Physician Notification of Their Diabetes Patients' Limited Health Literacy

A Randomized, Controlled Trial

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BACKGROUND: Many patients with chronic disease have limited health literacy (HL). Because physicians have difficulty identifying these patients, some experts recommend instituting screening programs in clinical settings. It is unclear if notifying physicians of patients' limited HL improves care processes or outcomes.

OBJECTIVE: To determine whether notifying physicians of their patients' limited HL affects physician behavior, physician satisfaction, or patient self-efficacy.

DESIGN: We screened all patients for limited HL and randomized physicians to be notified if their patients had limited HL skills.

PARTICIPANTS: Sixty-three primary care physicians affiliated with a public hospital and 182 diabetic patients with limited HL.

MEASUREMENTS: After their visit, physicians reported their management strategies, satisfaction, perceived effectiveness, and attitudes toward HL screening. We also assessed patients' self-efficacy, feelings regarding HL screening's usefulness, and glycemic control.

RESULTS: Intervention physicians were more likely than control physicians to use management strategies recommended for patients with limited HL (OR 3.2, P=.04). However, intervention physicians felt less satisfied with their visits (81% vs 93%, P=.01) and marginally less effective (38% vs 53%, P=.10). Intervention and control patients' post-visit self-efficacy scores were similar (12.6 vs 12.9, P=.6). Sixty-four percent of intervention physicians and 96% of patients felt HL screening was useful.

CONCLUSIONS: Physicians are responsive to receiving notification of their patients' limited HL, and patients support the potential utility of HL screening. However, instituting screening programs without specific training and/or system-wide support for physicians and patients is unlikely to be a powerful tool in improving diabetes outcomes.

KEY WORDS: health literacy; screening; diabetes mellitus; physician-patient communication.
DOI: 10.1111/j.1525-1497.2005.0189.x
J GEN INTERN MED 2005; 20:1001–1007.

Health literacy (HL) refers to the degree to which individuals can obtain and understand the basic information and services needed to make appropriate decisions regarding their health.[1] It is commonly measured by assessing one's ability to perform the reading tasks necessary to function in the health care environment.[2] As many as half of patients receiving care in public hospitals[3] and one-third of Medicare patients[4] have limited HL.

Both the Institute of Medicine[1] and the Agency for Healthcare Research and Quality[5] have recently released reports highlighting the clinical significance of limited HL. When compared to patients with adequate HL, patients with limited HL demonstrate lower knowledge of chronic disease prevention and management,[6–12] worse health status[7,13,14] and higher utilization of hospital and emergency room services.[15,16] The relationship between limited HL and poorer health outcomes, particularly among patients with chronic disease, may be mediated by sub-optimal physician-patient communication and patient self-management skills.[2,6,9,17,18]

Because physicians have difficulty recognizing patients with limited HL,[19,20] some health systems, HL experts, and accreditation bodies have expressed interest in routinely screening patients.[19,21–28] However, little is known about whether notifying physicians of their patients' HL limitations affects clinical care processes or outcomes. This trial evaluated the effects of notifying primary care physicians in a public hospital of their patients' limited HL skills. We focused on patients with diabetes because of the association between effective physician-patient communication,[29–32] patients' HL skills,[7,33] and diabetes outcomes.

We sought to determine whether notifying physicians of their patients' limited HL skills affected physicians' visit-specific management strategies, satisfaction, or perceived effectiveness, or patients' self-efficacy.[23,34,35] We hypothesized that notification would elicit from physicians more targeted efforts at communication resulting in stronger physician-patient alliances,[36] greater physician satisfaction and effectiveness, and enhanced patient self-efficacy.[29,32] These factors are associated with improved patient outcomes, including glycemic control.[37,38] However, we recognized that physician notification could potentially stigmatize patients,[22,39,40] thereby lowering patient self-efficacy scores.

METHODS

Study Description

We conducted a trial randomizing physicians to receive notification of their patients' limited HL skills. Physicians and patients provided informed consent to participate in a study of doctor-patient communication and barriers to patient understanding. Patients were told their reading comprehension would be measured and potentially conveyed to their physi-

The authors have no conflicts of interest, financial or otherwise, to report for this article or this research.

Portions of this work were presented in abstract form at the Society for General Internal Medicine regional (California) and national meetings in 2001 and 2003.

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See editorial by Montori, p. 1071

Received for publication April 7, 2005
and in revised form May 3, 2005
Accepted for publication May 3, 2005

cian. The Human Subjects Committee of the University of California San Francisco approved the protocol.

