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Development and testing of a tool for assessing and resolving medication-related problems in older adults in an ambulatory care setting: the individualized medication assessment and planning (iMAP) tool

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Abstract

BACKGROUND—Medications are one of the most important interventions for improving the health of older adults, yet have great potential for causing harm. Clinical pharmacists are well positioned to engage in medication assessment and planning. The *individualized* Medication Assessment and Planning (*i*MAP) tool was developed to aid clinical pharmacists in documenting medication-related problems (MRPs) and associated recommendations.

OBJECTIVE—To assess the reliability and usability of the *i*MAP tool in classifying MRPs and associated recommendations in older adults in the ambulatory care setting.

METHODS—Three cases, representative of older adults seen in an outpatient setting, were developed. Pilot testing was conducted and a gold standard key developed. Eight eligible pharmacists consented to participate in the study. They were instructed to read the case, formulate an assessment of MRPs and a plan, and document the information using the *i*MAP tool. Inter-rater reliability was assessed for each case, comparing the pharmacists identified MRPs and

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There are no conflicts of interest or financial interests to declare for any of the authors.

recommendations to the "gold standard." Consistency of categorization across reviewers was assessed using the kappa (κ) statistic

RESULTS—The mean κ across the eight pharmacists in classifying MRPs compared to the gold standard was 0.74 (range 0.54–1) for case 1 and 0.68 (range 0.36–1) for case 2, indicating substantial agreement. For case 3, percent agreement was 63% (range 40–100). The mean κ across the eight pharmacists when classifying recommendations compared to the gold standard key was 0.87 (range 0.58–1) for case 1 and 0.88 (range 0.75–1) for case 2, indicating almost perfect agreement. For case 3, percent agreement was 68% (range 40–100). Clinical pharmacists found the *i*MAP tool easy to use.

CONCLUSIONS—The iMAP tool provides a reliable and standardized approach for clinical pharmacists to use in the ambulatory care setting to classify MRPs and associated recommendations. Future studies will explore the predictive validity of the tool on clinical outcomes such as health care utilization.

Keywords

geriatrics; medication related problems; older adults; ambulatory care; reliability; medication assessment tool

Introduction

Medications remain one of the most important and common therapeutic modalities for improving the health and wellbeing of adults in the United States, yet their potential for harm is great [1,2]. Medication-related problems (MRPs) can be defined as a negative consequence of medication therapy that can compromise or have the potential to compromise one's health status, functional status, and quality of life. MRPs include problems such as adverse drug events, nonadherence, underuse of needed medications, and inappropriate prescribing [3,4]. Preventing medication-related problems as well as the associated morbidity and hospitalizations is important for all patients; however, given their multiple co-morbidities, multiple prescribers, and concurrent medication use, the quality of pharmacologic care is of particular concern in older adults [5,6].

Most efforts to minimize MRPs in older adults target high-risk drugs or pre-defined quality indicators related to appropriate medication use [4,7,8]. Such targeted approaches may identify only a fraction of the MRPs that an individual may be experiencing because they fail to examine and assess the individual's entire medication regimen [9]. Clinical pharmacists are well positioned to conduct comprehensive medication management. Most tools to assist pharmacists in classifying MRPs at the patient level either lack reliability and validity testing, are complex and difficult to use, or do not link MRPs with recommendations for addressing them [10–13]. For both clinical and research purposes, study investigators developed the *individualized* medication assessment and planning (*i*MAP) tool for classifying medication-related problems and recommendations. The objectives of this study are to assess: 1) the reliability of this tool in classifying MRPs and their associated recommendations in older adults in an ambulatory care setting and 2) its usability by clinical pharmacists.

Methods

Development of the *i*MAP tool

We first conducted an extensive literature search to identify existing tools which met the following criteria: 1) easy to use; 2) applicability in ambulatory care settings; 3) intuitive (i.e., pharmacists could relate to and easily identify categories of MRPs and

recommendations; 4) clear definitions of and distinctions between MRPs, their causes, and associated recommendations; and 5) good reliability and validity.

