

**Diabetes patients' medication underuse, illness outcomes,  
and beliefs about antihyperglycemic and antihypertensive treatments**

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*Objective:* To determine how patients' beliefs about antihyperglycemic and antihypertensive medications relate to medication underuse and health status.

*Research Design and Methods:* In diabetes patients from an economically distressed region, we assessed perceived necessity and harmfulness for antihyperglycemics (n=803) and antihypertensives (n=573), past year's medication underuse, hemoglobin A1c (HbA1c), systolic blood pressure (SBP) and diastolic blood pressure (DBP).

*Results:* After correction for multiple analyses, multivariate models indicated that perceived need for antihyperglycemic medication was associated with being younger, prescribed insulin, and prescribed multiple medications. Concern about antihyperglycemics was associated with being younger, African-American, dissatisfied with information received about medication, and of low health literacy. For antihypertensives, perceived necessity was associated with having numerous medical comorbidities and being dissatisfied with medication information; concern was associated with being younger, dissatisfied with information received about medication, and of low health literacy. Up to half of patients underused at least one of the types of medication, many of whom attributed this to cost. For both types of medications, concern was significantly associated with both cost-related and non-cost related underuse, and antihypertensive concern was associated with higher SBP and DBP.

*Conclusions:* Even after adjusting for economic factors, patients who are younger, African-American, or of low health literacy are especially concerned about medication harmfulness, which is in turn associated with medication underuse and higher blood pressure. To enhance adherence and outcomes, interventions should address patients' underlying concerns about potential adverse treatment effects, and tailor on both cultural factors and health literacy.

Despite advances in pharmacotherapy and decades of intervention trials to improve diabetes self-management support, adherence to diabetes medication regimens remains suboptimal (1). However, adherence is an “overdetermined” behavior, insofar as it is influenced by a diverse variety of demographic, psychosocial and economic factors. In this study, we focus upon one of the least studied of these factors – patients’ personal beliefs about their treatment – because this construct seems to be an adherence determinant in other illnesses, and is potentially modifiable through educational and psychosocial interventions.

On both conceptual and empirical bases, treatment beliefs can be subdivided into adherence-increasing beliefs about treatment necessity and advantages, and adherence-reducing beliefs about treatment harmfulness, risks, and barriers. Various forms of these constructs seem to explain adherence variation across several prevalent chronic illnesses, including human immunodeficiency virus (2), depressive disorder (3-5), and cardiovascular disease (6). Although beliefs also appear to play a role in diabetes adherence, this conclusion is based mainly upon single items from scales designed to measure other constructs and other non-standardized measures (7, 8).

The nature, intensity, and impact of medication beliefs may vary across sociodemographic subgroups. For example, lower-income patients may be more fatalistic about their likelihood of negative illness outcomes, and as a consequence be less motivated to pursue aggressive management or “tight control” regimens (9-12). Researchers and clinicians are also increasingly concerned about variation in health care trust, perceived discrimination, and outcomes between African-American and Caucasian patients (7). Potential variation in

diabetes treatment perceptions may provide an important window into these disparities.

In this current study, we examined diabetes patients’ beliefs about their medications necessity and potential harmfulness in an economically-distressed community. Given the importance of hypertension management for diabetes care, we also studied diabetes patients’ beliefs about their antihypertensives if applicable. After analyzing covariation between beliefs and sociodemographic characteristics, we modeled multivariate associations between beliefs, nonadherence (due to either cost or other reasons), and key medical outcomes.

## **METHODS**

**Participants:** This study was conducted in Flint, Michigan, an economically distressed, mid-sized city. Patients were identified from general medicine clinics of a large safety-net health system (17% of participants), its affiliated diabetes education center (58%), and the local network of federally-qualified community health centers (25%). Most (92%) were identified from electronic and paper records using diagnostic codes and recruited via telephone. Additional participants were recruited during outpatient visits. Patients were eligible for the study if they had type 2 diabetes, used antihyperglycemic medication, had not been hospitalized in the prior three years for serious psychiatric illness, and received most of their diabetes care in a participating site. Between July 2005 and December 2007, 3,800 patients were identified from medical records and screened by phone, and 322 were identified as outpatients. Of this pool of 4,122 patients contacted for screening and recruitment, 2,516 could not be reached, 450 refused, and 1,116 were screened. Of those contacted, 841 were determined eligible, and 806 (96%) participated. The study was approved by

ethics committees at the University of Michigan and participating health systems.