Setting and Participants

The study was conducted at an urban, academic, public hospital. Attending and resident physicians in the affiliated General Internal Medicine and Family Practice clinics provide primary care to patients who are generally poor, ethnically diverse, and publicly insured or uninsured. Resident physicians spend between 1 and 3 half-days per week in these clinics.

During the study period, no diabetes disease management programs were available. Some physicians had attended a local "grand rounds" lecture on limited HL, but there had been no systematic educational interventions to improve physicians' management of patients with limited HL.

This trial was nested within a larger study which explored physicians' communication with their patients who have diabetes.[7,17,41] The unit of recruitment was the patient. Physicians were eligible to participate if their primary care panel included a patient enrolled in the study. Physicians were aware a multi-methods study exploring their communication with their diabetic patients was ongoing, and that both they and their patients would be asked to complete study questionnaires.

Patients were eligible to participate if they had type 2 diabetes, were older than 30 years, and spoke English or Spanish. Patients also had to have an assigned physician in the clinic's database for at least 12 months, with at least 1 visit to that physician in the preceding 6 months.

Only patients with limited HL were eligible to participate in this trial, although enrolled physicians were not aware of this eligibility criterion. Exclusion criteria included psychotic disorders, dementia, acute intoxication, end-stage renal disease, and corrected visual acuity worse than 20/50, each of which can interfere with reliable HL measurement.[42]

Between May and December 2000, a bilingual research assistant approached eligible patients in the clinics' waiting rooms and screened consenting patients for visual problems using a pocket vision screener (Rosenbaum, Graham-Field Surgical Co., New York, NY). Patients completing the study received $5 compensation.

Intervention

We administered to all consenting patients an abbreviated English or Spanish version of the short form of the Test of Functional Health Literacy in Adults (s-TOFHLA), a well-established instrument shown to be reliable among English and Spanish speakers.[42,43] This abbreviated version of the s-TOFHLA is composed of 2 reading passages and is administered in 7 minutes.[44] Using established convention, we categorized HL scores of ≤ 16 "inadequate," 17 to 22 "marginal," and ≥ 23 "adequate." Patients with marginal or inadequate HL were considered to have "limited" HL and continued with the trial (Fig. 1).

For intervention physicians, we affixed the following notice to the patient's chart immediately prior to the study visit:

> Your patient, Mr/Ms.————, has undergone a screening measure of functional health literacy in [English/Spanish] and was found to have [inadequate/marginal] functional health literacy. Patients with low levels of functional health literacy may be more likely to have difficulties understanding written health materials, following prescribed treatment regimens, or processing oral communication.

We provided no other instructions, educational interventions, or reminders.

Blinding and Randomization

To avoid contamination, we randomized physicians prior to patient recruitment using a random number generator. Patients were assigned to intervention or control group based on their physician's randomization status, which was contained in a sealed envelope opened after the baseline patient interview.

Research assistants discussed neither randomization status nor screening results with patients or physicians. Control physicians were notified of their patients' limited HL after trial completion.

Outcome Measurements

Physician questionnaires were distributed immediately after the study visit and collected within 1 week. Physicians were asked to report which communication-enhancing management strategies they used during the visit. Options reflected consistent recommendations in the literature (current at the time of study design) and included: (a) involving patient's family members or friends,[21,45] (b) referring to a diabetes educator,[21] (c) referring to a nutritionist,[46] (d) using pictures or diagrams,[23,47,48] (e) reviewing understanding of medications,[21] or (f) spending time educating about diabetes.[21,45] We chose physicians' management strategies as our primary outcome because improvements in physicians' visit-based behavior is the most proximate intermediate endpoint through which screening in the primary care context might affect patient outcomes.[17,31,32,41,49]

Secondary physician outcomes included visit-specific satisfaction and perceived effectiveness. To measure satisfaction, we adapted 2 previously-published scales measuring physician satisfaction[50] and frustration[51] into a briefer 6-item scale (Cronbach $\alpha = 0.8$). We also developed a 10-item effectiveness scale that asked physicians to rate the extent to which they impacted their patients' diabetes management in specific areas such as foot care, diet, exercise, and glucose monitoring (Cronbach $\alpha = 0.8$). Using common factor analysis, we demonstrated that these scales measured unique aspects of physicians' experiences (data available upon request). Both scales contained 5-point Likert responses from "strongly agree" to "strongly disagree."