Several tools were identified, having a range of functions, formats, and constructs and were thoroughly reviewed by three clinical pharmacists [10–15]. Although no single tool met all of our criteria, each contributed to and informed the development of the *i*MAP tool. The three pharmacists used the identified tools to compile a complete list of MRPs and associated recommendations. The list was refined by eliminating duplicative/overlapping categories and adding categories felt to be missing. Because pharmacists felt it was important to separate the main MRP from information used to further describe the problem and also categorize associated recommendations, the *i*MAP tool was organized into three constructs:

- An assessment (i.e., the MRP)
- A cause or supporting information further describing the problem (i.e., subcategory classification)
- A plan (i.e., the associated recommendation)

These three constructs were aligned with the care plan process. In other words, the tool was developed to: (1) guide pharmacists' comprehensive assessment of an individuals' medication use, culminating in identified MRPs; (2) provide pharmacists with a mechanism for classifying clinically meaningful information about the cause of or supporting information to describe the MRP; (3) provide pharmacists with a mechanism for classifying their plan for addressing and resolving each MRP.

The MRP categories, subcategory classifications, and associated recommendations were developed, tested, and refined over a three-year period. The final modification resulted in 9 MRP categories, several accompanying sub-category classifications, and 20 categories for classifying recommendations. (Table 1) The tool also includes instructions and guidelines for use as well as detailed definitions for each of the 9 MRPs. The entire tool and accompanying guidebook is available from the author upon request.

Study Procedures

A residency trained, clinical pharmacist with expertise in geriatrics extracted three patient cases from the electronic medical record of an outpatient geriatric clinic in which she practiced. The cases were felt to be representative of medically complex older adults taking multiple medications. The clinical pharmacist developed the cases, compiling information about the patient and summarizing in the form of a comprehensive clinical note. Three clinical pharmacists with expertise in geriatric pharmacotherapy independently reviewed the three cases, each generating their own key. The three pharmacists discussed the cases and resultant keys and reached consensus on both the case write up itself as well as the corresponding gold standard key. Cases and keys were refined accordingly prior to the reliability testing. (Case1 with Gold Standard Key, Appendix). The Biomedical Institutional Review Board of the University of North Carolina at Chapel Hill approved this study.

We used e-mail to invite a convenience sample of ten clinical pharmacists to participate in the study. We felt that approximately 8–12 pharmacists was sufficient to conduct reliability testing on the tool. To be eligible to participate, participants had to be clinical pharmacists (defined as experts in the therapeutic use of medications who routinely provide medication therapy evaluations and recommendations to patients and health care professionals), have completed at least one year of post-graduate pharmacy residency training, and have an active clinical practice in an outpatient, ambulatory care setting in the local area [16]. We included clinical pharmacists who were in the midst of their second year of post-graduate

residency training (PGY2). The email contained an overview of the study and a demographic questionnaire. Completion and return of the demographic questionnaire served as the pharmacists consent to participate. Eight of the 10 clinical pharmacists (of which 4 were PGY2 pharmacy residents) consented to participate. Upon consenting, the pharmacists attended a two-hour meeting, at which time they were oriented to the study and the *i*MAP tool and provided instructions for completing the patient cases. The instructions asked the pharmacists to read each case and document the following using the *i*MAP tool (Table 1):

- Their assessment in the form of an MRP;
- The cause or supporting information for each MRP in the form of a subcategory classification;
- Their proposed plan for addressing each MRP in the form of a recommendation.

Each pharmacist was provided with a calculator. The pharmacists were advised not to discuss the cases with the other participants during the testing. The time to complete each case was recorded for each pharmacist. Following completion of all cases, the pharmacists, as a group, were asked a series of open-ended questions regarding usability of the tool.

