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RESEARCH NOTES

Using Indian Health Service (IHS) counseling techniques in an independent community pharmacy to improve adherence rates among patients with diabetes, hypertension, or hyperlipidemia

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ABSTRACT

Objectives: To 1) identify barriers to medication adherence and 2) examine the relationship between the Indian Health Service (IHS) 3 prime questions and medication adherence in patients with diabetes, hypertension, or hyperlipidemia before and 6 months after intervention.

Methods: This quasi-experimental study evaluated the effectiveness of an adherence program at an independent community pharmacy. Patients who met inclusion criteria were telephoned monthly to answer questions related to their medications. Patients served as their own controls to show comparison between pre- and postintervention adherence rates calculated according to proportion of days covered over the previous 6 months. Mean medication adherences before and after intervention were assessed via paired *t* test. Linear regression was used to analyze predictors of average medication adherence. The Charlson Comorbidity Index was used to measure the impact of comorbid conditions on medication adherence.

Results: Fifty-six of 354 patients met inclusion criteria, consented, and completed the study. The percentage of patients achieving an adherence rate of 80% or more increased from 9% initially to 59% at study completion. Each medication class showed improvement in adherence rates: diabetes from 66.24% to 80.06% ($P = 0.0153$), hypertension from 72.33% to 81.34% ($P = 0.0192$), and hyperlipidemia from 64.45% to 74.66% ($P = 0.0103$). Overall, average medication adherence increased by 11% ($P < 0.0001$). The top patient-reported barrier to adherence was convenience/forgetfulness (46.43%).

Conclusion: Pharmacist-led counseling sessions with the use of the 3 prime questions showed short-term improvement in adherence rates among patients participating in a medication adherence program. Future studies should assess if improved adherence is sustained long-term following active intervention.

Medication nonadherence greatly affects the U.S. health care system through increased morbidity, mortality, and societal costs.[1] Estimated nonadherence costs to the health care system may be as high as $300 billion each year.[2] More than one-third of American adults experience barriers to medication adherence, such as low socioeconomic status, poverty, and inadequate health literacy.[3] Although the association was weak, a systematic review and meta-analysis found an association between health literacy and adherence.[4] Key factors that may affect medication adherence include unwanted side effects, complexity of regimen, convenience, forgetfulness, cost, educational barriers, transportation barriers, no perceived value in therapy, and lack of understanding treatment or directions.[5]

Community pharmacists see patients an average of 35 times a year, presenting the opportunity to provide medication

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education and address patient barriers to adherence.[6] Previous literature showed improved adherence from community pharmacist interventions with medication therapy management and telephonic intervention with the use of the Drug Adherence Work-Up (DRAW) tool, a validated adherence scale.[7,8] A Cochrane Database Systematic Review published in 2014 reviewed previous studies assessing methods to improve adherence, concluding the current methods are complex and not very effective at improving medication adherence.[9]

Counseling communication methods were assessed for their impact on adherence, including motivational interviewing and cognitive behavioral therapy, but the Indian Health Services (IHS) technique was not investigated for impact on adherence.[9] It uses 3 prime questions to help patients recall important points regarding their medications.[10] These 3 questions are: 1) "What did your doctor tell you this medication was for?" 2) "How did your doctor tell you to take this medication?" and 3) "What did your doctor tell you to expect from this medication?"[10] Previous studies have assessed its impact on patient knowledge and disease state control. The Patient and Pharmacist Telephonic Encounters (PARTE) study used a communication guide based on the IHS patient-counseling model to evaluate and address patients' barriers to managing their asthma medications and to improve asthma control in underserved rural asthma patients. Patients received 3 telephone consultations regarding asthma self-management and medication use over a 3-month period, and pharmacists contacted the patient's primary health care provider if necessary to assist with resolving an identified problem.[11] That study found an improvement in asthma control and asthma control medication adherence.[11] The PARTE study guided the development of the present study, that is, a similar communication guide to be implemented in a community setting to improve adherence to diabetes, hypertension, and dyslipidemia medications, because nonadherence to these drug classes has been associated with worsened condition(s) and increased risk of mortality.[12-14]

In 2007, the Centers for Medicare and Medicaid Services (CMS) created the Star Ratings, with 5 quality measures specifically related to medication management: high-risk medications, appropriate glycemic control, diabetes medication adherence, hypertension medication adherence, and cholesterol medication adherence.[15] CMS does not issue Star Ratings to pharmacies, but health plans can issue their own ratings to alter their network to contain only pharmacies that are proficient at meeting CMS-defined quality measures.[15] Community pharmacies that want to remain in health plans' preferred networks must prioritize optimizing patients' medication adherence.[15] Therefore, the goal of the present study was to create a pharmacist-led adherence program using a communication guide based on the IHS 3 prime questions and to measure its impact on adherence.

