participants were followed for 12 months, with the last visit completed in August 2007. Of the 200 older adults completing a baseline visit, 92% completed the 6-month visit (n=183) and 88% completed the 12-month visit (n=176). Baseline demographic characteristics for the 200 older adults enrolled in the study are presented in Table 4. On average the participants were over 75 years of age, predominantly female, and used more than 10 medications. We anticipate that the results of this study will be reported at a later time.

Discussion

The quality of health care in the United States continues to fall short of expectations. A contributing factor is the suboptimal use of medications; a problem that is causing significant morbidity and mortality and costing the healthcare industry billions of dollars each year. The quality of medication use is a particular problem among older Americans. In an observational cohort study it was found that the quality of pharmacologic care provided to older adults ranged from 10% to 100% (avoiding inappropriate medications (97%); prescribing indicated medications (50%); patient education, continuity and documentation (81%); and medication monitoring (64%)).(4) This study highlights the range of medication-related problems affecting the quality of care of older adults.

Efforts to measure and improve the quality of medication use in older adults have traditionally focused on specific problems (e.g., inappropriate drugs and doses), pre-determined combinations of medication-related problems, or individual diseases (even when patients have multiple chronic conditions). While these issues are important, they fail to take into account a more patient-centered perspective that considers the overall quality of medication use. Although current measures have substantially advanced our ability to both understand and assess the quality of medication use in older adults, they too have limitations. For example, the Beers criteria, while relatively easy to apply, too narrowly define quality, focusing only on the use of inappropriate medications in the elderly.(14) The Medication Appropriateness Index (MAI) substantially broadens the scope of assessing medication appropriateness by rating each medication a patient is taking, but may not account for all elements important to quality medication use.(15) And, while the ACOVE quality indicators include medication-related

processes of care (e.g., monitoring, documentation), they were not intended to assess the quality of medication use at the level of the individual.(16,31)

Our current longitudinal study seeks to extend these approaches to measuring the quality of medication use. Notably, we have designed our measures to provide the basis for intervening with elderly patients to improve the quality of medication use. Although the pharmacist's assessment is guided by a list of potential medication-related problems, ultimately the quality assessment is determined based on the unique medication needs of the participant after a thorough interview and medical record review. Limitations inherent in our approach include the implicit assessment of quality medication use as determined by the clinical pharmacist and the lack of physician-pharmacist collaboration in arriving at the final assessment. However, we believe this is an initial and necessary exploratory step toward better defining the elements of quality medication use at the level of the patient.

Conclusions

Strategies to better measure and improve the quality of medication use in older adults are needed. This longitudinal study is part of a larger research agenda in which we seek to build a more comprehensive, patient-centered measure of quality medication use and develop and test interventions to improve the quality of medication use and health outcomes for older adults.