**Data collection and variable creation**—Data were collected by face-to-face research interviews conducted by research staff from various racial backgrounds. Survey items assessed medication use and beliefs, communication with clinicians, health status, and sociodemographics. The Bayer 2000™ analyzer was used to determine HbA1c. Blood pressure was measured from each arm with an Omron™ automatic blood pressure monitor and an appropriately-sized cuff, and averaged together with a third measure taken two minutes later from the arm with the higher reading.

**Medication beliefs**—Patients' treatment beliefs were measured using a well-validated scale, the Beliefs about Medications Questionnaire (13) with versions for antihyperglycemic and antihypertensive medications. The BMQ consists of eleven items tapping either perceived medication necessity (five items, e.g., "My health, at present, depends on my [diabetes / high blood pressure] medication.") or concern (six items, e.g., "I sometimes worry about the long-term effects of my [diabetes / high blood pressure] medicine.") paired with 5 point Likert scales ranging from "strongly agree," to "strongly disagree." Item means are computed for the Necessity and Concern subscales. Internal consistency for our medication-specific adaptations was suggested by respective Cronbach's alphas of .78 and .68 for the antihyperglycemic version and .81 and .73 for the antihypertensive version.

**Satisfaction with medication information**—Patients' perception of the adequacy of information about their prescription medication was measured using a modified version of the Satisfaction with Information about Medications Scale (14). This 16 item scale covers satisfaction with information received "from doctors and other

people working in the place where I get medical care" on topics such as medication effectiveness. Based on pretesting, the 5-point Likert scale used was replaced with simplified choices ("enough" versus "not enough"). The revised measure had an alpha of .89 in this dataset. Higher scores indicate greater satisfaction, and a median split was performed to facilitate interpretation.

**Medication underuse**—Cost-related underuse was measured using an item that has been used in several prior studies, "In the past 12 months, have you ever taken less of your [diabetes/hypertension] medication than prescribed by your doctor because of the cost?" Non-cost related underuse was measured using the item "Many people do not take their prescription medication exactly as prescribed by their doctor. In the past year, have you ever taken less of your [diabetes/hypertension] medication prescribed for any reason other than the cost?"

**Other variables**—Race/ethnicity was self-reported. Functional health literacy (FHL) was measured using three previously validated items (15). As previously validated against a widely accepted standard (16, 17), FHL deficit was indicated by difficulty reading forms or learning about their medical conditions. Other self-reported variables were educational attainment, income, insulin prescription, and monthly out of pocket medication costs categorized reduced by median split ( $\leq \$49$  vs.  $\geq \$50$ ).

**Statistical analysis:** We initially considered bivariate associations between selected patient characteristics (e.g., sociodemographic variables, satisfaction, etc.) and medication beliefs, using Spearman's rho correlation and matched-samples t-tests. We then developed four multivariate OLS regression models to evaluate the independent effect of patient characteristics on medication beliefs. Next, multinomial logistic models were fitted to examine the impact of perceived necessity and concerns (evaluated

simultaneously, i.e., in the same model) on cost-related and non-cost related medication underuse. Finally, ordinary least-squares regression models were fitted to examine the influence of perceived necessity and concerns (also evaluated simultaneously) on HbA1c, SBP, and DBP. Because multivariate analyses involved five outcomes, we applied a Bonferroni correction by interpreting only effects that reached the  $p < .01$  ( $p$  (crit) =  $.05/5$ ) level of significance.

## RESULTS

**Descriptive statistics:** Sample characteristics are summarized in Table 1. Slightly over half of the sample was African-American, and slightly over half was female. Over a third had low FHL. Participants showed reasonably good glycemic control (mean = 7.8%) and blood pressure control (mean SBP/DBP = 139/83). The majority (71%) was prescribed an antihypertensive medication. The only detected difference between participants who were prescribed antihypertensive medication and those who were not was that the former had higher SBP and DBP than the latter (both  $ps < .01$ ). Beliefs about both medications (summarized in Table 1) varied across their entire possible ranges and approximated a normal distribution.