Objectives

This study sought to 1) identify patient-reported barriers to medication adherence and 2) examine the relationship between the IHS 3 prime questions and medication adherence in patients with diabetes, hypertension, and hyperlipidemia before and 6 months following intervention.

Methods

Study design and setting

This observational study was conducted at a high-volume, neighborhood-based, independent community pharmacy located in southeastern North Carolina that offers a variety of patient care services. At the study site, barriers to adherence were apparent, with a majority of patients not adherent, defined as an adherence rate less than 80% according to proportion of days covered (PDC) over the past 6 months, to diabetes, hypertension, and dyslipidemia medications.[16] The site sought new ways to affect the pharmacy's projected contribution toward Star Ratings. Before implementation of this new adherence program, the pharmacy relied heavily on automated calls to notify patients of medication due for refill.

Participants

Patients were eligible for inclusion if they were taking a noninsulin medication for diabetes, renin-angiotensin system antagonist for hypertension, or statin for hyperlipidemia. Eligible patients were also at least 18 years of age, had a baseline medication adherence rate of 50% to 79% according to PDC measure for at least 1 of the study drug classes, had a working telephone number, spoke English, had no dose changes for any of the studied medications within the past 6 months, and had a medication fill history at the study site for at least 6 months. Of note, patients could be included if they had an adherence rate of 80% or more to one of the study drug classes but an adherence rate of 50% to 79% to another. Claims data from the software platform were used to identify potential patients.

Study procedures

A pool of 354 patients who met the inclusion criteria were identified. Letters, including information sheets describing the study and consent forms, were mailed to prospective patients to introduce the study. About a week later, a pharmacist contacted each prospective patient to determine his or her willingness to enroll in the study and answer any questions. If a patient was interested in participating, the pharmacist obtained oral consent and gathered baseline adherence rates for the qualified drug class or classes from the software platform. Interested participants were also allowed to provide written consent by mailing the form back or bringing it to the study site.

Intervention

Patients received 6 consultations (mainly telephone) from the study pharmacist regarding medication use and potential barriers to adherence over a 6-month period (approximately 1 call per month). Following a standardized communication guide (Appendix 1), the study pharmacist evaluated patients' knowledge of their medications and addressed barriers to managing their medications. The communication guide was based on the 3 prime questions used by the IHS technique and discussed adverse effects, drug interactions, and precautions and contained a list of potential perceived barriers to

Table 1
Medication adherence (PDC) by drug class

Parameter	All	Diabetes	Cholesterol	Hypertension
Average baseline	67.67%	66.24%	64.45%	72.33%
Average final	79.11%	80.06%	74.66%	81.34%
Mean change	11.4383%	13.5646%	11.1259%	8.0406%
P value	< 0.0001	0.0153	0.0192	0.0103

Abbreviation used: PDC, proportion of days covered.

Table 2
Linear regression

Variable	β	*P* value
Average baseline adherence	0.2572	0.2616
CCI	2.3854	0.0707
Race	0.7503	0.8851
Gender	−5.6637	0.3128
Insurance plan type	−7.1152	0.2200

Abbreviation used: CCI, Charlson Comorbidity Index.

medication adherence. The study pharmacist collaborated with patients to identify barriers and implement solutions. At the end of each month from September 2016 to February 2017, a report was generated from the software platform to contain patient adherence rates for the studied drug classes. The study pharmacist contacted the patient's primary health care provider with the use of the provider fax form (Appendix 2) if he or she deemed it clinically necessary to assist with resolving an identified problem. The provider fax form served as a template to communicate recommendations related to any issues discovered during the monthly consultation.

Measures

The following variables for each patient were collected via the software platform: age (in years), gender (male vs. female), insurance plan type (no insurance vs. private insurance vs. government insurance), and medication adherence rates before the intervention (as PDC). Patients reported their race (black vs. white) and comorbidities during the initial encounter. Adherence was measured with the use of the following PDC formula: number of days in period "covered" divided by number of days in the time period. The Charlson Comorbidity Index (CCI) was also calculated for each patient with the use of an online CCI calculator. The calculator consisted of 17 comorbidities, with 2 subcategories for diabetes and liver disease.[17]

The possible 13 patient-reported barriers to adherence were chosen based on the DRAW tool and noted potential causes for nonadherence on 2 major medication therapy management platforms (OutcomesMTM and Mirixa). The chosen list of barriers contained some of the most common patient perceived barriers, listed in Appendix 1, to adherence seen in practice.

