A Pilot Study to Assess Patient Adherence to New Chronic Medications Following the Use of a Novel Adherence Tool and Individualized Counseling

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Sarah A. Treadway, PharmD, BCPS¹, Robert S. Helmer, PharmD, BCPS^{2,3},
Michelle Z. Farland, PharmD, BCPS, CDE⁴, and Shaunta M. Ray, PharmD, BCPS⁵

Abstract

Background: Medication nonadherence leads to an increase in morbidity and mortality. In the United States, it results in an annual estimated cost of \$290 billion in patients with chronic diseases. Several adherence screening tools are available for use, but none have been adopted for widespread use. **Objective:** Examine the impact of using a novel 3-item adherence tool (The Adherence Estimator) and individualized patient counseling on medication adherence, as determined by rate of initial prescription fill. **Methods:** This prospective, descriptive study enrolled patients discharged home from an inpatient adult family medicine service who received a prescription for at least one new chronic medication. Patients completed the Adherence Estimator survey for each new medication prescribed. All patients received counseling from a pharmacist or student pharmacist. Date of initial fill was determined by contacting the dispensing pharmacy. **Results:** The survey was completed for 79 medications. The rate of first fill for medications identified as low, medium, and high risk for nonadherence was 76.5% (n = 28), 71.4% (n = 20), and 94% (n = 17), respectively. **Conclusions:** The brevity of The Adherence Estimator and the ease of scoring allow the possibility of adoption for widespread clinical use. The survey permits immediate results that allow the clinician to tailor medication counseling toward the 3 most common predictors of nonadherence. The rate of first fill for medications classified as high risk was improved following administration of the tool and targeted medication counseling, 94% in our population compared to predicted probability of adherence of <32%. Several factors, including targeted counseling or study/tool limitations, could account for these results. Consideration should be given to revising the statements in the tool to a lower reading level. This screening tool provides significant advantages over available tools; however, further research is needed to determine the most appropriate population and setting for use of this tool.

Keywords

medication adherence, screening tool, pharmacist counseling, chronic disease

Background

Medication nonadherence is a significant challenge within the health care community in the United States.¹ Patients with chronic disease states experience an increase in morbidity as a result of medication nonadherence, often leading to disease progression, complications resulting in hospitalizations, reduced functional abilities, and lower quality of life.^{2–5} Higher rates of mortality among patients with chronic diseases who are nonadherent to medications have also been reported.^{3,6–9} In addition to morbidity and mortality, financial consequences also exist. In the United States, medication nonadherence in chronic disease results in an annual estimated cost of \$290 billion. This includes direct costs such as emergency department visits, hospitalizations

and additional outpatient primary care visits, as well as indirect costs such as missed work days.¹⁰

Estimates suggest that approximately 20% of patients never fill a prescription for a prescribed medication.¹¹ Of

¹Lake Erie College of Osteopathic Medicine, Bradenton, FL, USA

²Auburn University, Auburn, AL, USA

³University of South Alabama, Mobile, AL, USA

⁴University of Florida, Gainesville, FL, USA

⁵University of Tennessee Health Science Center, Knoxville, TN, USA

Corresponding Author:

Sarah A. Treadway, PharmD, BCPS, Department of Pharmacy Practice,
Lake Erie College of Osteopathic Medicine School of Pharmacy, Bradenton
Campus, 5000 Lakewood Ranch Blvd, Bradenton, FL 34211, USA.
Email: streadway@lecom.edu

Table 1. Available Screening Tools for Medication Nonadherence.

Tool	Length	Flesch Kincaid ¹³ Grade Level	Assessment of General or Medication-Specific Adherence Barriers
The Adherence Estimator ¹¹	3 items	10	Medication specific
Medication Adherence Questionnaire (MAQ) ¹⁴	4 items	6.1	General
Brief Medication Questionnaire (BMQ) ¹⁵	17 items	6.5	General and medication specific
Self-Efficacy for Appropriate Medication Use Scale (SEAMS) ¹⁶	17 items	7.8	General
ASK-20 ¹⁷	20 items	5.1	General
Beliefs and Behavior Questionnaire (BBQ) ¹⁸	30 items	7.5	General

the patients who initially fill a new prescription, 50% will eventually stop taking medication as prescribed.¹² Because of high rates of nonadherence and associated consequences, the National Council on Patient Information and Education advocates routine screening of patients to identify those at risk for or engaging in medication nonadherence.¹ Several screening tools are available for use in many chronic disease states, but none have been adopted for widespread use (Table 1). Many are lengthy and require a considerable amount of time for the patient to complete and the clinician to score. Additionally, available tools are aimed at identifying overall barriers to medication adherence rather than barriers for specific medications.