[insert Table 1 about here]

**Univariate associations with medication beliefs**—Matched-samples t-tests indicated that for both types of medication, perceived necessity was stronger than concern (respective mean differences were 1.0 and 1.1 units on the 5-point BMQ scale (or 1.7 and 1.8 SD units), both  $ps < .0001$ ). Participants prescribed both types of medication rated antihyperglycemic medication as more necessary ( $p = .001$ ) and more concerning ( $p < .0001$ ) than antihypertensive medication, although these effect sizes were relatively

small (mean differences were both 0.1 BMQ units, or 0.17 SDs).

Bivariate associations between patient characteristics and medication beliefs are listed in Table 2. These were fairly consistent across the two types of medication. Perceived medication necessity tended to be stronger among participants who were younger, female (antihypertensive beliefs only), affected by more comorbid conditions, prescribed a higher number of medications, or prescribed insulin (antihyperglycemic beliefs only). Perceived harmfulness tended to be stronger among participants who were younger, African-American, low-income, affected by a greater number of comorbid conditions (antihyperglycemic beliefs only), dissatisfied with medication information, or of low FHL.

**Multivariate models of medication beliefs (see Table 3, upper portion)**—

**Antihyperglycemic beliefs:** After adjustment for sociodemographic covariates (age, gender, ethnicity and income), perceived need for antihyperglycemics was independently associated with having a greater number of prescriptions and being prescribed insulin. In contrast, concern about antihyperglycemics was associated with dissatisfaction with medication information, low FHL, and high out-of-pocket prescription costs.

**Antihypertensive beliefs:** After covariate adjustments, perceived need for antihypertensives was associated with having a greater number of comorbid conditions and being satisfied with medication information. Concern about antihypertensives was associated with being dissatisfied with medication information and having low FHL.

[insert Table 3 about here]

**Multivariate models of adherence and health status (see Table 3, lower portion)**—**Antihyperglycemic underuse:**

Almost half (46.6%) of participants reported

antihyperglycemic underuse, about one-third of whom (16.5% of all participants) reported cost-related underuse. Adjusted logistic regression models indicated that greater concern was associated with antihyperglycemic underuse. Specifically, each one point increase on the 5 point Concerns scale was associated with a 2.8 times increase in the risk of cost-related antihyperglycemic underuse, and also with a 1.7 times increase in the risk of antihyperglycemic underuse for other reasons (each compared to no underuse). Antihyperglycemic concern was furthermore associated with whether a patient reporting reduced adherence due to cost problems or due to other reasons. Specifically, each one point Concerns scale increase was associated with a 1.7 times increase in the risk of underuse due to cost versus other reasons. Figure 1 (left side) depicts this set of differences.

[insert Figure 1 about here]

**Diabetes outcomes:** Neither antihyperglycemic necessity nor concern was significantly associated with HbA1c. However, the regression coefficient for antihyperglycemic concern nearly reached the Bonferroni-adjusted significance level ( $\beta=.08$ ,  $p=.034$ , see Table 3).

**Antihypertensive underuse:** Of participants prescribed antihypertensives, 31.1% reported underuse, with cost being a reason for underuse for about half (i.e., 15.3% of those prescribed antihypertensives). As found for antihyperglycemics, concern was significantly associated with each type of underuse (versus no underuse), but perceived necessity was not (see Table 3). Specifically, each one point increase in Concerns was associated with a 2.6 times increase in risk of cost-related antihypertensive underuse, and with a 1.9 times increase in risk of antihypertensive underuse for other reasons,

each versus no underuse (see Figure 1, right panel). However, among those with one or the other form of antihypertensive underuse, concern was not associated with type of underuse.

**Hypertension outcomes:** Perceived antihypertensive necessity was not significantly associated with either SBP or DBP. However, concern was significantly associated with both SBP and DBP (see Table 3). Extrapolating from obtained beta coefficients and SDs, each one point increase in the Concerns score was associated with a 5.7 mm/Hg increase in SBP and with a 2.5 mm/Hg in DBP. To examine whether this effect of concern was mediated by underuse, we added to the model a variable reflecting the presence of any underuse. Although underuse was significantly associated with SBP ( $\beta=.14$ ,  $p=.002$ ),  $\beta(\text{Concerns})$  did not appreciably reduce ( $p(\text{reduction in } \beta) = .21$ ). The same pattern was found when DBP was analyzed as the dependent variable, and also when adjusting for each type of underuse was coded individually.

