Title
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Journal
The Science of Diabetes Self-Management and Care, 40(5)

ISSN
2635-0106

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Publication Date
2014-09-01

DOI
10.1177/0145721714540220

Peer reviewed

Published in final edited form as:
Diabetes Educ. 2014 September ; 40(5): 581–604. doi:10.1177/0145721714540220.

Update on Health Literacy and Diabetes

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Abstract

Purpose—Inadequate literacy is common among patients with diabetes and may lead to adverse outcomes. We reviewed the relationship between literacy and health outcomes in patients with diabetes and potential interventions to improve such outcomes.

Methods—We reviewed 79 articles covering three key domains: 1) evaluation of screening tools to identify inadequate literacy and numeracy; 2) the relationships of a range of diabetes-related health outcomes with literacy and numeracy; and 3) interventions to reduce literacy-related differences in health outcomes.

Results—Several screening tools are available to assess patients' print literacy and numeracy skills, some of which specifically address diabetes. Literacy and numeracy are consistently

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associated with diabetes-related knowledge. Some studies suggest literacy and numeracy are associated with intermediate outcomes, including self-efficacy, communication, and self-care (including adherence), but the relationship between literacy and glycemic control is mixed. Few studies have assessed more distal health outcomes, including diabetes-related complications, health care utilization, safety, or quality of life, but available studies suggest low literacy may be associated with an increased risk of complications, including hypoglycemia. Several interventions appear effective in improving diabetes-related outcomes regardless of literacy status, but it is unclear if these interventions can reduce literacy-related differences in outcomes.

Conclusions—Low literacy is associated with less diabetes-related knowledge and may be related to other important health outcomes. Further studies are needed to better elucidate pathways by which literacy skills affect health outcomes. Promising interventions are available to improve diabetes outcomes for patients with low literacy, but more research is needed to determine their effectiveness outside of research settings.

Diabetes is the 7th leading cause of death in the United States and is one of the most common chronic diseases, affecting 8.3% of the U.S. population.[1] Patients with diabetes are at risk for a range of adverse health outcomes, including heart attacks, strokes, amputations, blindness, and end-stage renal disease. Although longer duration of diabetes, poor control of intermediate risk factors (e.g., blood pressure, cholesterol levels, glycemic control) and genetic susceptibility are clearly associated with increased risk of adverse outcomes in patients with diabetes, non-clinical factors such as patients' socioeconomic and psychosocial characteristics play a key role in determining risk.[2-4]

In particular, health literacy, or “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions,” has been theorized to be one important, non-clinical factor that may decrease the risk of adverse outcomes in diabetes.[5,6] Inadequate health literacy is common in the US; according to the National Assessment of Adult Literacy, over a third of U.S. adults have basic or below basic health literacy and would have difficulty managing common health-related tasks.[6] Limited health literacy poses a significant economic burden to our society, with national estimates indicating that low health literacy costs the U.S. healthcare system from $106 to $238 billion each year.[7] Accordingly, health literacy is a national priority; Healthy People 2020 goals have called for significant improvements in health literacy to advance the health of the population.[8]

Conceptually, adequate health literacy in the context of diabetes includes a constellation of skills that are critical to patients for managing their condition and navigating the health care environment. These include: cultural and conceptual knowledge; aural and oral literacy (i.e., listening and speaking); print literacy (i.e., writing and reading); and numeracy (i.e., the ability to understand and use numbers). Health literacy skills specific to diabetes include reading labels on pill bottles, following written or verbal directions, and comprehending appointment information, educational brochures, and informed consent documents.[9] Numeracy,[10] is fundamental to diabetes self-management in understanding medication dosing, health insurance information, test results, insulin requirements, and interpreting food

labels. To date, however, no single measure of health literacy in diabetes has adequately captured the full range of skills described above.

Although adequate health literacy is important for optimal diabetes self-management, many questions, both practical and theoretical, remain about how to best measure health literacy, whether to measure literacy as a part of routine care, which outcomes are associated with health literacy, the mechanisms by which inadequate health literacy affects diabetes outcomes, and how interventions designed to support patients with limited health literacy might enhance patient outcomes. The purpose of this paper is to critically review the existing literature on the association between health literacy and outcomes among patients with diabetes and make recommendations for future research to help move the field forward in the coming years.

Methods

In an effort to bring together the broadest knowledge from a variety of study designs and methodologies, a modified narrative synthesis approach was utilized.[11] A narrative synthesis is an attempt to systematize the process of analysis when a meta-analysis or a systematic review may not be the most appropriate approach because of the diversity of methodologies utilized in the studies reviewed. The first step of this process was to search PubMed to identify English-language journal articles using the keywords “diabetes” AND (“health literacy” OR “numeracy”) for the period of January 2009 through December 2012. Only articles describing research conducted in the United States were included. Published systematic reviews were relied upon to capture findings that appeared in the published literature before 2009.[12,13] Next, studies were selected that addressed three key domains: 1) tools to identify inadequate health literacy and numeracy among patients with diabetes; 2) the relationship between health literacy or numeracy and a range of diabetes-related outcomes; and 3) interventions to reduce health literacy-related differences in diabetes-related health outcomes and/or to promote positive outcomes among all patients with diabetes regardless of literacy/numeracy skills. Relevant information was extracted from each of the studies and included in a table. This information was reviewed and synthesized to produce a textual summary of study findings for each of the domains.

To guide this work, a theoretical framework was developed, shown in Figure 1, which is based on the literature. The Figure shows several demographic factors that have been shown to be associated with health literacy. Health literacy itself is conceptualized as having several sub-domains and is presumed to be associated with several social cognitive constructs, for example self-efficacy. In turn, these constructs are linked to a number of self-care domains for diabetes. Self-care domains are linked to a range of intermediate and more distal diabetes-related health outcomes, including quality of life. Health system attributes and provider communication skills are theorized to modify the literacy-social cognitive (and self-care) relationships. This framework was used to guide our evaluation of the literature and recommendations for future work.

Results

The literature search returned a total of 79 articles, which were categorized into the three domains and summarized below.

Diabetes and Health Literacy Measures

Studies examining the role of health literacy in patients with diabetes used measures of general print literacy and numeracy (e.g., Wide Range Achievement Test [WRAT], National Adult Reading Test), general health literacy/numeracy (e.g., Short Test of Functional Health Literacy in Adults [STOFHLA], Rapid Estimate of Adult Learning in Medicine [REALM], Newest Vital Sign [NVS], Brief Health Literacy Screen [BHLS], Subjective Numeracy Scale [SNS], and *diabetes-specific* measures of print literacy and numeracy (Literacy Assessment for Diabetes [LAD] and Diabetes Numeracy Test [DNT]).[14,15] Table 1 summarizes recent psychometric findings, including the internal consistency reliability, construct validity, and predictive validity of measures used in recent studies.[16-33] In general, these studies have confirmed that measures have excellent internal consistency reliability and convergent validity – with strong associations between health literacy measures and patient characteristics, including educational attainment, income, and other measures of health literacy/numeracy. Many recent studies have focused on developing shorter versions of existing measures, or adapting measures for use in new patient populations (e.g., Spanish speakers, Americans Indians, adolescents).[17,18,22,25,26,28,30]

Most health literacy/numeracy measures that have been developed for or used with diabetes patients assess a narrow definition of the health literacy constructs, largely focusing on print literacy and computational numerical skills. Existing measures have not accounted for other elements of literacy/numeracy skills, including oral and aural literacy; understanding of and ability to apply information; the role of cultural and conceptual knowledge; and a wide range of numerical abilities, including “gist” numerical knowledge, which is a global, inexact interpretation of numerical information influenced by a person's background and experiences, amongst other factors.[5,34-36] For example, current measures of health literacy have not adequately addressed how patients interpret oral or multimedia instructions or educational material and apply this information to “real-world” situations.

Numeracy is of particular importance in patients with diabetes, given that many self-care skills, including medication management, interpretation of glucose meter readings, adjustment of insulin, and dietary assessment, rely on numerical skills.[37] Recent studies have demonstrated that numeracy is important in diabetes and that diabetes-related numeracy can be validly assessed.[14,16,38] Moreover, although current numeracy assessments have focused largely on mathematical skills, many patients make decisions based on their “gist” of numerical information.[34] Thus, a more robust assessment of how different aspects of health literacy and numeracy affect patients' decision making would better elucidate how to address health literacy/numeracy barriers to self-care in future behavioral diabetes interventions.