Statistical Analysis

Study pharmacist characteristics were summarized using descriptive statistics. The units of analysis for each case were the MRP category and recommendations compared to the gold standard key. Consistency of categorization across reviewers (inter-rater reliability) was assessed using the kappa (κ) statistic for both the main MRP category and the recommendation compared to the gold standard for cases 1 and 2 [17–18]. Agreement was categorized as chance agreement (<0), slight agreement (0.01–0.20), fair agreement (0.21–0.40), moderate agreement (0.41–0.60), substantial agreement (0.61–0.80), and almost perfect agreement (0.81–0.99) [19]. The percent agreement between the gold standard key and pharmacist-identified MRPs and recommendations was reported in Case 3 due to the lack of variability in MRP categories on the gold standard key, which limited use of the kappa statistic. Additionally, the average kappa and range across the eight clinical pharmacists is presented and further subdivided as clinical pharmacist and PGY2 specialty pharmacy resident.

Results

Pharmacists' characteristics are summarized in Table 2. Four of the eight pharmacists were PGY2 pharmacy residents. The average time required for completion of cases was 39 minutes (range 20–60) for case 1, 22 minutes (range 13–35) for case 2, and 26 minutes (range 14–35) for case 3. The number of problems identified on the gold standard key decreased for each case: 10, 7 and 5, respectively.

Classification of MRPs

The results of reliability testing are summarized in Table 3. For case 1, the mean κ across the eight pharmacists in classifying MRPs compared to the gold standard was 0.74 (range 0.54–1), indicating substantial agreement. Agreement was better and more consistent across clinical pharmacists (mean 0.85, range 0.75–1) than across pharmacy residents (mean 0.64, range 0.54–0.75). For case 2, the overall mean κ was 0.68 (range 0.36–1). There was also substantial agreement for clinical pharmacists κ = 0.62 (range 0.36–0.78) and PGY2 pharmacy residents κ = 0.74 (range 0.58–1). For case 3, the percent agreement was 63% (range 40–100) overall: 55% (range 40–60) for clinical pharmacists and 70% (range 40–100) for PGY2 pharmacy residents.

MRP categories identified by the clinical pharmacist participants which were not part of the gold standard key were not considered in the statistical analysis. Reasons for this are discussed in greater detail in the discussion section of the manuscript.

Classification of Recommendations

For case 1, the mean κ across the eight pharmacists when classifying recommendations compared to the gold standard key was 0.87 (range 0.58–1), indicating almost perfect agreement. Agreement was similar across clinical pharmacists (mean κ = 0.86 (range 0.58–1) and PGY2 pharmacy residents (mean κ = 0.88, range 0.80–1). For case 2, the mean κ statistic was 0.88 (range 0.75–1) overall and for both clinical pharmacists and PGY2 pharmacy residents. For case 3, the percent agreement was 68% (range 40–100) overall, 77% (range 40–100) for clinical pharmacists, and 59% (range 47–67) for PGY2 pharmacy residents.

Categories of recommendations identified by the clinical pharmacist participants which were not part of the gold standard key were not considered in the statistical analysis. Reasons for this are discussed in greater detail in the discussion section of the manuscript.

Usability

Overall, all pharmacists found the *i*MAP tool easy to use and recommended only minor modifications to enhance usability:

- Spend time orienting and training pharmacists on the tool, allowing time for application followed by questions regarding its use;
- Consider shifting placement of some of the MRPs on the tool (e.g., “dose too low” and “dose to high” should be placed close to each other on the form to aid in location of each category.)
- Consider the MRP category “more affordable alternative available” as a subcategory classification of “suboptimal drug,” since cost is really one reason for the drug itself not being optimal.

Discussion

Several tools exist for clinicians and researchers to use in classifying medication-related problems, including tools such as the medication appropriateness index and Hepler and Strand’s list of drug therapy problems.10–11 We identified shortcomings in many of the available tools and sought to develop a tool to meet our needs in both the clinical and research setting.

The *i*MAP tool was developed for use by clinical pharmacists practicing in ambulatory care settings and for research purposes. The *i*MAP tool demonstrated substantial agreement in clinical pharmacists classifications of MRPs and almost perfect agreement fin their classifications of recommendations. The tool was viewed positively by the pharmacists with only minor suggestions for improving its use, demonstrating its face validity and general acceptance. There appeared to be no substantial difference in the ability of second-year pharmacy residents to use the tool in classifying MRPs or recommendations compared to clinical pharmacists in practice.