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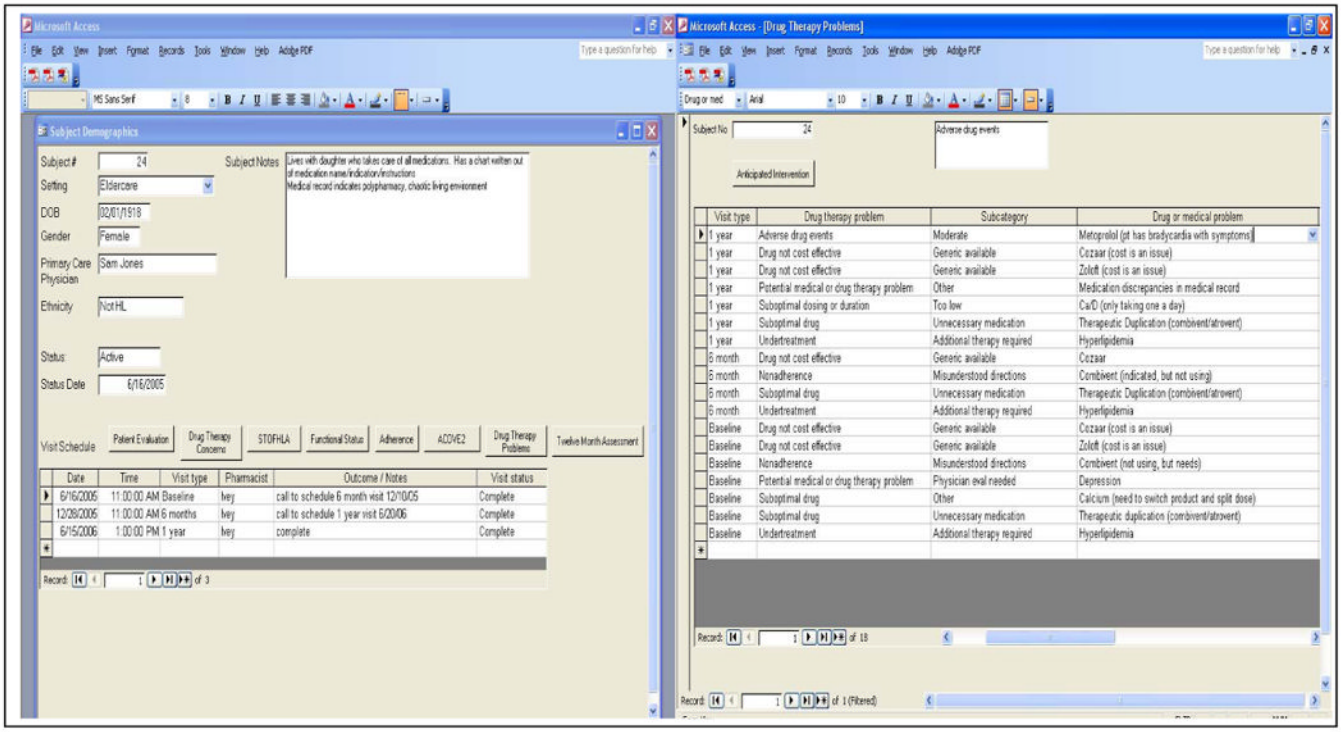