Intervention physicians were also asked their prenotification estimation of their patients' HL; whether they felt screening was useful; whether they discussed the results with their patients; and which tools (from a list of 10) would be particularly useful in improving care for their patients with limited HL.

A bilingual research assistant interviewed patients immediately after the study visit or, for the few patients who were unavailable, over the telephone within 1 week. Our primary patient outcome was self-efficacy. We measured self-efficacy using the previously validated Patient-Enablement Instrument, which measures the extent to which the physician visit affects patients' confidence in their ability to successfully manage their chronic disease.[52]

We also asked patients whether it was "useful to measure how well patients understand written medical information,

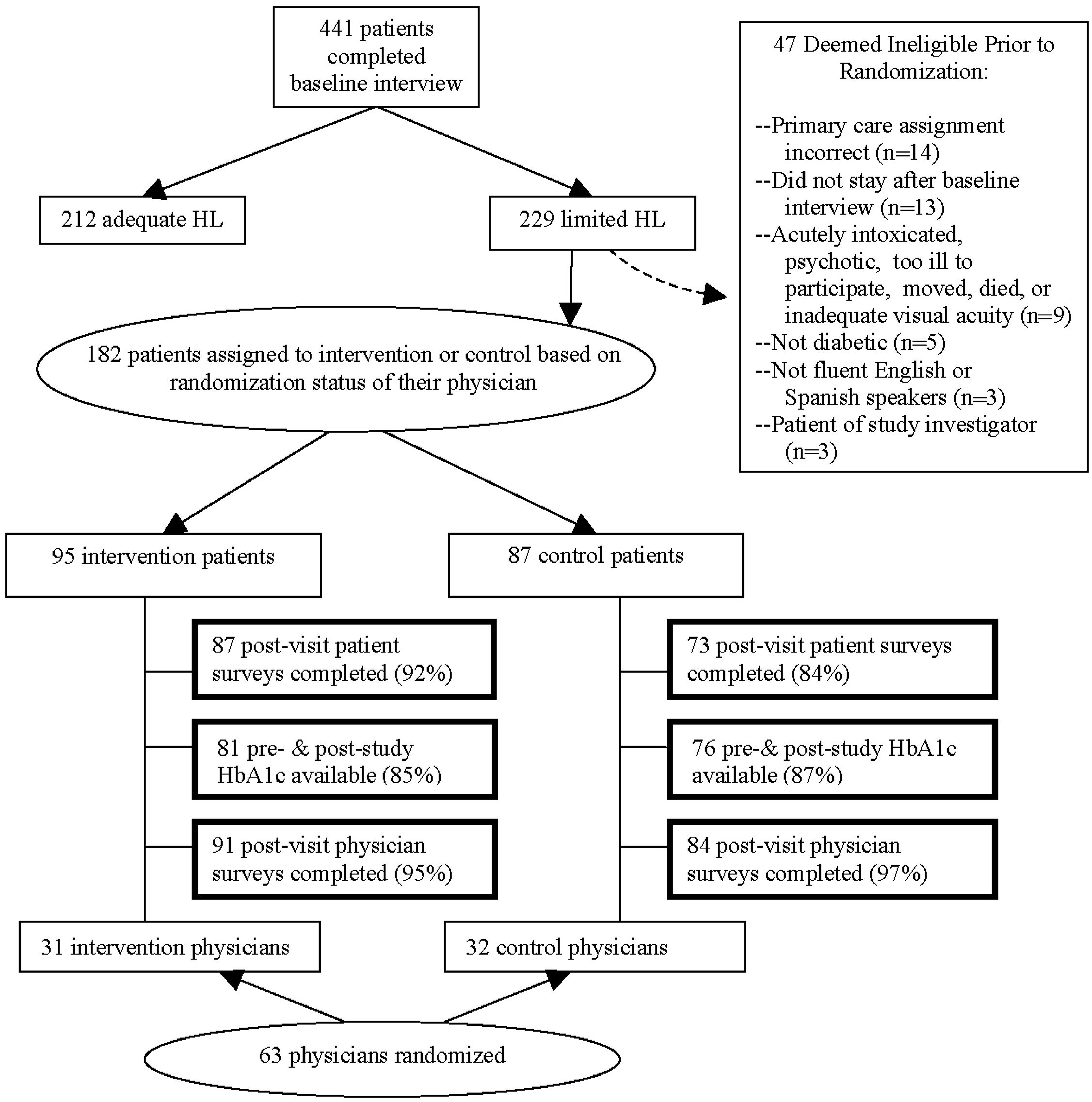

FIGURE 1. Enrollment and follow-up. HbA1c, glycosylated hemoglobin.

e.g., a diabetes brochure or a pill bottle." To assess glycemic control, we obtained patients' glycosylated hemoglobin (HbA1c) values from the hospital's database and calculated the change from baseline (most recent value in the 12 months before study enrollment) to follow-up (2 to 9 months after study enrollment).