Although inter-rater reliability was substantial to almost perfect, there will always remain some degree of implicit judgment and subjectivity to a clinical pharmacist or other health professionals assessment of medication-related problems and the recommendations warranted to address them. In this study, areas of disagreement fell into two categories: 1)

MRPs and recommendations identified by the pharmacists which *were not* on the gold standard key and 2) MRPs not identified by the pharmacists which *were* on the gold standard key. With respect to both of these areas, the main reasons for the discrepancies were attributed to a) the problem simply being overlooked; b) inadequate therapeutic knowledge regarding the care of older adults; and c) differences in clinical judgment.

The potential application of the iMAP tool is significant. The primary purpose for its development was to have a reliable and practical tool for categorizing medication-related assessments and associated recommendations within research studies. Variations of the tool have been used extensively in the investigator's research studies, with refinements made over several years [20,21]. Future directions include use of the *i*MAP tool within a planned intervention trial and additional reliability testing conducted as part of that trial. The *i*MAP tool also has applicability in clinical practice settings as a standardized approach for use by clinical pharmacists in documenting medication-related assessments and recommendations. Having a standardized approach to documenting assessments and recommendations could be of benefit to the profession as we seek to better standardize our approach to documenting clinical pharmacy services. Finally, the tool could be used in educational settings to train pharmacy students in classifying medication assessments and recommendations.

This study has several limitations. First, the reliability testing included only eight clinical pharmacists. Only half of the pharmacists work exclusively with the older adult population which may have had an impact on their ability to identify geriatric-specific MRPs. This, however, would only serve to increase agreement. The paper cases, though extracted from the medical record and developed to mimic real patient case scenarios are not the ideal mechanism for testing the reliability of the tool. We could have conducted actual medical record reviews of patients, but our interest in testing this across several pharmacists from different practices without access to the same medical records limited our ability to use such an approach. Additionally, it was not possible to conduct reliability testing of the tool in a real world clinical setting. This would have required multiple interviews by different pharmacists with the same patient, which has limitations of its own. Additionally, the case-based tool was tested for use by clinical pharmacists practicing in an outpatient, ambulatory setting. While the tool may be useful in other clinical settings, its use in these settings would need to be tested. Finally, with respect to case 3, the percent agreement between the gold standard key and pharmacist-identified MRPs and recommendations was reported in Case 3 due to the lack of variability in MRP categories on the gold standard key, which limited use of the kappa statistic. Unlike cases 1 and 2 in which there was substantial variability in the types of MRPs identified, the types of MRPs identified in case 3 were all in the same category (i.e., suboptimal drug), thereby limiting our ability to use the kappa statistic. In hindsight, when finalizing the cases it may have been better to have replaced case 3 with a case that yielded more variability.

Future studies will seek to conduct reliability testing as part of a planned intervention trial and will also seek to determine the predictive validity of the tool as it relates to the impact of MRP categories and associated recommendations on improvements in clinical outcomes and reductions in health services utilization.

Conclusion

The *i*MAP tool provides a reliable method and a standardized approach for clinical pharmacists caring for older adults to document medication-related assessments and recommendations in the ambulatory care setting. Further testing is needed to document the tools predictive validity in assessing impact on clinical outcomes such as health care utilization.

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Appendix. Case 1, with Gold Standard Key

CASE 1

Ms. G is a 72 year old female who lives independently in her own home. She has hypertension, diabetes, history of stroke, osteoarthritis, gastroesophageal reflux disease, osteoporosis, history of falls (fell and sustained hip fracture 6 months ago), anxiety, and depression. She was last seen 4 weeks ago by her primary care physician. At that visit she had a blood pressure of 150/74 (average for past six months). She complained of fatigue during the day. She reported difficulty sleeping at night, which seems to have worsened over the past several months. She also noted pain in her joints, which she said she has “lived with for years,” but would like to see if medication would help. Her daughter, who accompanied her to the doctor’s visit, noted an increase in her mother’s frequency of “chest pain” over the past few months and wishes her mother would “get out of the house and socialize more often.” At the conclusion of the visit with her primary physician, Ms. G was given a prescription for propoxyphene to help with her pain, labs were drawn, her blood pressure medication (ramipril) was increased, and she was scheduled to see cardiology for further work-up of her chest pain. She is to return to her primary care physician in 4 months and was instructed to call if her insomnia does not improve.