Recent measurement studies have relied on cross-sectional designs to assess the validity of health literacy measures among patients with diabetes.[17,22,23,25,28] As a result, we have

limited evidence of the test-retest reliability of these instruments (i.e., measurement stability over time) as well as their predictive validity for future diabetes self-care behaviors and glycemic control. Prospective studies are needed to answer these and other measurement-related questions.

In summary, significant advances have been made in the development and validation of health literacy/numeracy measures in diabetes. Although some research suggests diabetes-specific measures may be of greater value than general measures for this population,[38] more robust studies are needed to fully assess the reliability and validity of both general and diabetes-specific measures. In addition, instruments need to be broadened to include a more comprehensive array of health literacy/numeracy skills, such as oral literacy and gist numerical knowledge. Future scales will also need to be validated and adapted for additional populations, including children with diabetes and their parents and populations that primarily speak languages other than English and Spanish. Finally, the inclusion of health literacy/numeracy measures in prospective studies will allow for more robust evaluation of the psychometric properties and predictive validity of these instruments.

Association between health literacy, numeracy, and diabetes outcomes

Research on the relationship between health literacy and diabetes-related outcomes is presented in Table 2a,[10,18,24,38-54] which includes 20 recent studies that examine the association between health *literacy* and diabetes-related outcomes, and Table 2b,[10,38,55,56] which includes 5 recent studies that examine the relationship between *numeracy* and diabetes-related outcomes. Below is our summary of the literature on the association between health literacy, numeracy and select diabetes outcomes.

Prevalence of diabetes—One older study involving more than 2500 community dwelling elders[57] found that limited health literacy (measured using the REALM) was independently associated with a greater *prevalence of diabetes*, increasing the odds by 48%.

Knowledge—A number of studies have explored the relationship between health literacy and *diabetes-related knowledge*.[18,24,40,44,47,58-62] They have consistently found higher health literacy to be associated with greater diabetes-specific knowledge. One recent study[41] did not find an association between health literacy and knowledge, perhaps because of over-adjustment for related variables.

Comprehension/Communication—Several studies have explored the relationship between health literacy and domains of patient-clinician communication.[42,45,50,51,63,64]. One older study, involving over 400 public hospital patients with type 2 diabetes, found that patients with limited health literacy, measured with the STOFHLA, were more likely to report worse provider communication in the domains of general clarity, explanation of condition, and explanation of processes of care.[63] These results suggest that limited health literacy may be a marker for oral communication problems, particularly in the technical, explanatory domains of clinician–patient dialogue. A sub-study that used direct observation methods also determined that diabetes patients with limited health literacy had low rates of comprehension of medical terminology used in their visits.[64]

A large national study involving more than 800 patients from 4 public hospitals found that patients with limited health literacy (measured using the 3-item literacy measure developed by Chew et al.[19]) were more likely than those with adequate health literacy to report that both their diabetes would be better controlled if they had better communication with their health care provider and that they desired self-management support.[50]

One study found patients with lower health literacy to be less likely to use online patient portals for communicating with health systems, even though they had computer access and had registered with the portal [51]; other studies found no consistent association between health literacy and engagement with patient portals and health information technology.[42,45] One additional study linked limited health literacy with preferential use of phone support over health information technology.[50] These studies differed greatly, however, in terms of their study samples and research methodologies utilized. It is likely that the two studies with inconsistent findings were limited by a small sample size (N=59)[45] and a small percentage of study participants with limited literacy skills (5.9%).[42] In contrast, the study by Sarkar and colleagues among 14,102 patients (62% with some limitation in literacy skills) found significant differences in patient portal use by literacy skills, even after controlling for relevant covariates.[51]

Trust and participation in decision making—A study in a public university clinic setting found no associations between health literacy, measured with the REALM, and patients' reports of trust or facilitation of patient involvement, although this study did find that patients with lower health literacy reported less desire to participate in decision making.[61]

Self-efficacy—Some early studies failed to find a relationship between health literacy and diabetes self-efficacy, although in one study the relationship approached significance (p=.08).[61,65] However, a recent study showed a positive association between health literacy and self-efficacy.[10] This study utilized a different measure of diabetes-related self-efficacy than previous studies, included patients with type 1 diabetes, and had a larger sample size than the study by Dewalt et al., which may partially explain the variation in findings.[10]

Self-care—Some recent studies have shown an association between health literacy and self-care behavior.[38,40,53,66] In contrast, other recent studies failed to detect a health literacy-self-care linkage.[40,46,66] These studies varied greatly in terms of study sample demographics, methodologies and analyses conducted, limiting the ability to synthesize findings across studies. Similarly, a broad range of self-care behaviors were examined (diet, exercise, foot care, blood glucose testing, etc.), with some showing a significant association with literacy and/or numeracy skills and others not reaching significance.

Medication adherence—Several studies have evaluated the relationship between health literacy and adherence to medications. Two studies evaluated early stages of adherence: Karter and colleagues[43] found a linkage between health literacy and whether patients initiated newly prescribed insulin. Bauer et al.[39] reported that, among diabetes patients with newly prescribed antidepressants, limited health literacy was associated with larger gaps in pill supply and inadequate use of antidepressant therapy.

The studies regarding adherence to ongoing medications (also called secondary adherence) were less conclusive. Baines found that patients with low health literacy, defined as a grade 6 reading level or lower according to the REALM-R,[67] did not exhibit any differences in medication adherence in comparison to patients with adequate literacy skills.[24] However, Osborn et al. 2011[68] reported that low health literacy, as measured by the REALM, partially explained observed racial differences in diabetes medication adherence between African American and White adults.

Glycemic control—Several older studies examined the relationship between health literacy and the most diabetes-specific intermediate outcome, hemoglobin A1C. The aforementioned study in a public hospital setting involving 408 diverse, low-income patients[9] found that limited health literacy, as measured by the STOFHLA in English and Spanish, was independently associated with a two-fold greater odds of very poor glycemic control (>9.5%). A smaller study from an academic clinic in the US South found that patients with limited health literacy, measured with the REALM, had greater than 1% point higher absolute difference in A1C compared to those with greater than high school literacy.[58]

In contrast, two studies from university clinic settings found no association between health literacy and A1C.[61,62] Additionally, a large study conducted in a community-based sample from Vermont found no relationship between health literacy and glycemic control; of note, the sample had excellent glycemic control overall (median A1C 6.9%), 97% of participants were White, and fewer than 20% had less than adequate health literacy on the STOFHLA.[48]

The relationship between literacy and glycemic control continues to be mixed in recent studies.[38,40,44,55,56] Using a measure of health literacy that incorporated print literacy and numeracy, Brega and colleagues found a positive relationship among American Indians and Alaska Natives.[40] However, other investigators did not find such relationships in other populations.[38,44] Recent studies have found a linkage between the *numeracy* component of health literacy and glycemic control.[38,55] Numeracy skills also seemed to explain much of the racial disparity in glycemic control in the latter study.[56]

Diabetes complications—Three studies examined whether limited health literacy is associated with diabetes complications. The aforementioned study involved 408 diverse, low-income patients from a hospital setting,[9] and found that limited health literacy was associated with 2-fold greater odds of patients reporting micro- and macro-vascular complications of diabetes, such as retinopathy and cerebrovascular disease. Another study found that patients with diabetes and limited health literacy (measured using the STOFHLA) had 50% greater odds of having coexisting heart failure.[69] In contrast, Morris and colleagues did not find statistically significant relationships between health literacy and several diabetes-related complications, including retinopathy, nephropathy, gastroparesis, and cardiovascular disease. In some cases (e.g., retinopathy, gastroparesis), the point estimates suggested a relationship (odds ratios near 2.0), but the small numbers of patients with low health literacy reduced the power to detect statistically significant results.[48]

Health care utilization/costs/safety/mortality—We are unaware of any studies that have examined the relationship between health literacy and diabetes-related health care utilization or costs. In the only study regarding safety, limited health literacy was associated with a higher risk of hypoglycemia in insulin-treated patients with diabetes.[52] Finally, no studies have examined the relationship between health literacy and mortality among patients with diabetes specifically.