Given the drastic toll medication nonadherence may take on individual patients and the health care system as a whole, combined with the lack of a tool clinically feasible for routine screening in chronic diseases, researchers at Merck Sharpe & Dohme Corp developed and validated a 3-item screening tool to predict risk of nonadherence for specific medications.¹¹ This tool addresses the areas determined to be the most influential on medication adherence: one statement addresses perceived need for the medication, one statement addresses concern for harm, and one statement addresses medication cost.¹¹ Research suggests that different factors influence adherence by the same patient to different medications.¹¹ When the survey is administered to the patient for each new medication, he/she ranks the degree of agreement regarding that particular medication with the statement in the tool using a Likert-type scale, and each response corresponds with a specific point value. The clinician adds the point values in order to categorize risk of adherence problems. A score ≥ 8 indicates high risk for adherence problems, 2 to 7 indicates medium risk, and < 2 indicates low risk. Risk for nonadherence varies based on medication classification: low risk indicates $> 75\%$ probability of adherence, medium risk 32% to 75% probability of adherence, and high risk $< 32\%$ probability of adherence.¹¹ An online version of the tool is available.¹⁹ Although the tool is brief, the Flesch Kincaid reading level is higher than other medication nonadherence screening tools (Table 1). The recommended reading level on which health information should be written is fifth grade.²⁰

The purpose of this study was to examine the impact of using a novel adherence tool (The Adherence Estimator) and individualized patient counseling on medication adherence, as determined by rate of initial prescription fill.

Methods

This was a prospective, pilot study conducted at an academic medical center in patients discharged from an inpatient family medicine service. The study was approved by the institutional review board prior to patient enrollment. Permission was obtained from Merck Sharpe & Dohme Corp for the use of The Adherence Estimator.

Patients discharged from the inpatient family medicine service and prescribed at least one new chronic medication (intended for use for at least 6 months) were eligible for enrollment if they were older than 18 years of age, English speaking, and discharged home following inpatient admission. New medications included those never previously taken by the patient, or medications the patient had previously taken if at least 12 months had elapsed since last administered.

Once eligible patients consented and signed the release waiver for protected health information, they were asked by a pharmacist or student pharmacist to complete the Adherence Estimator survey for each new medication prescribed, as different factors influence adherence to different medications. Patients were also asked to provide the pharmacy at which prescriptions would be filled following hospital discharge. The survey(s) was completed by the patient using pen and paper. Responses were scored at bedside, immediately following completion by the patient, to determine risk of nonadherence for each medication for which a survey was completed. Medication counseling was provided immediately following scoring of the survey by a pharmacist or student pharmacist. For medications identified as medium or high risk for nonadherence based on survey results, counseling by the pharmacist or student pharmacist targeted areas identified by the survey to contribute most to adherence problems for that specific medication—perceived need for the medication, concern for harm, and medication cost. Administration of the survey, scoring of the survey, and

Table 2. Characteristics of the Study Population (N = 45).

Age, years (mean $\pm$ SD)	56.13 $\pm$ 14
Male (n, %)	24 (53.3%)
Race (n, %)	
White	40 (88.8%)
Black	5 (11.1%)
Prescription insurance (n, %)	
Private insurance	27 (60%)
Medicare	10 (22.2%)
State Medicaid	2 (4.4%)
None	5 (11.1%)
Unknown	1 (2.2%)

patient counseling occurred in a single session following entry of the pharmacist or student pharmacist into the patient room.

One week following discharge, the dispensing pharmacy was contacted to obtain the date of initial fill for each medication. Patient characteristics and rate of first fill were summarized using descriptive statistics.

Results

The Adherence Estimator was completed by 45 patients for 79 new medications. The majority of the study population was male, with an average age of 56 years (Table 2). The most common medication class prescribed overall was antihypertensives, followed by antiplatelets/anticoagulants and lipid lowering agents (Table 3). Of the 79 medications surveyed, 34 (43%) were classified as low risk, 28 (35.4%) as medium risk, and 17 (21.5%) as high risk for nonadherence. The overall rate of first fill within 7 days following discharge was 78.5%. The rate of first fill for low, medium, and high risk medications was 76.5%, 71.4%, and 94%, respectively.

Discussion

The Adherence Estimator is a brief 3- item survey that was validated to detect the probability of nonadherence for medications across an array of chronic disease states.^{11,21} The brevity of the tool and the ease of scoring make routine clinical use of the tool possible; however, the high reading level at which the survey is written may limit widespread use. The statements in the tool are written at a 10th-grade reading level, several grade levels above the fifth-grade reading level recommended for health information.^{13,20}

In the tool validation population, approximately 45% had at least some high school education and/or a high school diploma compared to 38% of the population of the county where this study occurred, although we did not collect education level of study participants.²¹ An unexpected observation made during the study implementation was that when

administering the tool, many patients asked the pharmacist or student pharmacist to interpret the statement(s) and/or had to read the statement and responses several times before providing a response. Misinterpretation or misunderstanding of the statements may have led to inaccurate responses, which may be a result of the high reading level of the items included in the tool.