Current Medications

The text in parentheses is information obtained by the pharmacist following a comprehensive medication review with the patient and her daughter

1. Aspirin 81 mg daily (patient may miss 3–4 times a week as she does not keep this one with her other prescriptions)
2. Ramipril 10 mg daily (increased at last primary care physician visit 4 weeks ago from 5 mg to 10 mg daily, taking each morning)
3. Glipizide XL 10 mg daily (taking daily, average fasting blood sugar over past few days is 150)
4. Metformin 500 mg three times daily (only taking once daily because having diarrhea)
5. Calcium citrate 600 mg 1 tablet twice daily (taking only once daily because can’t remember second dose)
6. Alendronate 70 mg once weekly (taking on Sunday morning with other medicines, started 6 months ago after fracture)

7. Sertraline 50 mg po daily at bedtime (started 6 months ago, does seem to be helping)
8. Nexium 20 mg daily in the morning (only taking twice weekly due to cost but really needs, could be causing atypical chest pain)
9. Propoxyphene N-100 1 tablet every 8 hours as needed for pain (taking about 2 tablets daily, pain somewhat improved)

Prescription Drug Insurance information

She is in a Medicare Part D prescription drug plan and is almost in the donut hole for the 2010 year. She does not qualify for the low-income subsidy. She prefers generics when possible.

Vitals (at today's visit)

BP 132/78, Pulse 72

LABS (at today's visit)

Serum creatinine 1.8 (1.6–1.8 baseline for past year)

Cholesterol: LDL 142, TG 240, HDL 32, and TC 222 (similar values 6 months ago)

HgA1c 7.2% (6 months ago—7.4%)

25-OH Total Vitamin D 45 ng/mL (30–50 ng/mL)

REPORTS

Last DEXA 6 mo ago (when bisphosphonate started) showed osteopenia (t-score -2.0 hip, t-score -1.8 spine)

Case 1 Gold Standard Key

1. Medication-related problem: Suboptimal drug

   Subcategory: Safer alternative available

   Associated Drug/Condition: propoxyphene

   Recommendation: Switch to safer alternative

   Note: Darvocet was still on the market at the time of the writing of this case and reliability testing
2. Medication-related problem: Drug therapy needed

   Subcategory: Additional therapy needed

   Associated Drug/Condition: Osteoporosis (Vitamin D)

   Recommendation: Add drug
3. Medication-related problem: Non-adherence

   Subcategory: Could not afford

   Associated Drug: Nexium

Recommendation: Switch to generic alternative

4. Medication-related problem: Non-adherence
   Subcategory: Memory
   Associated Drug: Aspirin
   Recommendation: Education; Provide adherence aid
5. Medication-related problem: Suboptimal drug
   Subcategory: Contraindication to therapy exists
   Associated drug: Metformin
   Recommendation: Discontinue drug
6. Medication-related problem: Medication monitoring needed
   Subcategory: Monitoring needed to assess for/prevent potential adverse drug events
   Associated drug: Ramipril
   Recommendation: Recommend lab test
7. Medication-related problem: Suboptimal regimen
   Subcategory: Administration not ideal or correct
   Associated Drug: Sertraline
   Recommendation: Change in administration time
8. Medication-related problem: Suboptimal regimen
   Subcategory: Administration not ideal or correct
   Associated drug: Alendronate
   Recommendation: Change in administration time
9. Medication-related problem: Drug therapy needed
   Subcategory: Untreated medication condition
   Associated condition: Hyperlipidemia or Diabetes
   Recommendation: Add drug
10. Medication-related problem: Non-adherence
    Subcategory: Memory
    Associated drug: Calcium
    Recommendation: Provide adherence aid; educate