Association between health literacy and diabetes- future research directions

This review identified a relatively extensive body of literature examining the relationship between health literacy and a range of diabetes-related health outcomes. These studies have generally identified positive relationships between health literacy and diabetes-related knowledge.[18,24,40,44,47,58-62] They have reached mixed conclusions as to whether low health literacy is associated with having less self-efficacy;[10,61,65] similarly, the relationship between low health literacy and suboptimal self-care behavior and glycemic control is mixed,[9,38,40,44,46,48,53,55,56,58,61,62,70] and appears to vary by the clinical context and the make-up of the patient population. Numeracy has been associated with glycemic control in a small number of studies,[38,56,65] but not others.[40] Few studies have examined more distal diabetes health outcomes, including complications, utilization, or quality of life, although two studies had findings demonstrating higher rates of complications[9,69] and one study identified limited health literacy as a patient safety risk.[51]

Recent studies have also better examined the pathways that may link health literacy and diabetes-related outcomes using exploratory and confirmatory causal techniques, such as structural equation modeling and marginal structural models.[10,18,40,49,66] Although this work has yet to fully elucidate the mechanisms linking health literacy to diabetes outcomes, studies have highlighted the important role that specific constructs may play in mediating the relationship between health literacy and diabetes outcomes. For instance, Brega et al.,[40] showed that the relationship between health literacy and glycemic control was mediated by diabetes knowledge. Osborn and colleagues found that the numeracy-glycemic control relationship was mediated by self-efficacy.[10]

One important and unresolved methodological issue in health literacy research (and a potential source of variation in results across studies) is the optimal strategy for adjusting for potential confounders. Ideally, studies will adjust for variables that are truly confounders, to avoid distorting the estimate of the effect of health literacy on the health outcome. However, it is important to recognize that adjustment for related variables, such as education, that can be part of the causal pathway between low health literacy and adverse health outcomes may lead to over-adjustment and produce “false negative” results (i.e., may suggest no relationship when a true relationship actually exists).[71] The ordering of these causal pathways (e.g., education before health literacy vs. health literacy before education) strongly depends on how one conceptualizes health literacy (e.g., whether it is reflects innate cognitive aptitude vs. learned functioning). Given the complexities of these causal webs, when planning the analytic strategy, it is recommended that researchers explicitly define the concept of health literacy and formalize the many potential causal linkages via techniques such as directed acyclic graphs (a diagram illustrating connectivity in conjunction with

causality),[72] with special attention and sensitivity analyses to evaluate the closely linked socioeconomic factors that may mediate, confound, or modify the health literacy-health effect.

Looking to the future of research regarding associations between health literacy and diabetes-related outcomes, several priority areas can be identified. Foremost, additional, large longitudinal cohort studies are needed that measure health literacy, other key predictive constructs such as provider communication skills, and a range of diabetes-related outcomes, including clinical events, safety, and quality of life. Ideally, such studies would incorporate not only measures of reading ability, but also those that examine quantitative skills (numeracy) and even domains such as the ability to communicate verbally (oral and aural literacy) and through writing (including email and text messaging). Because of the considerable potential measurement burden in studies of associations between health literacy and diabetes outcomes, more studies (both longitudinal and cross-sectional) are also needed to examine how measures of these different health literacy domains relate to one another. It is currently unknown if health literacy skills cluster together within individuals; it is also unknown if there are different thresholds at which literacy skills result in better or worse outcomes. It is also important to understand whether contextual factors, such as the type of health care delivery and financing system, may also influence outcomes, and whether limited health literacy is more strongly associated with health outcomes among certain ethnic minority subgroups.

Recent studies identified in this review have included a wider range of populations, including Latinos, Asian, Pacific Islanders, and American Indians/Alaska Natives.[40,41] It is important that future studies also examine diverse populations, particularly those with high risks of diabetes and diabetes-related complications. For those for whom English is a second language, measuring health literacy in both their primary and secondary languages and examining how these different measures affect health literacy-outcomes associations would also be helpful and could help target potential interventions for testing and implementation.

Exploring the real world implications of extant research findings is an important next step. Many of the studies on health literacy and numeracy have been conducted in the context of research. However, important work is needed to explore whether and how to practically assess health literacy and numeracy in usual care settings and how these measures would be implemented to guide approaches to care delivery.

Interventions to Improve Diabetes Outcomes

Table 3[73-85] summarizes 13 papers describing 11 unique interventions, including six randomized controlled trials and five studies that implemented pre-post designs to improve outcomes in diabetes. Studies typically involved one of four types of intervention: (1) patient education, (2) self-management support, (3) disease management, and (4) feedback of health literacy screening results to providers. Outcomes examined include diabetes knowledge, self-efficacy, self-care behavior, and glycemic control.

Education-based strategies—Five studies have targeted patient education as a means of improving diabetes outcomes.[73,75,77-79] Using a computerized diabetes education

program, Kandula and colleagues[77,78] demonstrated significant improvement in diabetes knowledge among participants with adequate and limited health literacy. The addition of the teach-back method to the educational program did not enhance diabetes knowledge. Those with adequate health literacy improved more than those with limited health literacy.

As part of a randomized controlled trial, Gerber et al.[75] also implemented a computerized educational intervention. Investigators found no improvement in knowledge, self-efficacy, use of recommended medical services, or clinical outcomes, although intervention participants with limited health literacy did experience a significant increase in perceived susceptibility to diabetes complications. Exploratory analyses of patients with poor glycemic control showed a statistically significant impact of the intervention on A1C for participants with lower literacy skills, but not for participants with higher health literacy skills.

Using a pre-post design, Kim et al.,[79] examined whether health literacy status modified the impact of diabetes education classes on self-care and risk factor control. Participants with adequate and limited health literacy showed significant pre-post improvement in knowledge, self-care, and A1C. Improvements in A1C were similar for those with adequate and limited health literacy.

As part of a randomized controlled trial, Cavanaugh et al.,[73] compared an enhanced, health literacy sensitive 3-month educational program vs. a standard disease management program. Intervention patients showed a greater improvement in A1C at three months that was statistically significant. However, these differences did not persist at 6 months. In addition, there was no difference in effect between those with adequate vs. limited health literacy.

Self-management support—Five studies have described interventions designed to improve diabetes self-management and the effect size was contrasted in those with vs. without health literacy limitations.[74,76,82,83,85] The effect of patient education combined with one-on-one counseling to encourage patient goal setting and action planning[74,85] showed improvement in knowledge, self-efficacy, activation, distress, and self-care, but the benefits did not differ by health literacy.[85]

Similarly, 2 randomized controlled trials found that employing technology to enhance diabetes self-management was effective in improving eating habits, fat intake, physical activity, and distress, but showed no difference by patient health literacy levels.[76,82,83] Schillinger et al.[82,83] tested two self-management support interventions: (1) automated telephone self-management (ATSM) and (2) group medical visits (GMV) compared to usual care. Both interventions showed improvements in patient experience of chronic illness care, self-efficacy, and self-care, but not for clinical outcomes. Compared to the GMV group, the ATSM condition showed greater improvement in self-care, days restricted to bed, and mental health quality of life,[83] in addition to being associated with higher levels of patient engagement, especially among low-literate patients.[82]

Hill-Briggs et al.,[86] found that an intensive diabetes self-management training adapted for patients with low health literacy led to significantly greater change in A1C (-0.72%) than a

condensed program, but whether this program had differential effects by literacy status was not assessed.

Disease management—Two studies conducted by Rothman et al. tested an intensive diabetes disease management intervention led by clinical pharmacists.[80,81] In a randomized controlled trial, intervention participants received one-on-one education, evidence-based management of blood pressure and glucose-lowering medications, and assistance from a diabetes care coordinator to address patient barriers.[80] At 12 months, intervention participants showed clinically and statistically significant greater improvement in measures of glycemic control and systolic blood pressure compared with usual care controls. Significant improvement in glycemic control was only seen for participants with limited health literacy. In a similar study, conducted using a pre-post design, both participants with limited and adequate health literacy showed significant improvement in A1C.[81]

Feedback of health literacy screening—One randomized controlled trial examined the impact of notifying doctors of their diabetes patients' health literacy limitations.[84] When notified that a patient had limited health literacy skills, physicians were significantly more likely to use 3 or more recommended communication strategies. However, providers notified of their patients' health literacy status felt less satisfied with visits and, for 36% of visits, did not think the notification was valuable. Those in the screening notification group did not have better glycemic control than those in the control group.

Of note, there are currently a fair number of intervention studies that have been recently completed or that are currently being completed that evaluate the role of health literacy-focused interventions for patients with diabetes. Several of these studies are highlighted in Table 4. Many of these studies have developed health literacy sensitive interventions that attempt to provide accommodations for patients with lower health literacy and assess health literacy at enrollment to try to ascertain the role of health literacy as an effect modifier or mediator of the intervention. The results of these studies will provide important additional information about the value of measuring and intervening on health literacy among patients with diabetes.

