Articles

A Drug by Any Other Name: Patients' Ability to Identify Medication Regimens and Its Association With Adherence and Health Outcomes

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Understanding and organizing medication regimens can be challenging, and many patients struggle to properly dose prescribed medicine, potentially leading to less effective treatment or even harm. Generic prescriptions are increasingly common and may change in appearance, adding further complexity. The authors aimed to investigate familiarity with the drug regimen among a cohort of patients with diagnosed hypertension. Specifically, they determined the prevalence of patients' knowledge of their prescribed drug names and dosages compared to those who relied only on physical characteristics (size, shape, color) of their medications. The relationship between patients'

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identification strategies, self-reported adherence, and health outcomes (blood pressure control, hospitalization) were investigated. Patients who were dependent on the visual identification of their prescription medicine reported worse adherence. In addition, they had significantly lower rates of blood pressure control and greater risk of hospitalization. The ability to identify prescribed medicines by name may be helpful for screening and responding to patients at greater risk of making medication errors or being less engaged with their regimen for adherence purposes.

Patients often rely on the visual characteristics of their medications as a way to ensure that they are taking the right drug (Cohen & Smetzer, 2011; Fritch, 2006). However, because of the increasing prevalence of generic medications in the prescription drug marketplace, the appearance of a patient's medication may change considerably over time (Fritch, 2006). Trade dress protection, a portion of U.S. copyright law entitling companies to claim ownership of the physical characteristics of their products, allows drug manufacturers to protect the size, shape, and color of their medications (Greene & Kesselheim, 2011). Consequently, in situations in which numerous generic versions of the same medication exist, a patient may receive pills of a different size, shape, or color with each refill (Cohen & Smetzer, 2011).

If patients depend solely on the shape and/or color of their pill to ensure accurate dosing without knowing other characteristics of the medication—ideally its name and dosage—there is potential for adverse drug events and poor health outcomes. These consequences may be the result of inadequate time spent reconciling their medication with their providers or of taking too much or too little of the medicine. For the latter, in either case the risk of less effective treatment or actual patient harm is increased. To determine whether visual-identification-only schemas were correlated with poorer patient behaviors and health outcomes, we investigated these relationships among a cohort of hypertensive patients receiving primary care at multiple community health centers. The association between patients' self-reported regimen adherence, blood pressure control, and their ability to identify their medications by name versus visual characteristics—or in any manner—was specifically explored. The role of certain patient attributes, including patient age, literacy skills, and comorbidity, was also evaluated.

Method

This study represents a secondary analysis conducted from a multisite cross-sectional investigation examining the role of health literacy in chronic disease self-management. Methods and related findings have been reported upon previously (Pandit et al., 2009; Persell, Osborn, Richard, Skripkauskas, & Wolf, 2007; Persell, Bailey, Tang, Davis, & Wolf, 2010).

Participants

Consecutive patients were recruited from six primary care safety net clinics (community clinics providing care to low-income patients) in Chicago, Illinois; Grand Rapids, Michigan; and Shreveport, Louisiana. Participants were eligible if they were older than 50 years of age, had a diagnosis of hypertension within the medical record, and an appointment at the clinics between July 2005 and August 2007. Patients were excluded if they did not speak English or if the clinic nurse deemed they were too ill or cognitively impaired to participate. Clinic nurses reviewed the medical records of scheduled patients and referred potentially eligible patients to study staff. Eligible consenting

patients were then scheduled for an interview. The institutional review board at each location approved the study procedures.

Procedure

We conducted a structured in-person interview. Participants were asked whether they were taking any medications for high blood pressure, and, if so, whether they could name these medications. If the patients were unable to name their medications, they were asked to describe the appearance of the medication. Trained chart abstractors retrospectively recorded the patients' most recent blood pressure measurements (up to 10 readings), number of chronic conditions, and their current list of medications from the medical record. In addition, self-reported data were collected on demographic factors (age, sex, race) and hospitalizations and emergency department visits in the past year. We assessed patients' literacy using the short version of the Test of Functional Health Literacy in Adults (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). For the purpose of this study, patients were classified as having either limited (marginal/inadequate) or adequate literacy skills.