Figure 1. Sample Data Screen from Study Database

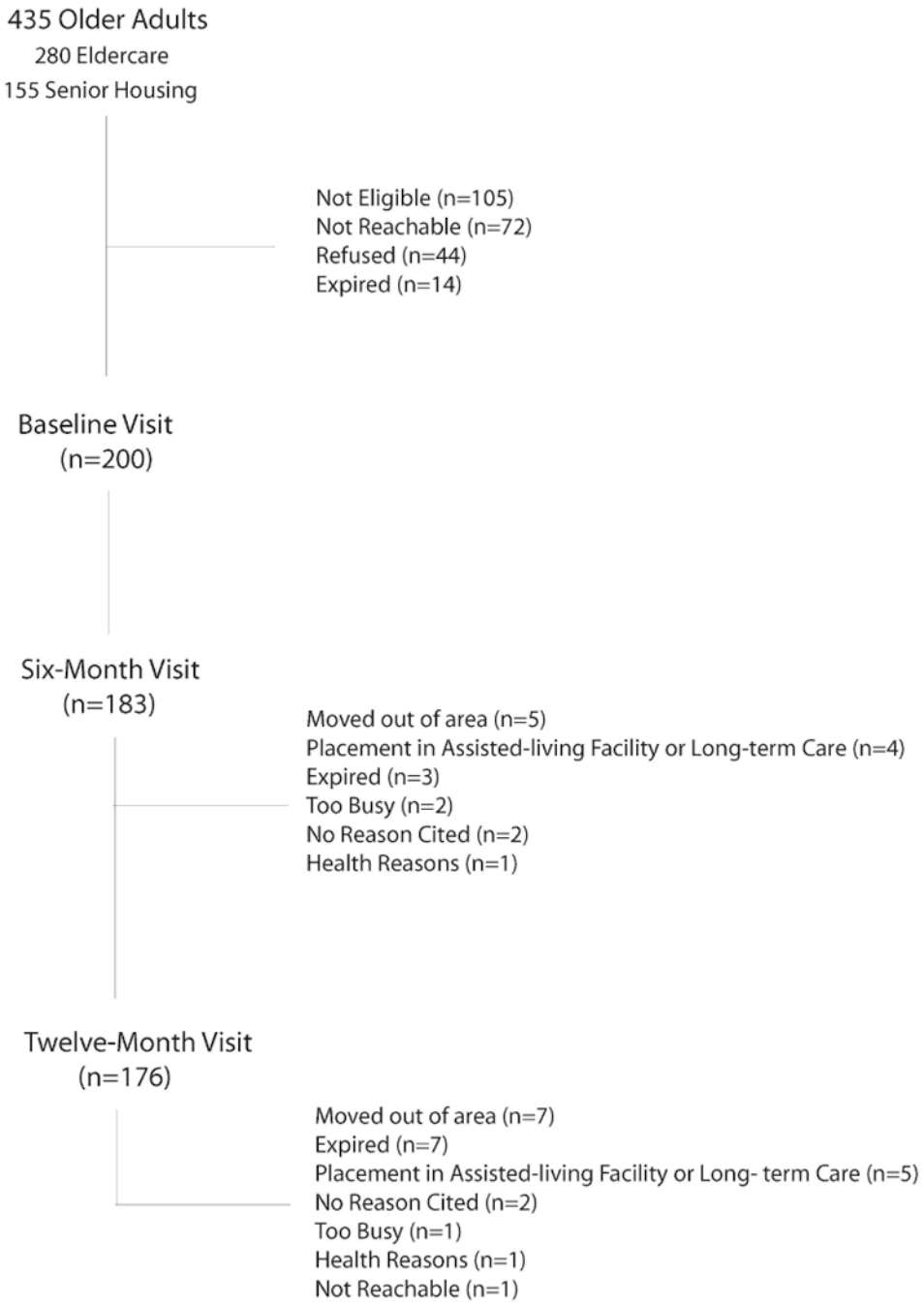

Figure 2. Subject Recruitment, Enrollment and Follow-Up

Table 1

Data Collection Schedule

MEASURE	SCHEDULE		
	Baseline	6 months	12 months
Demographic Characteristics	X		
Short-Test of Functional Health Literacy in Adults (S-TOFHLA)	X		
Drug Therapy Concerns	X	X	X
Instrumental Activities of Daily Living Scale	X	X	X
Clinical Pharmacist Assessment of Quality Medication Use	X	X	X
ACOVE-2 Quality Indicators of Medication Use	X	X	X
Healthcare Utilization			X

Table 2

Framework for Assessing the Quality of Medication Use

Potential Medication-Related Problem	Definition
Suboptimal Drug†	The individual is receiving a drug that has no indication, is not effective, or is potentially not safe (i.e., risk of using drug outweighs benefit).
Suboptimal Dosing or Duration	The individual is taking an appropriate medication, but the dose, duration, or frequency is not optimal to achieve desired response, or has the potential for harm.
Adverse Drug Events	The individual is experiencing adverse consequences attributed to a drug or the inappropriate use of a drug.
Nonadherence††	The individual has not filled a prescription, is not taking a drug, or is not using a drug as prescribed, whether intentional or unintentional.
Drug Not Cost Effective	The individual is prescribed a medication for which a less costly, equally effective and safe drug is available, and preferred by the patient, but the patient is receiving a more expensive product; or the patient could benefit from enrollment in a prescription drug program, but is not receiving the benefit and desires to.
Undertreatment	The individual has a medical condition that requires drug therapy (clear indication) and the patient has no contraindications to the drug, but the drug was not prescribed.
Inadequate medication monitoring	The individual is receiving a drug and monitoring is required to assess response to therapy or ensure safety, but has not been done.
Other (Potential Medical or Drug Therapy Problem)	The individual is receiving a drug for which there is a potential medication-related problem that cannot be categorized as one of the above problems.

† Problems, such as drug-drug, drug-food, and drug-disease interactions, when encountered, were classified as Suboptimal Drug, with a subcategory designation indicating a drug interaction. For this reason, a separate medication-related problem for Drug Interactions was not developed.

†† Table 3 provides detail regarding the pharmacist's assessment of nonadherence used in this study.