Conclusions

This review has identified many new studies relevant to understanding the role of health literacy in diabetes. The growing body of research in this field, however, continues to provide mixed results, making it challenging to summarize, with confidence, our current understanding of how health literacy and diabetes outcomes are related; how best to detect limited health literacy skills; and what interventions to employ to reduce literacy-related health inequities.

In terms of measurement, several effective ways exist to identify limited health literacy and numeracy skills. However, there is no single best measure; available tools require trade-offs between accuracy and feasibility. The research on associations between health literacy or numeracy and a range of outcomes in patients with diabetes is extensive. For the most part, studies have found strong associations between health literacy or numeracy and diabetes-

related knowledge.[18,24,40,44,47,49,58-62] However, the relationships with other intermediate outcomes, including communication, self-efficacy, adherence, and glycemic control have been mixed. Some studies have found associations between limited health literacy and adverse outcomes or markers for adverse outcomes,[9,10,39,43,50,51,58,63,64] whereas others have not.[24,42,45,61,62,65] In some cases, absence of a statistically significant relationship may be attributed to small sample sizes/low power. In other cases, it may reflect over-adjustment for potential confounders, particularly educational status, which may be co-linear with health literacy.

Few studies have rigorously examined more distal outcomes among patients with diabetes, including diabetes-related complications or health-related quality of life, and those that have done so have had variable conclusions.[9,48,69] Again, limited power and over-adjustment may explain some of these discrepancies. Of note, the finding by Sarkar and colleagues[52] that patients with low health literacy have an increased risk of hypoglycemia does suggest that providers should be cognizant of patients' health literacy levels when starting medications, particularly insulin, that have increased risk of hypoglycemia.

In terms of interventions, a range of interventions seem effective in improving diabetes outcomes, including ones focusing primarily on patient education, self-care training, or reorganization of the care process (disease management). However, whether such interventions can reduce health literacy-related disparities in intermediate and clinical outcomes remains unclear. Some studies[80] suggest interventions may work better in patients with limited health literacy, whereas others have found no difference or even more improvement for those with adequate health literacy. Further research is required to understand how to best reduce health literacy-related differences in health outcomes, including interventions to ensure adequate health literacy through initial or remedial education, in addition to interventions to improve overall quality of care. Further, more research is needed to investigate the most effective strategies for enhancing both acquisition and retention of diabetes knowledge, as well as to examine different media and strategies for delivering interventions to patients.

Whether or not to screen for limited health literacy in patients with diabetes is a challenging question. On the basis of the trial conducted by Seligman and colleagues, it does not appear that screening and feedback alone improves outcomes.[84] However that trial was relatively small and did not have sufficient power to examine rare but important outcomes like differences in serious hypoglycemia. A larger trial that combines screening with a health literacy-sensitive intervention may be required to determine whether screening is warranted. On the other hand, some have suggested that screening is not a good use of resources and that instead providers should implement “universal precautions” and assume that every patient is at-risk.[87-89] Whether such an approach is preferable will require further testing, as there is not current sufficient evidence to decide whether universal screening or universal precautions should be the preferred approach.

There are limitations to this review that should be noted. First, only English-language articles describing research conducted in the United States were included, and systematic reviews were relied upon for studies published before 2009. It is therefore possible that

some relevant studies may have been excluded from our synthesis. Secondly, a comprehensive, systematic review was not conducted of the selected literature. Instead, a narrative synthesis approach was used to broadly summarize findings from three key domains. This was necessary given the diverse methodologies utilized across studies. Despite these limitations, this review is a notable addition to the literature as it summarizes findings on: 1) tools to identify inadequate health literacy and numeracy among patients with diabetes; 2) the relationship between health literacy or numeracy and a range of diabetes-related outcomes; and 3) interventions to reduce health literacy-related differences in diabetes outcomes and promote positive health outcomes among patients with diabetes regardless of literacy/numeracy skills. Prior reviews have not addressed all three of these domains, have not been focused solely on diabetes, or have not included the most recently published research.[12-14,90]

Implications for Educators

Diabetes educators should recognize that inadequate literacy is common and that care of diabetes can be even more challenging for patients when they have limited print and numerical literacy skills. Clinicians and educators should ensure they provide easy to understand information and reduce unnecessary complexity when developing care plans with patients. Checking understanding by using “teach-back” can reduce the chance of misunderstanding and potentially prevent adverse effects.[91]

Acknowledgments

Barbara Moeykens, MS, literature review, manuscript preparation

Funding: NIDDK P30DK093002 UNC Center for Diabetes Translation Research to Reduce Health Disparities; NIDDK P30DK092924 HMORN UCSF Center for Diabetes Translation Research; and the Diabetes Literacy Project of the European Commission Seventh Framework Programme for Research

Funding: NIDDK P30DK092986 Vanderbilt University Center for Diabetes Translation Research; NIDDK 5P30DK092923-03 Center for American Indian and Alaska Native Diabetes Translational Research; NIDDK P30DK092924 Health Delivery Systems Center for Diabetes Translation Research; NIDDK P30DK093002 University of North Carolina at Chapel Hill Center for Diabetes Translation Research to Reduce Health Disparities; NIDDK 1P30DK092950 Washington University Center for Diabetes Translation Research; NIDDK K01 DK087894 Career Development Award; The Diabetes Literacy Project of the European Commission Seventh Framework Programme for Research. A collaborative project of the NIDDKM-funded Centers for Diabetes Translation Research Centers' Health Literacy Interest Working Group.

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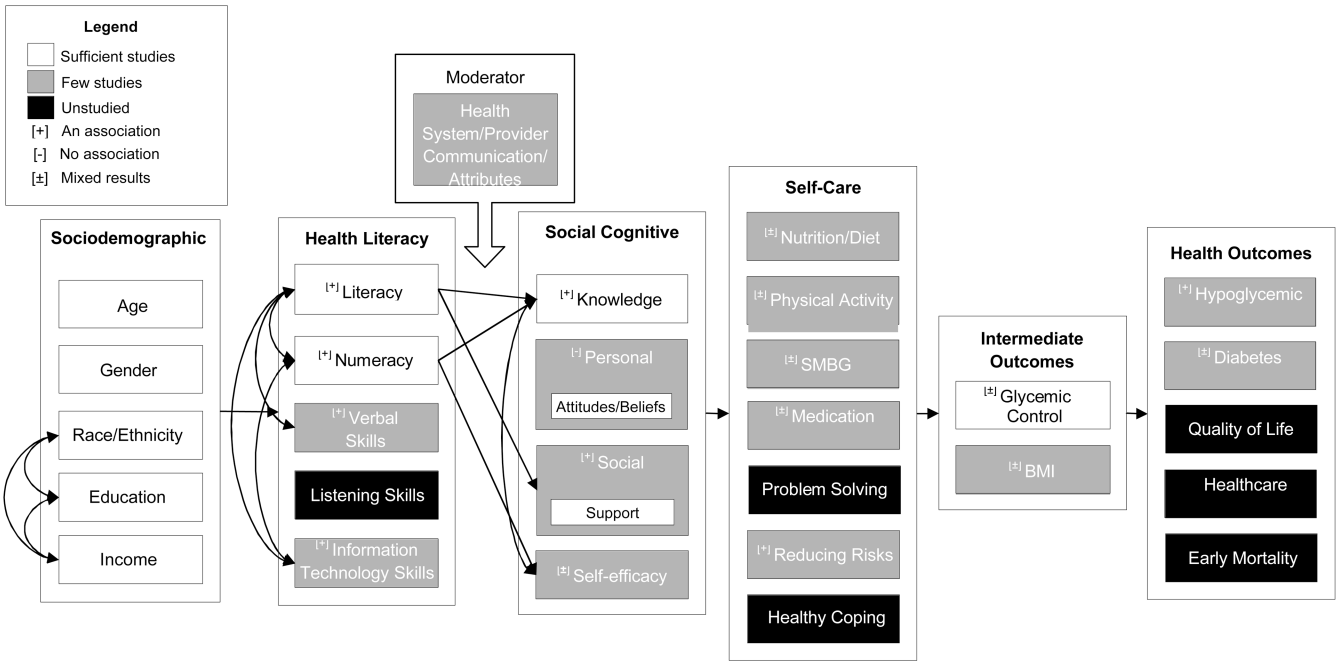

Figure 1.

A framework illustrating sociodemographic determinants of health literacy and health literacy's association with diabetes mechanisms and outcomes.