## **DISCUSSION**

In this study conducted in an economically-vulnerable community, diabetes patients reported significant concerns about the necessity and safety of their antihyperglycemic and antihypertensive medications. Those with the strongest concerns about medication harmfulness tended to underuse both types of medication, due to both cost and other reasons. Concern was furthermore associated with blood pressure control among patients prescribed antihypertensive medications. These associations persisted after statistical adjustment for multiple sociodemographic factors, including key economic variables such as household income, total out-of-pocket prescription costs, and total number of prescriptions.

It is interesting to note that perceived necessity and harmfulness had different determinants, as has also been demonstrated outside of diabetes (5). Specifically, perceived necessity was related to *medical* factors such as number of comorbidities, number of medications, insulin use). In contrast, perceived medication harmfulness was related to *psychosocial* factors, namely FHL and dissatisfaction with medication information received. Because only the latter belief relates to adherence and outcomes, it seems far more important to address key psychosocial factors in nonadherent patients, rather than assume that they fail to grasp the medical necessity of treatment.

The findings highlight multiple possible opportunities for clinicians and health systems. Because cost-related underuse was explained by factors other than income and costs, approaches in addition to direct financial assistance might be effective (18). Prescribing clinicians should address patients' preferences for information about side effects and other potential consequences of pharmacotherapy, especially among patients with poor functional health literacy. This may build trust and enhance adherence and outcomes (19). Because medication underuse related to perceived medication harmfulness but not perceived necessity, we speculate that patients may view their prescribed medication as relatively more necessary than safe. If so, then it would be most productive to address patients' worries about side effects, and the personal meanings of taking medication (20).

Notably, African-Americans were generally more concerned about medication harmfulness than their Caucasian counterparts. Moreover, this pattern exists regardless of income, medication costs and FHL. Given that perceived discrimination and distrust in health care has been documented in African-Americans with diabetes (21), the most culturally sensitive

interventions will be those that deal directly and skillfully with medication fears.

Screening for nonadherence using archival data is increasingly feasible, as health systems transition to integrated electronic medical record and pharmacy systems. Nevertheless, educators and prescribers might consider direct screening for medication concerns, especially worry about requiring medication, likely side effects, dependency potential, and lifestyle disruption. Such information may be a useful basis for patient-centered medication decision-making, ultimately improving health outcomes.

Study limitations include self-report assessment methods, which can inflate adherence estimates. However, our detected rates of nonadherence were similar to those we found in a prior study using refill data (22), our measurement approach was pre-validated, and a recent literature review concludes that standardized self-report adherence measures correspond adequately with objective measures (23). Our cross-sectional design precludes the examination of whether the detected associations persist across time, making causal inference impossible. Medication concerns might simply reflect actual adverse effects that prevent the regimen intensification required to improve outcomes. Finally, the single study site might not resemble other regions due to geographical variation in community, cultural, clinical, and economic factors. Therefore, the results should only be generalized after careful consideration of the sample characteristics and any unmeasured factors.

We conclude that diabetes patients with significant treatment-related concerns are more likely to underuse their diabetes and (if applicable) antihypertensive medication. This pattern occurs whether the underuse is cost-related or not, consistent with growing evidence that patients' adherence in the context of cost pressures is jointly influenced

by economic and diverse non-economic factors (23).] This is a key point, because clinicians in economically-challenged communities may feel powerless about improving patients' ability to afford medication. Because medication concerns may directly influence cost-related underuse, improved illness outcome may be achievable by simultaneously addressing attitudinal and economic issues.

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**Table 1. Sample characteristics.**

	<b>Medication prescribed</b>	
	<b>Antihyperglycemic (n=803)</b>	<b>Antihyperglycemic plus antihypertensive (n=573)</b>
Age (years)	55.3 ± 11.8	57.2 ± 10.7
Gender (% male)	38.4	31.7
African-American	58.3	61.9
<u>Level of education (%)</u>		
< 12 years	21.6	22.8
12 years (H.S. degree)	35.7	36.6
> 12 years	42.7	40.6
<u>Household income bracket (%)</u>		
\$0 - \$10,000	30.2	32.5
\$11,000 - \$20,000	23.7	24.4
\$21,000 - \$30,000	7.4	6.9
\$31,000 - \$60,000	20.2	19.6
> \$60,000	18.5	17.0
Number of medical conditions	2.7 ± 1.9	3.0 ± 1.9
Number of prescription medications	4.3 ± 1.2	4.6 ± 1.0
Prescribed insulin (%)	39.9	41.8
Hba1c	7.8 ± 2.0	7.7 ± 2.0
Systolic BP (mm/Hg)	139.2 ± 21.2	142.0 ± 22.5
Diastolic BP (mm/Hg)	83.1 ± 12.0	83.7 ± 12.8
Low health literacy (%)	37.2	39.5
Has a primary care provider (%)	75.1	73.0
Prior diabetes education (%)	60.2	59.8
<u>Medication beliefs</u>		
Necessity	3.8 ± 0.6	3.7 ± 0.6
Concerns	2.8 ± 0.7	2.7 ± 0.6

Note: Cell entries are either percents of column sample or mean ± SD.