Statistical analysis

All analyses were conducted with the use of SAS v9.2 (SAS Institute, Cary, NC). Descriptive statistics were used for the demographic, medication, and adherence variables. A paired *t* test was used to examine whether there was a difference in medication adherence rates from baseline for each medication class separately and then for a patient's overall medication rate (average of adherence rates for each studied disease state). A linear regression was conducted to determine the effect of the following variables on final medication adherence: baseline medication adherence (PDC), CCI (online calculator), race (black vs. white), gender (male vs. female), and insurance plan type (no insurance vs. private insurance vs. government insurance). Before analyses, histograms and qq-plots were evaluated to ensure ordinary least square assumptions were met. An alpha level of 0.05 was used to assess statistical significance. The Wingate University Research Review Board approved this study.

Results

Fifty-six of 354 patients met inclusion criteria, consented, and completed the study. The average patient was a 60.62-year-old black woman who was insured by Medicare and had a CCI of 4.42. The average baseline adherence was 67.67% for all medications (diabetes, hypertension, and hyperlipidemia), 66.24% for diabetes medications, 72.33% for hypertension medications, and 64.45% for hyperlipidemia medications.

The pharmacist-led intervention resulted in an increase of 50% more patients achieving the adherence rate of at least 80% to one of the study drug classes: from 9% (n = 5) of patients initially to 59% (n = 33) at study completion. Of note, all of the patients with at least 80% average adherence at baseline maintained that level at the final visit. The adherence rates for each drug class improved by approximately 10% from baseline. The pharmacist-led intervention resulted in statistically significant different adherence rates for all 3 drug classes. Table 1 presents the pre- and post-intervention values for each drug class. Specifically, diabetes medication adherence increased from 66.24% to 80.06% ($t = 2.85$; $df = 19$; $P = 0.0153$), hypertension medication adherence increased from 72.33% to 81.34% ($t = 2.54$; $df = 37$; $P = 0.0192$), and hyperlipidemia medication adherence increased from 64.45% to 74.66% ($t = 2.47$; $df = 32$; $P = 0.0103$). Overall, average medication adherence increased by 11% ($t = 4.25$; $df = 55$; $P < 0.0001$).

A total of 8 out of a possible 13 barriers to adherence were reported during the pharmacist-led counseling intervention among all patients included in the study. The 8 reported barriers included cost, stockpile, transportation, forgetfulness, health status, drug regimen complexity, no value seen in therapy, and adverse effects. Most participants reported convenience/forgetfulness (46.43%) as their main barrier to getting their medication(s) refilled on time each month. Patients were able to report multiple barriers to adherence. Table 2 presents results of the linear regression. According to the linear regression, which explained ~4% of variance, there were no significant predictors of postintervention adherence.

Discussion

The primary goal of this study was to examine the relationship between the IHS 3 prime questions and medication adherence in patients with diabetes, hypertension, or hyperlipidemia before and 6 months after intervention. The intervention sessions aimed to improve patients' understanding of the purpose of their medications, directions for use, and how to monitor for adverse effects, as well as identify barriers to

adherence and ways to overcome them to reach an adherence rate of 80% or above. The principal finding was that study participants demonstrated significantly improved short-term medication adherence during the intervention. Future research should investigate whether improved adherence can be sustained over a longer time period. Although there is evidence of pharmacist-led interventions in improving medication adherence,[11,18,19] assessing the impact of the 3 prime questions as an effective intervention to increase medication adherence is novel. This is the first study, to the authors' knowledge, to examine the relationship between the IHS counseling technique of 3 prime questions and its impact on patient adherence. Given the complexity of adherence and findings from a Cochrane review that existing interventions are not very effective at improving adherence, results of this study must be validated in a larger and more diverse population.[9] Use of the 3 prime questions may help to improve patients' understanding of their medications and potentially improve medication adherence.[10]

Forgetfulness was the most prevalent patient-reported barrier to adherence in this study. This result was consistent with previous studies in which majorities of patients attributed their medication nonadherence to forgetfulness.[20,21] Medication aids such as pill boxes and automated telephone reminders have the potential to address forgetfulness as a barrier to adherence.[11] A systematic review conducted by Cutrona et al. found that pharmacist intervention via reminder tools improved cardiovascular medication adherence from 7% to 27%.[22] A counseling session with a pharmacist moderates the high risk of nonadherence and helps patients to establish a daily routine to potentially improve their long-term clinical outcomes.[23]