Notes. SMBG = self-monitoring of blood glucose; BMI = body mass index. Factors are color-coded to indicate whether there is sufficient, few or unstudied associations between health literacy and diabetes mechanisms/outcomes in the health literacy literature to our knowledge to date. [+]Denotes evidence of an association between health literacy and a mechanism/outcome,[-]Denotes evidence of no association between health literacy and a mechanism/outcome; [±]Denotes mixed evidence of an association between health literacy and a mechanism/outcome.

Table 1

Measures of Health Literacy and Numeracy in Diabetes

Measure	Items	Measurement Description	Sample	Findings		
				Internal Consistency Reliability	Construct Validity	Predictive Validity
General						
Brief Health Literacy Screen (BHLS[a])[17]	3	Respondents are asked to rate their confidence completing medical forms, state how often they have problems learning, and if they need help completing medical forms.	296 English and Spanish-speaking adults with T2DM[b] [17]	N/A	Each BHLS item and the BHLS summative score were associated health literacy (STOFHLA[c]) [17]	N/A
Brief Measures of Print Literacy and Numeracy[18]	3 (HL[d]), 4 (HN[e])	3 item HL screener adapted from Chew et al.[19] 4 item HN items adapted from Lipkus[20] and STOFHLA[c] [21]	3,033 American Indian and Alaska Natives[18]	α = 0.67 for HL[d] items[18]	Both HL[d] and HN[e] associated with key demographics (age, education level, income) and diabetes and other disease related knowledge[18]	N/A
Newest Vital Sign (NVS[f]) [22]	6	Respondents are asked to read and interpret a nutritional label.	205 adults with diabetes[22]	N/A	NVS associated with educational attainment and health literacy (STOFHLA[c], *r* =.54)[22]	N/A
Rapid Estimate of Adult Literacy in Medicine (REALM[g])[23]	66	Respondents read medical words, and a correct response is given for each correct pronunciation.	240 adults with diabetes[23]	N/A	REALM associated with health literacy (SKILLD[h])[23]	N/A
Rapid Estimate of Adult Literacy in Medicine - revised (REALM-R[i])[24]	8	Respondents read medical words, and a correct response is given for each correct pronunciation.	125 adults with T2DM[b]; 71% AA; 68% less than HS[24]	α=0.95; item-test correlations, *r*=0.78-0.91[24]	N/A	REALM-R[i] associated with diabetes knowledge, but not A1C[24]
Rapid Estimate of Adult Literacy in Medicine - short form (REALM-SF[j])[22]	7	Respondents read medical words, and a correct response is given for each correct pronunciation.	243 adults with diabetes[22]	N/A	REALM-SF associated with educational attainment and health literacy (STOFHLA[c], *r* =.48)[22]	N/A
Single-Item Literacy Screener (SILS[k])[25]	1	Respondents rate how often they need to have someone help them read instructions, pamphlets, or other written material from their doctor or pharmacy.[26]	225 adults with diabetes[25]	N/A	SILS was associated with health literacy (STOFHLA[c]) [25]	N/A
Short Estimate of Functional Health Literacy	41	Respondents read two health-related passages, and complete	180 adolescents	N/A	N/A	STOFHLA[c] associated with

Measure	Items	Measurement Description	Sample	Findings		
				Internal Consistency Reliability	Construct Validity	Predictive Validity
in Adults (STOFHLA[c])[17,22,25,27,28]		37 Cloze items and 4 numeracy items.	with asthma and diabetes[27]			intent to use online health resources[27]
			225 adults with diabetes[25]	N/A	Low scores on the STOFHLA[c] associated with black race, lower self-rated reading ability, lower educational attainment, and health literacy (SILS[k])[25]	N/A
			490 adults with diabetes[22]	N/A	STOFHLA[c] associated with educational attainment and health literacy (NVS[f] [*n*=205, *r*=.54] and REALM-SF[j] [n=240, *r* =.48])[22]	N/A
			296 English and Spanish-speaking adults with T2DM[b] [17]	N/A	STOFHLA[c] categories associated with health literacy (each BHLS[a] item and the BHLS[a] summative score)[17]	N/A
			144 Latino adults with diabetes[28]	N/A	STOFHLA[c] associated with the DNT-15[l] Latino[28]	N/A
Diabetes-specific						
Diabetes Numeracy Test-15 (DNT-15[l])[28]	15	Latino version of the original DNT.[16,29] Items require respondents to perform addition, subtraction, understand fractions, divide, understand number hierarchy and perform calculations.	144 Latino adults with diabetes[28]	KR-20=0.78[28]	DNT-15 Latino associated with educational attainment, general numeracy (WRAT[m]), and health literacy (STOFHLA[c])[28]	DNT-15 Latino was associated with acculturation, but not self-care or A1C[n] [28]
DNT-Adolescent and DNT-14 Adolescent[30]	39 (DNT-A[o]), (DNT-14[p])	Adolescent versions of the original DNT.[16,29] Items require respondents to perform addition, subtraction, understand fractions, divide, understand number hierarchy and perform calculations related to common diabetes tasks.	Sample 1=61 adolescents; Sample 2=72 adolescents[30]	Sample 1: KR-20=0.93 Sample 2: KR-20=0.83 Combined Sample (DNT-14[p]), KR-20=0.82[30]	In Sample 1, DNT-39[q] and DNT-14 associated with parent education, and adolescent reading skills (WRAT[m]) [30] In Sample 2, DNT-14 associated with diabetes problem solving skills.	In Sample 1, DNT-39[q] and DNT-14[p] associated with insulin pump use. In combined sample analysis, DNT-14[p] associated with A1C[n].[30]

Measure	Items	Measurement Description	Sample	Findings		
				Internal Consistency Reliability	Construct Validity	Predictive Validity
Diabetes-specific Health Literacy Index (DHLI[r])[31]	10	An index of diabetes specific health literacy was constructed from responses to 10 diabetes self-care regimen items.	1318 adults with diabetes[31]	α=0.93[31]	Compared to patients with the lowest DHLI[s] literacy level, patients with the highest DHLI[r] literacy level were more likely to be younger, White, have more education, but modestly less income[31]	DHLI associated with self-graded diabetes self-care, but was not associated with the average number of days performing five self-management behaviors or A1C[n] [31]
Literacy Assessment for Diabetes[33]	60	Respondents read words related to diabetes management and care, and a correct response is given for each correct pronunciation.	203 adults	High test-retest reliability; ICC=. 86	LAD had high concurrent validity with WRAT3 (*r*=.81) and REALM (*r*=.90)	N/A
Spoken Knowledge in Low Literacy in Diabetes Scale (SKILLD[h])[23]	10	Further validation of the original SKILLD[h].[32] Respondents answer open-ended questions about behaviors to manage diabetes.	240 adults with diabetes[23]	α=0.54[23] Inter-rater reliability on 23 interviews; all kappas p<.001, Spearman's rho= 0.79% (95% CI 0.56 to 0.91, p<0.001)[23]	SKILLD associated with higher education, health literacy (REALM[g]), and diabetes knowledge (DKT[s])[23]	N/A

[a] BHLS = Brief Health Literacy Screen

[b] T2DM = Type 2 Diabetes Mellitus

[c] STOFHLA = Short Test of Functional Health Literacy in Adults

[d] HL = Health Literacy

[e] HN = Health Numeracy

[f] NVS = Newest Vital Sign

[g] REALM = Rapid Estimate of Adult Literacy in Medicine

[h] SKILLD = Spoken Knowledge in Low Literacy in Diabetes Scale

[i] REALM-R = Rapid Estimate of Adult Literacy in Medicine – Revised

[j] REALM-SF = Rapid Estimate of Adult Literacy in Medicine – Short Form

[k] SILS = Single-Item Literacy Screener

[l] DNT-15 = Diabetes Numeracy Test – 15

[m] WRAT = Wide Range Achievement Test

[n] A1C = Hemoglobin A1C

[o] DNT-A = Diabetes Numeracy Test - Adolescent

[p] DNT-14 = Diabetes Numeracy Test 14

[q] DNT-39 = Diabetes Numeracy Test 39

[r] DHLI = Diabetes Specific Health Literacy Index

[s] DKT = Diabetes Knowledge Test

Table 2a

Recent Studies Examining the Association between Literacy and Diabetes-Related Outcomes