Data Analysis

We compared baseline characteristics of physicians and patients using χ^2 tests. Subsequent comparisons were performed using an intention-to-treat analysis at the level of the patient. Results were adjusted for patient clustering within physician using generalized estimating equations (GEE) with a symmetric correlation structure.[53] Data was analyzed using SAS software.[54]

To assess differences in management strategies between intervention and control physicians, we categorized physicians as "management-intensive" if they employed >3 of the 6 recommended management strategies during the patient visit. We performed a sensitivity analysis dichotomizing this outcome at >2 strategies. We also compared the proportion of physicians using each individual strategy.

We calculated a physician satisfaction score for each patient by averaging responses on the physician satisfaction measure. We categorized the physician as "satisfied" with the visit if the average score ranged from 4 ("agree") to 5 ("strongly agree"). We performed the same dichotomization for physicians' perceived effectiveness.

We used GEE linear or logistic models to compare intervention and control physicians' management strategies, satisfaction, and perceived effectiveness; and intervention and control patients' perceptions of the usefulness of the screening and absolute change in HbA1c. We included in the HbA1c analysis only patients with both baseline and follow-up HbA1c values. For the patient self-efficacy outcome, there was essentially no within-physician correlation. Therefore results are from a standard linear regression model rather than a linear mixed model.

To ensure our results were not due to unbalanced randomization, we performed multivariable modeling adjusting

Table 1. Baseline Characteristics of the 63 Randomized Physicians and 182 Patients

	Intervention (%)	Control (%)	P Value
Physician characteristics	n=31	n=32	
Male	13 (42)	11 (34)	.6
Spanish-speaking	14 (45)	17 (53)	.5
Attending (vs resident) physician	11 (35)	10 (31)	.7
Patient characteristics	n=95	n=87	
Male	42 (44)	29 (33)	.1
Age, years (mean, SD)	62.3 (11.3)	63.4 (9.5)	.5
Ethnicity			
Caucasian	7 (7)	10 (12)	.7
African-American	18 (19)	18 (21)	
Hispanic	55 (58)	42 (48)	
Asian	14 (15)	15 (17)	
Other	1 (1)	2 (2)	
Spanish-speaking	45 (48)	32 (39)	.2
Language Discordant*	17 (18)	13 (15)	.6
<3 years with primary care provider	41 (45)	58 (69)	<.001
Marginal HL	20 (21)	27 (31)	.1
Inadequate HL	75 (79)	60 (69)	
HbA1c (mean, SD)	8.70 (1.72)	8.54 (1.62)	.6

**Language discordant was defined as interactions where an interpreter was used or would have been preferred by the physician, based on physician report in the questionnaire.*
HL, health literacy; HbA1c, gylcosylated haemoglobin.

for baseline characteristics that were unequally distributed (P value ≤ .2). We present unadjusted results in the text, and unadjusted and adjusted results in the tables.

The study was powered to detect a 20% increase in the number of patient visits where physicians employed >3 management strategies (80% power, 2-tailed α=0.05).

RESULTS

Of the 471 potentially eligible patients approached for the larger study, 30 (6%) declined participation and 441 completed the baseline questionnaire and HL screening. 229 (52%) had limited HL skills. Forty-seven of these patients were excluded prior to randomization (Fig. 1). Excluded patients did not significantly differ from randomized patients by gender, ethnicity, age, or HL score.

No physicians of eligible patients refused participation. Sixty-three physicians were randomized, 31 in the intervention group and 32 in the control group. The 182 remaining patients were assigned to intervention (n=95) or control group (n=87) based on their physician's randomization status. The mean cluster size was 2.9 patients per physician (median 2.0, range 1 to 16). Overall, study patients were elderly and ethnically diverse with poorly controlled diabetes (Table 1). Control patients were more likely than intervention patients to have spent fewer than 3 years in a relationship with their physician (P<.001).

Compared with control physicians, intervention physicians were more likely to use >3 recommended management strategies during the visit (21% vs 8%, odds ratio (OR)=3.2, P=.04) (Table 2). We found similar results if we dichotomized this outcome at >2 recommended management strategies (unadjusted 44% vs 31%, OR 1.8, P=.05; adjusted 49% vs 32%, OR=2.03, P=.02). With regard to individual strategies, intervention group physicians were more likely to involve patient's family members and friends in their patient discussions and to refer patients to nutritionists.