**Table 2. Bivariate associations between patient characteristics and medication beliefs.**

	Medication beliefs			
	Antihyperglycemics (n=803)		Antihyperglycemics (n=573)	
	Necessity	Concerns	Necessity	Concerns
Age (years)	-.11 ***	-.18 ***	-.09 *	-.16 ***
Gender (male)	-.03	-.07 *	-.11 **	.02
Ethnic minority	-.04	.11 ***	.00	.09 *
Level of education	-.02	.01	-.07	.02
Household income bracket	-.08 *	-.09 *	-.05	-.14 ***
Number of prescription medications	.22 ***	.05	.18 ***	.004
Prescribed insulin	.28 ***	.06	.05	-.03
Number of medical conditions	.21 ***	.12 ***	.18 ***	.07
Satisfaction with medication information	.03	-.16 ***	.10 *	-.17 ***
Low functional health literacy	.01	.14 ***	.03	.23 ***
Out-of-pocket prescription costs > \$50 / month	.08 *	.05	.08	-.03

Note: Cell entries represent Spearman's rho values.

\* p<.05

\*\* p<.01

\*\*\* p<.005

**Table 3. Multivariate associations between beliefs, adherence, and health status.**

	Medication beliefs (as dependent variables) <sup>a</sup>			
	Antihyperglycemics (n=803)		Antihypertensives (n=573)	
	Necessity	Concerns	Necessity	Concerns
<u>Independent variables predicting medication beliefs</u>				
Age (years)	-.12 ***	-.17 ***	-.08	-.17 ***
Gender (male)	-.02	-.05	-.10 *	.05
Ethnic minority	-.03	.12 ***	.03	.09 *
Household income bracket	-.08 *	-.05	-.04	-.07
Number of prescription medications	.12 **	-.02	.07	-.06
Whether prescribed insulin	.23 ***	.03	-.06	-.04
Number of medical conditions	.09	.11 *	.14 **	.08
Satisfaction with medication information	.05	-.15 ***	.11***	-.14 ***
Low functional health literacy	-.02	.12 ***	.01	.22 ***
Out-of-pocket prescription costs > \$50 / month	.05	.09 *	.07	.04
	Medication beliefs (as independent variables) <sup>b</sup>			
	Antihyperglycemics		Antihypertensives	
	Necessity	Concerns	Necessity	Concerns
<u>Binary dependent variables (medication underuse)<sup>c</sup></u>				
Cost-related underuse vs. no underuse	1.4	2.8 ***	1.2	2.6 ***
Non-cost-related underuse vs. no underuse	1.0	1.7 ***	1.2	1.9 ***
Cost-related underuse vs. non-cost-related underuse	1.4	1.7 ***	1.0	1.3
<u>Continuous dependent variables (health status)<sup>d</sup></u>				
HbA1c %	.03	.08 *	---	---
Systolic BP (mm/Hg)	---	---	.09 *	.16 ***
Diastolic BP (mm/Hg)	---	---	.07	.12**

- a. Each column represents a separate OLS regression model, with dependent variables listed as column headers and independent variables listed in rows. Cell entries represent standardized regression coefficients.
- b. All models adjusted for age, gender, ethnic minority status, household income, number of prescription medications, insulin use, number of comorbid conditions, out-of-pocket prescription costs, and FHL.
- c. Cell entries are odds ratios (p value) of adjusted association between medication beliefs (independent variable, in columns) and underuse of the corresponding medication (dependent variable, in rows), with the second type of underuse as the reference group.
- d. Cell entries are standardized beta coefficients (p value) of adjusted association between medication beliefs and the medical outcome variable.

\* p<.05 (not significant with Bonferroni correction)

\*\* p<.01

\*\*\* p<.005

**Figure 1.** Concern ratings by medication and type of underuse.