Author	Associations examined	Key Findings	Literacy assessment
Bauer Journal of General Internal Medicine. 2013. [39]	Literacy, Adherence for antidepressants among diabetes population	N=1,366 Limited health literacy associated with poorer adherence (more time without sufficient pill supply: (41 % vs. 36%, p<0.01) to newly prescribed antidepressants	3-item screener
Bains Diabetes Technology and Therapeutics 2011[24]	Literacy, Diabetes Knowledge, Self-care and glycemic control	N=125 Health literacy associated with diabetes knowledge (beta 0.55) but not adherence or glycemic control (beta -0.03)	REALM-R[a]
Brega Patient Education and Counseling 2012[40]	Literacy/numeracy, diabetes knowledge, self-care behavior, and glycemic control in American Indians and Alaska Natives	N=2594 Literacy was related to diabetes knowledge (beta 0.695) and to glycemic control (unadjusted beta -0.070), partly explained by glucose monitoring and by knowledge	Adapted Chew 3-item literacy screener 4 numeracy items adapted from Lipkus[20] and STOFHLA[b]
Brega Ethnicity & Disease 2012[18]	Literacy and numeracy with diabetes and cardiovascular knowledge	N=3033 Literacy and numeracy were associated with 4 types of knowledge: general diabetes, insulin use, blood pressure, and cholesterol	Adapted Chew 3-item literacy screener 4 numeracy items adapted from Lipkus[20] and STOFHLA[b]
Cavanaugh Annals of Internal Medicine 2008[38]	Literacy and glycemic control	N= 398 Literacy not associated with A1C[c] in adjusted analysis	REALM[d]
Coffman Journal of Cultural Diversity 2012[41]	Literacy and diabetes symptoms in Latinos	N=144 46.5% low literacy; Health literacy not associated with diabetes knowledge in multivariate analysis	STOFHLA[b] (Spanish)
Glasgow 2011 JMIR[42]	Literacy and use of diabetes self-care website	N = 270 Health literacy not related to website use (data not shown)	STOFHLA[b]
Karter 2010 Diabetes Care[43]	Literacy and insulin initiation adherence	N=169 Non-adherent patients more likely to report inadequate health literacy: 51% vs. 30%	Single question (trouble learning about condition because of difficulty understanding written information)
Mancuso Nursing and Health Sciences 2010[44]	Literacy, trust and glycemic control	N=102 literacy not related glycemic control (r = -0.063) (beta = - 0.070) or to trust (r = 0.063) but is related to diabetes knowledge (r = 0.296)	STOFHLA[b]
Mayberry Diabetes Techol Ther 2011[45]	Literacy and use of web portals for diabetes	N=61 Participants with limited health literacy or numeracy were no less likely to access web portals but lower health literacy was associated with less frequent use of a computer to research diabetes medications or treatments	3-item screener
Mbaezue J National Med Assoc 2010[46]	Literacy and self-monitoring of blood glucose	N = 189 Literacy not related to daily blood glucose testing but was related to keeping a record of blood glucose levels (77.3% vs. 88.6%)	STOFHLA[b]

Author	Associations examined	Key Findings	Literacy assessment
McCleary-Jones ABNF Journal 2011[47]	Literacy and diabetes knowledge	N=50 Literacy associated with diabetes knowledge in bivariate analysis	REALM[d]
Morris BMC Family Practice 2006[48]	Literacy, glycemic control, and diabetes complications	N=1002 Literacy not related to glycemic control or diabetes-related complications	STOFHLA[b]
Osborn Diabetes Technology and Therapeutics 2010[49]	Health Literacy, self-care and glycemic control	N = 130 literacy not directly related to self-care or glycemic control but literacy related to these outcomes somewhat through social support	REALM-R[a]
Osborn 2010[10] Journal of Health Communication	Literacy, self-efficacy, medication adherence, and glycemic control in diabetes	N = 383 Literacy associated with adherence (r = 0.12) Literacy associated with self-efficacy, but literacy was not associated with glycemic control directly (r = -0.02), only indirectly though self-efficacy	REALM[d]
Sarkar Patient Education Counseling 2008[50]	Literacy and patients' reported preferences for diabetes self-management support and (b) perceived need for better communication to improve diabetes control;	N=796 Limited literacy was significantly associated with greater interest in telephone self-management support (OR 1.74 (1.19–2.54) 52% with limited literacy vs. 31% with adequate literacy reported that better communication with provider would improve their diabetes control;	Chew 3-item screener
Sarkar 2010 J Health Comm[51]	Literacy and use of electronic patient portal	N=14,102 Patients with limited literacy had higher odds of never signing on to the patient portal (OR 1.7, 1.4 to 1.9) compared with those with adequate literacy.	Chew 3-item screener
Sarkar JGIM 2010[52]	Literacy and risk of hypoglycemia in patients with Type 2 diabetes	Low literacy associated with increased risk of hypoglycemia (adjusted OR 1.3-1.4 for each screening question)	3-item screener (modified)
Vassy MDM 2012[53]	Literacy and motivation to implement lifestyle change after genetic testing	Patients with high literacy (but not those with low literacy) were less highly motivated to make lifestyle change after receiving low-risk results	
Wallace - Nursing research 2010[54]	Literacy and patient-rating of self-management support	Higher self-management support noted in patients with higher literacy	

[a] REALM-R = Rapid Assessment of Adult Literacy in Medicine - Revised

[b] STOFHLA = Short Test of Functional Health Literacy in Adults

[c] A1C = Hemoglobin A1C

[d] REALM = Rapid Estimate in Adult Literacy in Medicine

Table 2b

Numeracy and Diabetes Outcomes

Author	Associations examined	Key Findings	Numeracy assessment
Cavanaugh Annals of Internal Medicine 2008[38]	Association between diabetes-related numeracy and self-management skills and glycemic control	N=398 adults with diabetes. DNT[a] associated w/self-management skills (misinterpreting glucometer readings, miscalculating carb load, and medication dose) and glycemic control. DNT was also associated with health literacy and general numeracy skills	Diabetes Numeracy Test (DNT[a])
Huizinga Obesity 2008[38]	Association between diabetes-related numeracy, health literacy and BMI	N=160 English-speaking, adult primary care patients. Numeracy was associated with BMI[b] after adjusting for health literacy. Health literacy was not associated with BMI[b]	WRAT-3[c]
Marden Diabetic Medicine 2012[55]	Association between diabetes-related numeracy, health literacy and glycemic control	N=112 adults with type 1 diabetes. Numeracy was associated with A1C[d], but health literacy was not associated with A1C[d].	Skills for Life Initial Assessment
Osborn Diabetes Care 2009[56]	Evaluated whether diabetes-related numeracy, health literacy and general numeracy mediated association between race and glycemic control	N=383 adults with type 2 diabetes. Diabetes-related numeracy largely explained African American-white differences in A1C[d]. Health literacy was not associated with A1C[d] and did not explain African Am-white differences in control.	Diabetes-related numeracy (DNT), general numeracy (WRAT-3[c]), literacy (REALM[e])
Osborn J Health Comm 2010[10]	Evaluated whether self-efficacy explains the association between diabetes-related numeracy and health literacy and glycemic control	N=383 adults with diabetes. Literacy and numeracy were bi-variately associated with self-efficacy. However only numeracy was independently associated with self-efficacy. Self-efficacy was in turn was associated with A1C[d] control. Numeracy and literacy were not associated with A1C[d] after adjustment for confounders, study suggests an indirect effect of numeracy→self-efficacy→A1C[d]	Diabetes-related numeracy (DNT[a]), general numeracy (WRAT-3R[f]), literacy (REALM[e]), 8-item Perceived Diabetes Self-Management Scale (PDSMS[g])