Intervention physicians were less likely than control physicians to be satisfied with the visit (81% vs 93%, OR=0.3, P=.01). They also perceived themselves as somewhat less effective in the visit, although this did not reach statistical significance (38% vs 53%, OR=0.5, P=.10).

Intervention physicians overestimated the HL level of 62% of their patients, and felt the screening was useful in 64% of their visits. They discussed screening results with only 2% of their patients, and planned future discussions in 27%. Intervention physicians felt that increased access to allied health professionals (88%), more appropriate educational materials (77%), improved pill-bottle labeling (69%), communication skills training for patients (66%), and case management services (64%) would be useful in improving care for their patients with limited HL.

Patients in the intervention and control groups had similar post-visit self-efficacy scores (12.6 vs 12.9, P=.60) (Table 3). Almost all patients felt the screening was useful, regardless of randomization status (96% vs 97%, P=.77).

We included in the HbA1c analysis all 157 eligible patients (86%). The interval between physician notification and follow-

Table 2. Physicians' Report of Management Strategies Employed, Satisfaction, and Effectiveness During the Visit

	Unadjusted				Adjusted*			
	Intervention (%)	Control (%)	Odds Ratio (95% CI)	P Value	Intervention (%)	Control (%)	Odds Ratio (95% CI)	P Value
Management intensive†	21	8	3.2 (1.1 to 9.8)	.04	20	7	4.7 (1.4 to 16.0)	.01
Physician strategies employed								
Involved family members or friends	25	16	1.7 (1.0 to 2.9)	.04	27	17	1.9 (1.0 to 3.5)	.04
Referred to a nutritionist	13	5	2.9 (0.8 to 10.0)	.09	11	3	4.0 (1.0 to 15.6)	.05
Used pictures or diagrams	11	5	2.4 (0.5 to 12.7)	.30	8	1	7.9 (0.9 to 74.7)	.07
Referred to a diabetes educator	26	29	0.8 (0.4 to 1.8)	.60	28	31	0.9 (0.4 to 1.9)	.60
Reviewed understanding of medications	89	87	1.3 (0.5 to 3.0)	.60	92	90	1.3 (0.5 to 3.5)	.60
Spent time teaching about diabetes	66	65	1.1 (0.5 to 2.1)	.8	69	63	1.3 (0.6 to 2.8)	.5
Satisfied with visit	81	93	0.3 (0.1 to 0.8)	.01	82	96	0.2 (0.1 to 0.5)	<.001
Felt effective during visit	38	53	0.5 (0.3 to 1.2)	.10	34	50	0.5 (0.2 to 1.2)	.10

Odds ratios are for the intervention group, compared to the control group. All values account for clustering within physicians.
**Adjusted for patient language, gender, years with primary care provider, and HL score.*
†Management intensive physicians employed >3 management strategies.
HL, health literacy; CI, confidence interval.

Table 3. Patient Outcomes

	n	Unadjusted			Adjusted		
		Intervention	Control	P Value	Intervention	Control	P Value
Self-efficacy score (mean)	160	12.6	12.9	.60	12.6	12.6	.61
Feel HL screening is useful (n, %)*	160	81 (96)	69 (97)	.77	—	—	—
	n	**Intervention**	**Control**	**Difference in Change, 95% CI, P Value**	**Intervention**	**Control**	**Difference in Change, 95% CI, P Value**
Change in % HbA1c (mean)	157	−0.21	0.05	−0.26, −0.73 to 0.20, .26	−0.10	0.17	−0.27, −0.80 to 0.27, .32

*Too few patients felt that HL screening was not useful to estimate adjusted proportions.
HL, health literacy; HbA1c, glycosylated hemoglobin; CI, confidence interval.

up HbA1c was similar in the intervention and control groups (87 vs 106 days, $P=.2$). HbA1c fell by 0.21% in the intervention group and rose by 0.05% in the control group ($P=.26$).

DISCUSSION

To our knowledge, this is the first study to examine the effects of notifying physicians of their patients' HL skills. Physicians notified of their patients' limited HL were more likely to use management strategies recommended to improve communication with these patients, but felt less satisfied and perceived themselves as marginally less effective than control physicians. While patients in this study considered HL screening to be useful, the increased intensity of physician management did not result in improved patient self-efficacy, at least in the short term.