Table 1

The *individualized* Medication Assessment and Planning (*i*MAP) tool

ASSESSMENT	
Medication-Related Problem[1]	**Subcategory Classification**
1. Drug therapy needed	**1.a** Additional therapy required **1.b** Untreated medical condition **1.c** Other
2. Dose too low	**2.a** Dose too low
3. Medication monitoring needed	**3.a** Monitoring needed to assess effectiveness/response to therapy **3.b** Monitoring needed to assess for/prevent potential adverse drug events **3.c** Monitoring needed for both of the above **3.d** Other
4. Suboptimal drug	**4.a** Safer alternative available **4.b** Not effective **4.c** No indication or need for therapy **4.d** Potential for drug interaction **4.e** Therapeutic duplication **4.f** Contraindication to therapy exists **4.g** Other
5. Dose too high	**5.a** Dose too high
6. Adverse drug event present	**6.a** Moderate **6.b** Severe
7. More affordable alternative available	**7.a** Generic alternative **7.b** Preferred formulary alternative **7.c** OTC alternative **7.d** Drug strength **7.e** Combination therapy **7.f** Other
8. Suboptimal regimen	**8.a** Duration too short **8.b** Duration too long **8.c** Administration not ideal or correct **8.d** Frequency not correct **8.e** Other
9. Nonadherence	**9.a** Misunderstood directions **9.b** Transportation **9.c** Could not afford **9.d** Felt better

ASSESSMENT	
Medication-Related Problem[1]	**Subcategory Classification**
	9.e Regimen complex **9.f** Felt worse **9.g** Fear of adverse events **9.h** Patient not aware of medication changes **9.i** Disbelief in drug effectiveness **9.j** Patient overusing medications **9.k** Memory/cannot remember to take medications **9.l** Other
RECOMMENDATION	
1. Add drug	**11** Recommend lab test
2. Change in administration time/route/dosage form	**12** Recommend other test
3. Change duration	**13** Refer to other health care professional
4. Change frequency	**14** Refer to physician
5. Discontinue drug	**15** Switch to preferred formulary agent
6. Decrease dose	**16** Switch to generic alternative
7. Educate	**17** Switch to more effective agent
8. Enroll in prescription benefit	**18** Switch to safer alternative
9. Increase dose	**19** Switch to OTC alternative
10. Provide adherence aid; educate	**20** Other

[1] Medication-related problem categories and subcategory classifications have been explicitly defined. Definitions are not included here, but are part of the *i*MAP tool and guidebook which is available upon request.

Table 2

Demographics of clinical pharmacists

	Clinical pharmacist (n=4)	PGY2 pharmacy resident (n=4)
Characteristic		
Age, median yrs (range)	35 (30–42)	28 (26–34)
BCPS[1] certification, %	100	50
Collaborative practice agreements, %	100	0
Practice Site		
Provide disease state management services, median % (range)	58 (30–75)	75 (70–80)
Provide comprehensive medication therapy management services, median % (range)	41 (25–70)	25 (20–30)
Patient population served, median yrs (range)	72 (18–100)	63 (18–100)

[1] Board Certified Pharmacotherapy Specialist

Table 3

Agreement in classifying MRPS and associated recommendations

	Case 1 Mean κ[1] (range)	Case 2 Mean κ[1] (range)	Case 3 % Agreement
MRP			
Overall (n=8)	0.74 (0.54–1)	0.68 (0.36–1)	63 (40–100)
Clinical pharmacists (n=4)	0.85 (0.75–1)	0.62 (0.36–0.78)	55 (40–60)
Pharmacy residents (n=4)	0.64 (0.54–0.75)	0.74 (0.58–1)	70 (40–100)
Recommendation			
Overall (n=8)	0.87 (0.58–1)	0.88 (0.75–1)	68 (40–100)
Clinical pharmacists (n=4)	0.86 (0.58–1)	0.88 (0.75–1)	77 (40–100)
Pharmacy residents (n=4)	0.88 (0.80–1)	0.88 (0.76–1)	59 (47–67)

[1]Kappa co-efficient: 0–0.2 slight agreement; 0.21–0.4 fair agreement; 0.41–0.6-moderate agreement; 0.61–0.8-substantial agreement; 0.81–1-almost perfect agreement [19]