[a] DNT = Diabetes Numeracy Test

[b] BMI = Body Mass Index

[c] WRAT-3 = Wide Range Achievement Test 3

[d] A1C Hemoglobin A1C

[e] REALM = Rapid Assessment of Adult Literacy in Medicine

[f] WRAT-3R = Wide Range Achievement Test 3 – Revised

[g] PDSMS = Perceived Diabetes Self-Management Scale

Table 3

Diabetes-Related Interventions Designed to Address Health Literacy

Source	Study Design (N)	Intervention / Population	Health Literacy Measure	Outcomes	Key Findings
Cavanaugh Diabetes Care 2009[73]	RCT[a] (198)	Compared treatment group (providers educated on HL, numeracy, and communication; patients educated using Diabetes Literacy and Numeracy Education Toolkit) with control group (enhanced diabetes care program). Participants were adult, English-speaking patients with type 1 or 2 diabetes and A1C[b] ≥ 7.0% who were referred for participation in the enhanced diabetes care program of one of two academic medical centers.	REALM[c] (<9th grade vs. higher) Diabetes Numeracy Test (DNT[d])	Self-efficacy Self-care Satisfaction A1C[b]	Adjusted Analyses: Compared to controls, treatment group showed significantly greater improvement in A1C[b] from baseline to 3 months (p = 0.03) but not baseline to 6 months. There were no significant group differences in change in self-efficacy, self-care or satisfaction from baseline to 6 months. Analyses were not stratified by patient HL level.
DeWalt Patient Education and Counseling 2009[74]	Pre-Post (250)	Examined whether Living with Diabetes Guide – designed to facilitate problem solving and goal setting – helped patients achieve behavioral goals. Participants were adult, English- or Spanish-speaking patients with a diagnosis of type 2 diabetes.	STOFHLA[e] (inadequate/ marginal vs. adequate)	Goal setting Problem solving Achievement of behavior goals Satisfaction	Most participants established goals related to diet and/or nutrition. 93% achieved ≥1 goal, 73% achieved ≥2. 33% reported achieving their goals at each of three follow-up visits. Some participants exhibited problem-solving behavior and most were satisfied with the Guide. No differences in behavior change were found by HL[f] level or language spoken.
Gerber Diabetes Care 2005[75]	RCT[a] (244)	Examined use and effect of "Living Well with Diabetes" intervention, delivered via touch-screen computers in clinic waiting rooms. Controls received computerized diabetes quizzes plus usual care. Participants were adult patients with self-reported type 1 or type 2 diabetes in 5 public outpatient clinics in Chicago, Illinois. Patients who never used study computer or who had incomplete data were excluded from analyses.	STOFHLA[e] (inadequate/ marginal vs. adequate)	Knowledge Self-efficacy Perceived susceptibility to complications Use of recommended medical care Study computer use A1C[b] BMI[g] BP[h]	Participants with lower HL[f] showed lower knowledge at baseline, compared to those with higher HL (p < 0.05). Intervention had no significant effect on A1C[b], BMI, BP, self-efficacy, knowledge, or use of medical care (ps > 0.10). Intervention group experienced significantly greater increase in perceived susceptibility to diabetes complications compared to control group (p = 0.009). A significant increase in perceived susceptibility was seen in the lower HL group (p = 0.016), but not the higher HL group (p > 0.10). Exploratory analyses of low-literate participants with poor glycemic control showed greater improvement in A1C[b] in the intervention compared to the control group (p < 0.05); a similar intervention effect was not seen among high-literate participants with poor glycemic control. Mean duration of study computer use was greater in intervention group (p = 0.001). Within the intervention group, computer use was greater for participants with higher HL[f] (minutes of use, p = 0.006; times used, p = 0.002).

Source	Study Design (N)	Intervention / Population	Health Literacy Measure	Outcomes	Key Findings
Glasgow Patient Education and Counseling 2012[76]	RCT (463)	Examined impact of computer-assisted self-management (CASM[i]) and CASM plus human support (CASM+[j]) versus enhanced usual care. Participants were overweight patients with type 2 diabetes and at least one other risk factor for heart disease. Patients were age 25-75, had access to a telephone and internet, and were able to read and write in Spanish or English.	3 Chew items Subjective Numeracy Scale	Self-efficacy Problem-solving Supportive resources Eating behaviors Fat intake Caloric expenditure Medication adherence Health status Distress BMI[g] A1C[b] Lipids Mean arterial pressure 10-year coronary heart disease risk	Combined intervention arms showed significantly greater improvement at 12 months than the control condition on eating habits, fat intake, physical activity, and distress (ps<0.05). Groups did not differ at 12 months on medication adherence, clinical outcomes, self-efficacy, problem solving, supportive resources, or health status. The CASM[i] and CASM+[j] groups did not differ on behavioral outcomes. Patient HL[f] level did not moderate intervention effects.
Kandula Patient Education and Counseling 2009[77]	Pre-Post (190)	Examined knowledge before and after participants were exposed to Multimedia Diabetes Education Program (MDEP[k]). Participants were English-speaking patients age 35-75 from one of two primary care clinics. Some patients had type 2 diabetes, whereas others did not have diabetes.	STOFHLA[e] (inadequate, marginal, adequate)	Knowledge	MDEP[k] resulted in improved knowledge in each of three HL[f] groups: adequate, marginal, and inadequate (p<0.001). Controlling for pre-test score, age, gender, diabetes status, and race/ethnicity, people with inadequate HL[f] learned less than did those with adequate HL (beta -2.3, p<0.01). When education was included as a covariate, the association of HL[f] with knowledge gain became nonsignificant (-0.91).
Kandula Journal of Health Communication 2011[78]	Pre-Post Experiment 1 (113) Experiment 2 (58)	Experiment 1 examined knowledge before and after exposure to MDEP[k]. Experiment 2 examined knowledge before and after participants received MDEP[k] plus teach-back. Participants were adults aged 35-75 either with or without type 2 diabetes.	STOFHLA (inadequate/ marginal vs. adequate)	Knowledge	Experiment 1 Unadjusted analyses: MDEP resulted in immediate improvement in knowledge (p<0.001). Knowledge declined significantly over the following two weeks (p < 0.001) but remained significantly higher than baseline (p<0.001). This pattern held true for those with adequate and marginal/inadequate (M/I[l]) HL[f]. Although those with adequate HL[f] scored better at each time point than did those with M/I[l] HL[f] (ps<0.001), pre-post knowledge gain and knowledge decline from post-test to 2-week follow up did not differ by HL[f] level. Experiment 2 Unadjusted analyses: Knowledge improved significantly from pre- to post-test (p<0.001) and post-test to post-teach back (p<0.001), significantly declining from post-teach back to 2-week follow up (p<0.001). Knowledge at 2 weeks remained significantly higher than pre-test (p<0.001). This pattern held true in both

Source	Study Design (N)	Intervention / Population	Health Literacy Measure	Outcomes	Key Findings
					HL[f] groups. Those with adequate HL[f] scored significantly better than scored significantly better than did those with M/I HL[f] scored significantly (p<0.01). Those with M/I HL[f] showed greater decline from post-teach back to 2-week follow up than did those with adequate HL[f] (p<0.001). Overall knowledge gain did not differ by HL [f] group. Combined samples: Controlling for age, education, gender, diabetes, and baseline knowledge, teach back did not result in improved knowledge (beta -0.5). There was no difference between the HL[f] groups in knowledge retention once education was controlled.
Kim Diabetes Care 2004[79]	Pre-Post (92)	Examined impact of University-based diabetes education classes. Participants were English-speaking adults with type 1 or type 2 diabetes already enrolled in class	STOFHLA[e] (inadequate/ marginal vs. adequate)	Knowledge Self-care A1C[b]	Patients with limited HL[f] had significantly lower levels of knowledge at baseline and 3-month follow up than did participants with higher HL [f] (ps ≤ 0.01). Participants showed significant improvement in knowledge and self-care. Patients with adequate HL[f] showed a significant increase in exercise, whereas those with limited HL [f] showed a significant improvement in diet, SMBG[m], and foot care. A1C[b] also significantly improved (effect sizes of 0.53 and .49 for those with adequate and limited HL [f], respectively). HL groups did not differ on A1C[b] at 3 months.
Rothman JAMA 2004[80]	RCT (217)	Examined impact of an intensive diabetes management program. Control received single educational visit with clinical pharmacist and usual care. Participants were English-speaking adults with type 2 diabetes and poor glycemic control (A1C[b] ≥ 8.0%)	REALM (low HL[f] [≤6th grade] versus higher HL[f])	A1C SBP	Compared to controls, intervention participants experienced significantly greater improvement in A1C[b] from baseline to 12 months (p=0.001) and were more likely to attain their goal A1C[b] of ≤7.0% (p=0.05). When stratified by HL[f] group, only participants with low HL[f] showed significant improvement in A1C[b] (p<0.001) and were more likely to attain goal A1C [b] levels (p=0.02). Intervention participants showed significant improvement in SBP[n] over time, in comparison to controls (p=0.006). The intervention effect did not differ by HL[f] group.
Rothman Diabetes Educator 2004[81]	Pre-Post (159)	Examined impact of a pharmacist-delivered diabetes management program designed for patients with limited literacy. Participants were adult patients with a diagnosis of type 2 diabetes and poor glycemic control (A1C[b] ≥ 8.0%)	REALM (low HL [f] [≤6th grade] versus higher HL[f])	A1C [b]	Participants with lower and higher levels of HL[f] both showed significant improvement in A1C[b] between baseline and 6-month follow up. Controlling for patient characteristics, baseline A1C[b], and time between baseline and follow-up A1C[b] values, health literacy was not