Additionally, inaccurate responses may have been a result of administering the survey at hospital discharge. This differed from the tool validation population in that patients who participated in the validation of the tool were outpatients identified using a claims database when an index medication was filled, and contacted 2 weeks following the date of initial fill to complete the survey.²¹ Unlike the validation population, our patients were unable to form opinions about newly prescribed medications based on information received from the outpatient pharmacy and personal use. When administering the survey to patients in this study near discharge, we found that many patients had not yet been informed of new medications and were ill-equipped to accurately complete the survey given the limited baseline knowledge. Administration of the survey at hospital discharge rather than in outpatients limits the ability to directly compare adherence rates for these populations. Additionally, adherence was assessed using fill information provided by the pharmacy in our study, which differed from the self-reported adherence assessed in the validation population. This also limits the ability to directly compare adherence rates. As well, since patients provided pharmacy information at discharge, if the prescription was filled at a different pharmacy than was provided, this would limit the information investigators were able to gather regarding whether or not the prescription was filled.

Another consideration is that the tool was used in this study to detect risk of adherence problems for medications that treat additional disease states outside of those used for validation of the tool as well as across in a broader patient age range. The tool was validated for medications in patients >40 years old with 1 of 5 chronic diseases and in some cases specific medications used to treat those diseases, including cardiovascular disease, dyslipidemia, diabetes (oral hypoglycemic agents), osteoporosis (oral bisphosphonates), and asthma.²¹ Our study population differed from the validation population in that we included patients ≥ 18 years old; however, only 3 patients, accounting for 4 of the 79 medications included in the study, were from patients who were under the age of 40 years. We also included chronic medications for other disease states and indications, including chronic obstructive pulmonary disease (COPD), gastrointestinal disorders, psychiatric disorders, and seasonal allergies. This accounted for approximately 13 medications, although the exact number is unknown since inhaled medications for both asthma and COPD were grouped together as pulmonary agents. The expanded use of the tool in our study limits the ability to directly compare the

Table 3. Characteristics of Medications.

	High-Risk Medications (n = 17)	Medium-Risk Medications (n = 28)	Low-Risk Medications (n = 34)
Generic medication dispensed (n, %)	13 (76.47%)	17 (60.71%)	20 (58.82%)
Cost per medication, ^a US\$ (median, IQR)	5.00 (4-13.15) ^b	5.15 (2.88-15.27) ^c	4.00 (1.42-9.28) ^c
Medication category			
Antihypertensive	5	8	17
Antiplatelet/anticoagulant	4	8	6
Lipid-lowering agent	4	6	4
Pulmonary	1	2	3
Gastrointestinal	1	1	2
Oral hypoglycemic	0	1	1
Allergy medicine	1	1	0
Antiarrhythmic	1	0	1
Psychotropic	0	1	0

Abbreviation: IQR, interquartile range.

^aRefers to the price the patient paid at the pharmacy to retrieve the medication.

^bData missing for 1 medication.

^cData missing for 4 medications.

rate of first fill to the original validation data, as rates of first fill may vary based on medication used and disease state treated. Use of the tool for additional chronic disease states and medications outside of those used for validation of the tool is an important consideration when evaluating widespread clinical utility of the tool.

An identified limitation of the tool is the measured specificity in the original validation study for the Adherence Estimator. The identified specificity of the tool is 59%, leading to the potential for up to 41% of patients who are actually adherent to their medications to be misclassified as medium or high risk.¹¹ This high rate of false positives for nonadherence may support the reason medications in this study that were classified as high risk for adherence problems had a high rate of first fill. In clinical practice, this high false positive rate would not likely have a negative effect on patients, as it would result in patients receiving additional beneficial medication education.

Overall, the rate of first fill for new chronic medications was 78%, which is consistent with previous reports that 80% of new prescriptions are initially filled.¹² First fill rates for low-risk (76.5%) and medium-risk (71.4%) medications were consistent with estimates of the probability of adherence according to the Adherence Estimator; however, the rate was much higher than predicted for high-risk medications at 94%. Although there may be several explanations for the high rate of first fill for high-risk medications, 94% compared to the predicted rate of probability <32%, the clinical utility of administering the survey and providing patient-directed counseling by pharmacists may be an important factor in contributing to increased adherence.

Conversely, limitations of the study and the survey tool may have contributed to falsely inflated first fill rates. Therefore, study results will need to be confirmed with a larger sample size and more diverse patient population

Conclusion

The Adherence Estimator is a brief 3-item survey that has the potential to be adopted for routine clinical use. The availability of a brief tool for use across an array of disease states allows clinicians to target medication counseling and potentially increase medication adherence preventing morbidity and mortality associated with medication nonadherence in chronic diseases. Use of this tool provides an impetus for pharmacists and student pharmacists to counsel patients regarding newly prescribed medications and efficiently use that time to target specific contributors to medication nonadherence. Revisions of the statements in the tool to the fifth-grade reading level should be considered in order to ensure accurate patient responses, and encourage widespread use. Following revisions to the tool, revalidation of the modified tool may be necessary. Future studies should aim to determine the timing (eg, before or after the first fill of the medication) and setting (eg, hospital discharge, physician office, dispensing pharmacy) to administer the tool for best accuracy. Additionally, time required to administer the survey and provide targeted counseling should also be evaluated, as this would significantly affect feasibility of routine clinical use. While this screening tool provides significant advantages over available tools, further research is needed before widespread use of this tool can be adopted.

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Authors' Note

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Michelle Z. Farland served on the speaker's bureau for Merck & Co, Inc, 2009-2011. The other authors have no known or suspected conflicts of interest.

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