The independent variable of interest was patients' ability to identify their antihypertensive medications by name; by visual identification of pill size, shape, or color; or not at all. Patients' reported list of medications was compared to the list from the medical record. Antihypertensive medications that were correctly identified by name or by using colloquial terms for the type of medication prescribed (i.e. "my water pill") were accepted as naming the particular medication. Unintelligible answers or drug names that did not exist were not accepted. Patients were not penalized for giving names of medications prescribed for other conditions. Patients were classified into one of three categories on the basis of their entire antihypertensive regimen: (a) being able to name all of their medications, (b) identifying any of their medications exclusively by their physical "trade dress" characteristics (visual elements such as size, shape, and color) or (c) being unable to identify any of their medications by either name or visual identification.

Outcomes

The outcomes of interest were medication nonadherence, poor blood pressure control, and number of emergency department visits and hospitalizations within the past year. Medication nonadherence was determined by self-report when patients were asked whether they had missed any doses of their identified blood pressure medications in the past week. Blood pressure control was categorized dichotomously (yes/no); this was determined by the average of patients' three most recent blood pressure readings in the medical record. Uncontrolled blood pressure was defined as systolic >140 mm Hg and diastolic >90 mm Hg (or >130 mm Hg systolic and >80 mm Hg diastolic if the patient had diabetes). Past-year emergency department visits and hospitalizations were based on patient self-report.

Analysis Plan

We calculated descriptive statistics (percentage, mean, and standard deviation) for demographic variables and compared them by how participants identified their medications (name, visual characteristics, unable) using a one-way analysis of variance and chi-square analyses. We performed similar analyses for each of the outcomes of

interest. Generalized linear models with a Poisson distribution and log link function were used to estimate the risk ratio for each outcome of those who identified medications by appearance or not at all compared to those who identified by name, controlling for age, gender, race, health literacy, number of antihypertensive medications taken, and number of comorbid conditions (Greenland, 2004; Zou, 2004). Robust error estimation was used to correct for overestimation of variance resulting from using the Poisson distribution for binomial outcomes (Zou, 2004). All statistical analyses were performed using Stata version 12 (College Station, Texas).

Results

Sample Demographics

Table 1 shows sample demographics. The mean age of patients was 60 years ($SD = 8.0$ years); 68% were female, and 80% were African American. In addition, 47% of the sample had inadequate literacy skills (low and marginal) and 26% of the sample had three or more chronic conditions. Approximately 60% of patients were able to identify all of their hypertension medications by name. These patients were less likely to have limited literacy (37.7%) than those who identified medications by appearance (67.3%) and those who were unable to identify any of their medications (50.0%, $p = .001$). As a related factor, 21.0% of patients had medication changes that occurred in the past

Table 1. Key demographic characteristics

Variable	Total ($N = 215$)	Hypertensive medication identification			p
		Identified by name ($n = 130$)	Identified by appearance ($n = 55$)	Unable to identify ($n = 30$)	
Age, M (SD)	60.2 (8.0)	59.3 (7.1)	61.5 (9.1)	61.7 (8.8)	.12
Female, %	68.2	75.2	54.6	63.3	.02
African American, %	80.4	80.0	90.9	62.1	.01
Health literacy, %					.001
Adequate	53.0	62.3	32.7	50.0	
Limited	47.0	37.7	67.3	50.0	
Number of antihypertensive medications taken, %					.60
1	42.6	41.5	41.8	50.0	
2	33.2	34.6	36.4	19.2	
3 or more	24.2	23.9	21.8	30.8	
Number of chronic conditions, %					.85
0	13.0	13.1	12.7	13.3	
1	31.2	33.1	25.4	33.3	
2	29.8	26.9	38.2	26.7	
3 or more	26.0	26.9	23.6	26.7	

Table 2. Ability to identify hypertensive regimen and outcomes of adherence, blood pressure control, emergency department visits, and hospitalizations

Variable	Total (<i>N</i> = 215)	Hypertensive medication identification			<i>p</i>
		Identified by name (<i>n</i> = 130)	Identified by appearance (<i>n</i> = 55)	Unable to identify (<i>n</i> = 30)	
Missed doses, past week, %	25.4	22.5	21.8	44.8	.03
Uncontrolled blood pressure, %	49.5	46.3	60.0	44.8	.23
Visited emergency department in past year, %	44.0	38.9	50.0	55.2	.17
Hospitalized in past year, %	28.1	22.5	38.5	34.5	.07

month. This, however, was not significantly associated with one's ability to identify their medicine.