Table 3
Pharmacist Clinical Assessment of Adherence

The pharmacist, in meeting with the older adult, begins by having the individual explain how he/she uses each medication and the indication for each medication. Following the individual's explanation, the pharmacist asks the older adult a series of questions to determine whether the individual is likely adhering to the medication as prescribed. Following each question, the pharmacist inquires further to gather more information, as needed. Examples of questions include:

- In the past 2 weeks how many times have you missed taking a dose of this medication?
- In the past 4 weeks how many times have you missed taking a dose of this medication?
- Have you missed any doses in the last week?
- Overall, do you think you have taken your medication as prescribed?

In addition to the questions, the pharmacist also:

1 Inspects the medication bottles and pill boxes to assess the amount of medication remaining based on prescription fill date.

2 Inquires about reasons for not taking the medication as prescribed.

3 Assesses individual response to the medication through evaluation of medical conditions, laboratory values, or other signs or symptoms.

4 Examines the extent to which factors such as cost, access, cognition, polypharmacy, regimen complexity and other factors may impact ones ability to adhere to their prescribed regimen.

The pharmacist, taking into account all of the above, arrives at an implicit, clinical assessment of adherence (i.e., adherent, nonadherent) for each medication a person is taking. This results in *multiple* responses for each older adult with the total number of responses (medications) varying across individuals. We sum these binary variables and globally define adherence per person as the proportion of adherent medications out of the total medications prescribed, with ≥80%=adherent and <80%=nonadherent.(44) Additional analyses will be conducted to further explore rates of nonadherence (e.g., based on type of medication used, comparing various methods of assessment of adherence).

Table 4

Demographics and Baseline Characteristics (N=200)

	Whites (N=100)	African Americans (N=100)	P-value
Age (mean, SD)	78.3 (8.2); range 62 – 96	75.5 (8.5); range 60-95	0.017
Marital Status (%)			0.022
Married	33	23	
Widowed	40	50	
Divorced	24	15	
Never Married	3	8	
Other	0	4	
Female (%)	72	81	NS
Education (highest level completed,%)			<0.001
Some College or Technical School	24	12	
Postgraduate	23	4	
High School Graduate	21	35	
College Graduate	18	6	
Elementary	8	24	
Some High School	6	19	
Physicians, (mean, SD)	3.6 (1.8); range 1 – 9	2.8 (1.5); range 0-8	<0.001
Living Alone (%)	64	49	0.032
Medications† (mean, SD)	11.6 (5.0); range 3-26	9.7 (4); range 4-21	0.003
Chronic Conditions†† (mean, SD)	8.4 (3.1); range 2 - 19	7.4 (2.8); range 2-18	0.014
Pharmacies (mean, SD)	1.3 (0.57); range 1 – 3	1.3 (0.5); range 1-3	NS
Has Help with Medications (%)	16	16	NS
Uses Medication Aid (%)†††	70	57	0.056
Pill Box	47	50	NS
Written List of Medications	30	16	0.019
Other	16	6	0.024
Shows Written List to Physician (%)	18	11	NS
Has Some Form of Prescription (%) Drug coverage	91	94	NS
Could Not Purchase Meds Due to Cost (%)	12	28	0.005
Monthly Medication Expenses (%)			0.009
<$100	46	65	
$100 - $249	30	27	
$250 - $499	16	4	
$750 - $999	2	0	
Don't Know	6	4	
Time Spent Interviewing Minutes (mean, SD)	83.8 (20.9);range 50-165	78.8 (14.9); range 45-135	0.050
Time Acquiring Medical Record in Days (mean, SD)	4.2 (4.9);range 0- 28	4.2 (4.9); range 0-23	NS
Time Reviewing Records and Formulating Assessments in Minutes (mean, SD)	91.2 (60.7);range 0- 270	97.8 (53); range 0-255	NS

	Whites (N=100)	African Americans (N=100)	P-value

† Includes prescription, over-the-counter, and complementary and alternative medications.

†† Defined as any chronic condition documented in the medical record.

††† Do not total 100% since individuals could have reported use of more than one medication aid.

NS=Not Significant