The increased management intensity of physicians in the intervention group demonstrates that physicians are receptive to HL screening and recognize HL's importance in chronic disease management. Lower satisfaction rates in these physicians, despite their actively engaging in strategies to overcome this communication barrier, suggest that physicians lack appropriate training, evidence-based recommendations, and/or systematic support to best respond. A similar phenomenon has been reported in education research. Teachers who work with students who have barriers to learning are less satisfied than general education teachers,[55] particularly when adequate training for teachers and system support for students are lacking.[56] Similarly, in studies of screening for other complex, psychosocial issues such as depression, alcoholism, and domestic violence, physician satisfaction has been achieved by linking screening results with specific educational interventions and structural supports.[57–60]

We measured patients' self-efficacy because of the conflicting hypotheses regarding the effects of HL screening. On the one hand, HL screening could enhance self-efficacy by enabling physicians to employ tailored communication strategies and more realistic goal-setting; on the other hand, it could lower self-efficacy by eliciting feelings of shame in patients. The lack of a difference in self-efficacy scores between the intervention and control group patients suggests that the management strategies physicians employed need to be reinforced over a number of patient visits, had effects that could not be detected with the measures we used, or were not particularly effective.[61]

The low rate at which physicians discussed screening results with their patients suggests that physicians felt unprepared to address the subject or were concerned about stigmatizing patients. Physician detection of communication barriers without open acknowledgement and mutual problem-solving with patients is unlikely to improve outcomes,[36] and may partially explain our negative patient outcomes. Since patients in our study considered HL measurement to be potentially useful, and intervention group patients did not report lower self-efficacy, physicians should feel less reluctant to discuss this barrier with their patients. Without a more robust measure of patient stigma, however, we cannot definitively determine whether patients who reported the screening to be useful nonetheless may have felt stigmatized.

The lack of patient benefits may illustrate the need to refine our understanding of the mechanisms whereby physician notification of patients' limited HL could lead to improved health outcomes.[60,62,63] In the case of biomedical conditions, acceptable screening tests must detect diseases for which effective treatments exist.[64] With regard to screening for HL deficits, this prerequisite suggests that widespread screening will not be warranted until rigorous trials identify specific actions clinicians can take to change the trajectory of patients' disease.[63]

Our study has several limitations. Because we made only a single assessment of many outcomes, we could not determine whether observed differences in physician behaviors between the intervention and control groups were related to unmeasured baseline differences or were sustained over time; whether intervention group patients' self-efficacy scores would have improved over a longer observation period; or whether the screening test itself may have lowered self-efficacy scores in both groups. Second, we relied on physician self-report of management strategies, rather than objective assessment. Prior research, however, has demonstrated a high correlation between physician reports of their counseling strategies and direct observation.[65] Third, while our study may have overestimated the management strategies of physicians because they were aware they were enrolled in a study, this bias may have disproportionately affected intervention physicians insofar as control physicians did not receive a "control notification."

Fourth, because some patients may have refused study participation because of misgivings related to HL testing, we may have overestimated the degree to which HL screening is acceptable to patients. Assuming the most conservative scenario, in which all 30 patients who refused participation had limited HL and would have found the screening stigmatizing, 83% of patients would still have found screening to be useful. Fifth, our negative results with regard to glycemic control should be considered inconclusive since our study was underpowered for this outcome and our follow-up time was brief. Finally, our results may not generalize to patients without diabetes, private practice settings, or non-primary care relationships.

The increased attention to HL[1,5] and the evolution of shorter screening instruments[25,27,28] has increased interest in developing screening programs in the clinical context. This trial suggests we exercise caution before implementing such programs. While it is encouraging that physicians respond to the notification of their patients' limited HL skills, and reassuring that patients report screening to be useful, system-wide training programs and/or support for physicians and patients may be essential to an effective screening program. Future research should explore the ways in which health care providers and systems can more effectively engage patients with limited HL. Without this step, HL screening and notification of physicians of their patients' HL deficits is unlikely to be a powerful tool in improving diabetes outcomes.

Dr. Seligman was supported by a DHHS-HRSA Research Fellowship Grant 5 D14HP00178-03-00. Dr. Piette is a VA Research Career Scientist. Dr. Schillinger was supported by a NIH Mentored Clinical Scientist Award K-23 RR16539-03, UCSF Hellman Family Research Award, and a Pfizer Inc. Health Literacy Research Award. Electronic data were made available through the San Francisco General Hospital GCRC grant M01RR00083-42.

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