Participants who were unable to identify their hypertension medications either by name or by appearance were more likely to miss taking a medication in the past week compared with those who were able to identify by either name or appearance (44.8% unable to identify, 22.5% identified by name, and 21.8% identified by appearance, $p = .03$). Those who identified all medications by name tended to be less likely to have uncontrolled blood pressure or to visit an emergency department or be hospitalized in the past year compared with those who could not identify by name, although these relationships were not significant (see Table 2). However, when controlling for the aforementioned covariates, those who identified by appearance were more likely to have uncontrolled blood pressure (relative risk = 1.26; 95% CI [1.00, 1.59]; $p = .05$) and report being hospitalized in the past year (relative risk = 1.71; 95% CI [1.00, 2.92]; $p = .05$) compared with those who identified medications by name (Table 3). Those who were unable to identify medications were also more likely to be hospitalized (relative risk = 1.35; 95% CI [1.00, 1.81]; $p = .05$) and remained more likely to miss a medication in the past week (relative risk = 1.81; 95% CI [1.07, 3.08]; $p = .03$).

Discussion

In our study, patients had considerable difficulty recalling their medications by name, and we found that the ability to properly name medications was associated with health literacy. In addition, we found that the inability to name medications, and reliance on the visual appearance of a medication in particular, was independently associated with uncontrolled blood pressure and increased hospitalizations. Specifically, patients who only used visual identification of their regimen were 1.26 times more likely to have uncontrolled blood pressure and 1.35 times more likely to have hospitalizations in the past year when compared with patients who could name their antihypertensive medications. Furthermore, patients who could not identify their medications by either name or appearance were more likely to self-report poorer adherence than were those who could identify their medications.

Table 3. Predictors of adherence, blood pressure control, emergency department visits, and hospitalizations

Variable	Medication nonadherence			Uncontrolled blood pressure			Emergency department visit			Hospitalization		
	RR	95% CI	p	RR	95% CI	p	RR	95% CI	p	RR	95% CI	p
Medication identification												
Identified by name	Ref	—	—	Ref	—	—	Ref	—	—	Ref	—	—
Identified by appearance	0.95	0.69, 1.30	0.74	1.26	1.00, 1.59	0.05	1.32	0.80, 2.15	0.28	1.71	1.00, 2.92	0.05
Unable to name	1.81	1.07, 3.08	0.03	1.00	0.73, 1.38	0.98	1.33	0.90, 1.96	0.15	1.35	1.00, 1.81	0.05
Age	0.98	0.94, 1.01	0.19	0.99	0.97, 1.00	0.17	0.99	0.97, 1.00	0.12	1.00	0.97, 1.03	0.94
Female	0.65	0.39, 1.07	0.09	0.94	0.70, 1.26	0.68	0.94	0.77, 1.15	0.55	0.81	0.54, 1.22	0.32
African American	0.94	0.52, 1.70	0.83	1.41	0.78, 2.56	0.26	1.13	0.68, 1.89	0.63	1.23	0.56, 2.70	0.60
Health literacy												
Adequate	Ref	—	—	Ref	—	—	Ref	—	—	Ref	—	—
Inadequate/marginal	0.80	0.44, 1.46	0.47	1.31	1.03, 1.68	0.03	0.94	0.58, 1.52	0.79	0.74	0.51, 1.08	0.12
Number of antihypertensive medications taken												
1	Ref	—	—	Ref	—	—	Ref	—	—	Ref	—	—
2	0.79	0.57, 1.10	0.17	1.26	0.86, 1.86	0.24	0.86	0.49, 1.53	0.62	0.73	0.25, 2.18	0.58
3 or more	1.34	0.96, 1.88	0.09	1.76	0.96, 3.21	0.07	0.79	0.51, 1.22	0.30	0.78	0.43, 1.44	0.43
Number of chronic conditions												
0	Ref	—	—	Ref	—	—	Ref	—	—	Ref	—	—
1	1.12	0.86, 1.46	0.40	0.96	0.70, 1.32	0.79	1.28	0.64, 2.58	0.49	1.48	0.62–3.56	0.38
2	1.02	0.67, 1.54	0.93	0.70	0.52, 0.92	0.01	1.43	0.93, 2.20	0.11	1.56	0.66–3.67	0.31
3 or more	1.41	0.79, 2.51	0.24	0.67	0.44, 1.01	0.05	2.49	1.25, 4.97	0.01	1.76	0.61–5.04	0.30

Note. RR = relative risk.