Future research should be conducted to assess the impact of other covariates, such as patient's knowledge, on medication adherence in the community pharmacy setting and to validate the use of the present methodology to improve patient adherence. The longevity of improved adherence after cessation of active intervention is unknown. This will be an important area for future research, because health behavior researchers have provided evidence that patients' ideas about their diseases and medications is one of the predictors of medication adherence.[24]

Limitations

This study has several limitations. It used patient data from a single independent pharmacy, so results may not be generalizable. The interview instrument was not validated. The study used claims data to measure adherence and was not able to determine whether the medications were actually taken as prescribed. Inaccuracy may have occurred because monthly data collection was based on claims data and could not account for patients who were instructed to discontinue their medication for a specified period of time or permanently.

Conclusion

Medication counseling is critical for patients' understanding of their medication regimens. Brief counseling interventions using the IHS 3 prime questions allowed identification of patient medication knowledge and identification of potential barriers that could be remedied, which significantly improved medication adherence, but we did not assess long-term maintenance of adherence without active intervention. Using the IHS 3 prime questions may present a novel method to improve patient medication knowledge and adherence, but more robust and confirmatory long-term studies are needed.

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Appendix 1

Communication guide

Introduction
Identify patient on telephone call using first and last name, date of birth
Introduce yourself by name
Establish purpose, importance, and length of counseling
Explain medication(s)
State medication name and dose
State generic name when appropriate
Ask: “What did your doctor tell you this medication was for?”
Verify medical condition being treated
Explain how the medication works in layman's terms and how long to take effect
Ask: “How did your doctor tell you to take this medication?”
State schedule
State duration of use
Probe for adherence problems and recommend strategies to enhance adherence with this medication
Instruct on how to handle a missed dose
Discuss refills of medication
Explain any special instructions
Recommend proper storage and ancillary instructions (e.g., shake well, refrigerate, etc.)
Ask: “What did your doctor tell you to expect from this medication?”
Explain or verify expected outcome
Explain how to monitor for efficacy
Explain any beneficial activities (e.g., exercise, reduced salt intake, diet)
Discuss adverse effects/drug interactions/precautions
Explain adverse effects of high frequency or clinical significance
Explain how to avoid or manage adverse effects
Explain drug interactions (drug-drug, drug-food, drug-disease) or medications to avoid
Discuss precautions (any activities to avoid, etc.)
Final verification
Find out any barriers the patient perceives:
1. adverse events/adverse effects
2. care transition
3. complexity of drug/dosing/regimen
4. convenience/forgetfulness
5. cost
6. educational barriers
7. lack of motivation/well-being/depression/fear/anxiety
8. health status or illness
9. lack of knowledge/understanding of treatment/directions
10. religious barriers
11. social barriers including family/friend acceptance/judgment
12. patient does not see or understand value in therapy
13. Other
Provide appropriate closing and recheck for any questions or concerns (e.g., teach-back)
Schedule follow-up if appropriate to assess problems and monitor effectiveness of new therapy
Make yourself available in the future
Thank the patient by name

Appendix 2

Seashore Discount Drug
2059 Carolina Beach Road
Wilmington, NC 28401
P: (910) 762-6278 • F: (910) 343-0710

Recommendations from Pharmacist to Provider

Physician:	
Patient:	**DOB:**

This patient is currently under the joint care of your practice and our retail pharmacy where he/she gets the majority of their prescriptions filled. The attached information includes a list of concerns/discrepancies for you to review and address. Please note any issues or changes and fax back to (910) 343-0710.

Current Medications:

Patient reported PMH:

Please review and complete requested actions

Pharmacist recommendation(s)	MD response		
	Accept	Reject	Comments, including strength and dosing instructions for regimen modification

_____ _____ _____
Pharmacist Signature Date Printed Name

_____ _____ _____
Prescriber Signature* Date Printed Name

*SIGNATURE OF THE PRIMARY CARE PROVIDER IS REQUIRED BY MEDICARE PROGRAM TO ACKNOWLEDGE THAT THIS PATIENT'S MEDICATIONS HAVE BEEN REVIEWED BY BOTH THE PHARMACIST AND THE PRESCRIBER

After signing, please fax back to pharmacist at Seashore at (910) 343-0710.