Source	Study Design (N)	Intervention / Population	Health Literacy Measure	Outcomes	Key Findings
					a significant predictor of improvement in A1C a significant predictor of improvement in A1C[b]
Schillinger Health Education and Behavior 2008[82]	RCT[a] (224)	Examined participation in two self-management support (SMS[o]) interventions as part of the Improving Diabetes Efforts Across Language and Literacy (IDEALL[p]) project: (1) weekly automated telephone disease management with nurse follow-up when clinically warranted (ATDM[q]) and (2) monthly group visits facilitated by physician and health educator (GMV[r]). Participants were adult patients with diagnoses of type 2 diabetes and A1C[b] ≥8.0% and who spoke English, Spanish or Cantonese.	STOFHLA (limited [inadequate/marginal] vs. adequate)	Intervention reach: (1) Participation (2) Representativ-eness (3) Engagement	Most clinics recruited agreed to participate (67%). The majority of clinicians from those clinics (84%) referred at least one patient to one of the SMS[o] interventions. Enrolled patients were similar to eligible patients from participating clinics on age, sex, and A1C[b], but differed with regard to language, race/ethnicity, and insurance coverage. ADTM: Most patients (93.8%) responded to at least 1 call, with no difference by literacy level. Ever users responded to 56.6% of calls. Among English speakers, patients with lower HL[f] were more likely to develop action plans as a result of nurse follow-up calls (p=0.03). GMV[r]: 69.6% of participants attended at least one session. Ever users attended 53.1% of sessions. Participants with limited HL attended fewer visits and were less likely to participate fully (ps < 0.05).
Schillinger Diabetes Care 2009[83]	RCT[a] (339)	The Improving Diabetes Efforts Across Language and Literacy (IDEALL[p]) project compared 2 SMS interventions to usual care: (1) weekly automated telephone self-management support with nurse follow-up when clinically warranted (ATSM[s]), (2) GMV[r]. Participants were adult patients with type 2 diabetes and poor glycemic control (i.e., A1C[b] ≥ 8.0%) who had been seen in the Community Health Network of San Francisco in the past year. Patients spoke English, Spanish or Cantonese.	STOFHLA[e] (limited [inadequate/marginal] vs. adequate)	Patient experience with chronic illness care Self-efficacy Self-care Engagement Quality of life Functional status A1C[b] DBP[t] SBP[n] BMI[g]	Compared to usual care, ATSM[s] and GMV[r] participants showed improvements in patient experience of chronic illness care (effect sizes=0.51 and 0.53, respectively, ps<0.001), self-efficacy (effect sizes=0.41 and 0.38, respectively, ps<0.01), and self-care (effect sizes=0.62 and 0.30, respectively, ps<0.05). Improvement in self-care was significantly greater in the ATSM[s] than the GMV[r] arm (effect size=0.34, p = 0.02). ATSM[s] participants reported significantly fewer days restricted to bed than did usual care (p = 0.05) and GMV[r] participants (p = 0.004) and reported less restricted activity than usual care participants (p = 0.03). The ATSM[s] group showed significant improvement in mental health quality of life compared to the GVM[r] group (effect size 0.31, p<0.03). Clinical outcomes did not show significant improvement. Analyses were not stratified by HL[f] level.
Seligman Journal of General Internal Medicine 2005[84]	RCT[a] (63 doctors, 182 patients)	Examined the impact of notifying primary care physicians of patient HL[f] status. Intervention physicians were notified that patient had limited HL[f]. Control providers were not.	STOFHLA[e] (limited [inadequate/marginal] vs. adequate)	Perceived usefulness of HL[f] screening Use of recommended communication	Intervention physicians were more likely than control physicians to use 3 or more recommended communication strategies (p = 0.04). Intervention physicians were less likely to feel satisfied with the visit (p = 0.01). Patient self-efficacy did not differ by treatment arm at follow up. Nearly all patients thought

Source	Study Design (N)	Intervention / Population	Health Literacy Measure	Outcomes	Key Findings
		Participants were English- or Spanish-speaking patients >30 years of age with type 2 diabetes, limited HL[f] Participants were English- or Spanish-speaking patients >30 years of age with type 2 diabetes, limited HL[f] Participants were English- or Spanish-speaking patients >30 years of age with type 2 diabetes, limited HL[f] existing treatment relationship with a provider in the General Internal Medicine or Family Practice clinics at the participating academic hospital.		HL screening HL visit Provider satisfaction with visit Provider perceived effectiveness Patient self-efficacy A1C[b]	HL screening was useful. Providers thought it was useful for 64% of visits and discussed results with only 2% of patients. No changes in A1C[b] were seen in either treatment arm.
Wallace Patient Education and Counseling 2009[85]	Pre-Post (250)	Examined impact of Living with Diabetes Guide, which was designed to facilitate problem solving and goal setting. Participants were adult, English- or Spanish-speaking patients with type 2 diabetes from one of three academic internal medicine practices.	STOFHLA[e] (limited [inadequate/marginal] vs. adequate)	Knowledge Self-efficacy Motivation Self-care Distress	Participants showed significant improvement in knowledge, self-efficacy, activation, distress, and self-care behavior from baseline to study completion ($p<0.001$). Results did not differ by literacy level, although some outcomes differed by participant language. Diabetes distress declined significantly more for Spanish than English speakers ($p = 0.03$). Self-efficacy ($p < 0.001$) and self-care improved more in the English- than Spanish-speaking participants ($p = 0.05$).

[a] RCT = Randomized Controlled Trial

[b] A1C = Hemoglobin A1C

[c] REALM = Rapid Assessment of Adult Literacy in Medicine

[d] DNT = Diabetes Numeracy Test

[e] STOFHLA = Short Test of Functional Health Literacy in Adults

[f] HL = Health Literacy

[g] BMI = Body Mass Index

[h] BP = Blood Pressure

[i] CASM = Computer Assisted Diabetes Management

[j] CASM+ = Computer Assisted Diabetes Management plus Human Support

[k] MDEP = Multimedia Diabetes Education Program

[l] M/I = Marginal/Inadequate

[m] SMBG = self-monitoring of blood glucose

[n] SBP = Systolic Blood Pressure

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[o] SMS = Self-Management Support

[p] IDEALL = Improving Diabetes Efforts across Language and Literacy

[q] ATDM = Automated Telephone Diabetes Management

[r] GMV = Group Medical Visit

[s] ATSM = Automated Telephone Self-Management

[t] DBP = Diastolic Blood Pressure

Table 4

Current or Recently Completed Interventions Addressing Health Literacy in Patients with Diabetes

ClinicalTrials.Gov Identifier	Title	Description (from study)
NCT01876485	Point-of-care Health Literacy and Activation Information to Improve Diabetes Care	This hybrid effectiveness/implementation trial will be conducted in two phases over four years. In Phase 1, we will evaluate the process of implementing a collaborative, diabetes goal-setting intervention (Empowering Patients in Chronic Care [EPIC]) personalized to self-reported patient activation and functional health literacy (FHL) levels into routine primary care practices. In Phase 2, we will conduct a randomized, clinical trial to compare the effectiveness of EPIC to enhanced usual care (EUC).
NCT00973830	The Missouri Health Literacy and Diabetes Communication Initiative	To evaluate the efficacy of the American College of Physicians Foundation (ACPF) Diabetes Guide (Living with Diabetes: An Everyday Guide for You and Your Family) to improve diabetes self-management.
NCT01344668	The Public Private Partnership Addressing Literacy-Numeracy to Improve Diabetes Care (PRIDE)	This cluster randomized trial will evaluate the effectiveness of addressing health literacy and numeracy to improve diabetes care in state health department safety net clinics.
NCT00848315	Diabetes Management in Low-Income Hispanic Patients	The overall goal of this randomized clinical trial (RCT) is to test the efficacy of a culturally- and literacy-tailored cognitive-behavioral intervention designed to enhance adherence to diabetes self-management behaviors and improve glycemic control among low-income Hispanic individuals with type 2 diabetes mellitus.
NCT00964587	Cardiovascular Disease Education and Problem-Solving Training in People With Type 2 Diabetes (DECIDE)	The purpose of this study is to determine if patient education and problem-solving training, delivered in self-study, group, and individual intervention modalities, will produce substantial improvements in Cardiovascular Disease (CVD) risk profile via improved self-management in urban African Americans with type 2 diabetes and a high CVD risk profile.