The prevalence of inadequate regimen recognition, either because of the inability to identify medicines altogether or because of the reliance solely on the visual appearance of a medicine, was high; 2 in 5 patients were deemed at risk. Approximately 15% of patients were unable to identify their medications by any means (name or visual characteristics), despite the fact that half of them had adequate literacy levels. These patients had lower medication adherence; however, this inability to identify their medications did not seemingly affect their blood pressure or visits to the emergency department. Given the relatively small sample, it is possible that these associations could not be adequately investigated. Furthermore, the role of the number of antihypertensive medications taken has been addressed by Persell and colleagues (2010). In multivariable models, the number of medications was not significantly associated with any of the outcomes, controlling for other factors, although it approached significance in the uncontrolled blood pressure model (Persell et al., 2010).

To our knowledge, no previous research has associated patients' medical outcomes with their ability or inability to identify their medicines by name or physical characteristics. Previous studies regarding visual identification of medicines have taken divergent stances on the value of color and shape identification, with some arguing that these characteristics can reduce medication errors by building in redundancy, and others positing that visual identification alone may be a "dangerous shortcut to reading labels" (Hellier, Tucker, Kenny, Rowntree, & Edworthy, 2010). Our findings of poor blood pressure control and increased hospitalization support the latter theory—that the inability to name medications is potentially dangerous. However, they do not negate the former theory. It is possible that patients who use two forms of medication identification (name and visual identification) may have better outcomes; our study does not address this.

Kripalani and colleagues (2006) also found that patients with adequate literacy were more likely to identify their medications by name, but they found that patients of all literacy levels were likely to view the pills in the bottle as a means of identifying them. Unlike the Kripalani and colleagues (2006) study, in our sample, patients did not have the pills bottles in hand, and with the lack of this physical stimulus, we found that patients with higher literacy levels were still able to identify medications by name, without viewing the pills in the bottle.

A patient's ability to accurately identify their daily medications is crucial for optimal health. For patients who are not able to name their medications, it may be wise to have protections in place to control the changes in medication appearance that may impede their ability to accurately identify their medications. In 2011, The Institute for Safe Medication Practices called for the elimination of any barriers to a standard appearance of bioequivalent brand and generic medications (Cohen & Smetzer, 2011). At present, AMA Policy H-115.974 discourages changes in the manufacturer or distributor when refilling a generic medication (as cited in Engelberg, 2011, p. 321). When the manufacturer or distributor changes, it is recommended that the pharmacist counsel the patient about any potential changes to appearance and affix an additional label that states, "This is the same medication you have been getting. Color, size, or shape may appear different" (American Medical Association, 2007).

Limitations

Our study has several limitations. All patients were recruited from safety-net clinics and federally qualified health centers and may not fully reflect patient populations

from other health care settings; however our research targets populations most at risk for limited health literacy and who are disproportionately affected by socioeconomic barriers. These groups reflect target populations for reducing known health care disparities, the primary public health objective in the United States (Healthy People 2020). The sample was also fairly racially homogeneous (83% African American), and a larger sample size in general would have allowed for a more robust analysis. In addition, the secondary outcomes were measured using self-report (medication adherence, emergency department visits, and hospitalizations). Additional studies are needed to examine the pathways that lead from this reliance to clinically significant consequences. However, this study takes a first step in describing this important association.

Conclusion

Our data suggest that if a patient is unable to identify his or her antihypertensive medications by name, but only by physical characteristics, concerns are raised for the patient's blood pressure control and health care utilization. Although there are many factors that potentially influence a patient's hypertensive outcomes (including lack of adherence or refractory disease), this particular finding is important because it could inform doctor–patient and pharmacist–patient communication. These data underscore the need for attention during the medication reconciliation process to not only the accuracy of the medication list, but also to patients' understanding of their medications. Those who struggle with the task would disproportionately benefit from more intensive efforts to improve their identification and comprehension of their own medication regimens, in terms of indication and safe use.

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