

AHA SCIENTIFIC STATEMENT

Health Literacy and Cardiovascular Disease: Fundamental Relevance to Primary and Secondary Prevention

A Scientific Statement From the American Heart Association

ABSTRACT: Health literacy is the degree to which individuals are able to access and process basic health information and services and thereby participate in health-related decisions. Limited health literacy is highly prevalent in the United States and is strongly associated with patient morbidity, mortality, healthcare use, and costs. The objectives of this American Heart Association scientific statement are (1) to summarize the relevance of health literacy to cardiovascular health; (2) to present the adverse associations of health literacy with cardiovascular risk factors, conditions, and treatments; (3) to suggest strategies that address barriers imposed by limited health literacy on the management and prevention of cardiovascular disease; (4) to demonstrate the contributions of health literacy to health disparities, given its association with social determinants of health; and (5) to propose future directions for how health literacy can be integrated into the American Heart Association's mandate to advance cardiovascular treatment and research, thereby improving patient care and public health. Inadequate health literacy is a barrier to the American Heart Association meeting its 2020 Impact Goals, and this statement articulates the rationale to anticipate and address the adverse cardiovascular effects associated with health literacy.

Jared W. Magnani, MD, MSc, FAHA, Chair
Mahasin S. Mujahid, PhD, MS, FAHA
Herbert D. Aronow, MD, MPH
Crystal W. Cené, MD, MPH, FAHA
Victoria Vaughan Dickson, PhD, RN, FAHA
Edward Havranek, MD, FAHA
Lewis B. Morgenstern, MD, FAHA
Michael K. Paasche-Orlow, MD, MS, MPH
Amy Pollak, MD
Joshua Z. Willey, MD, FAHA
On behalf of the American Heart Association Council on Epidemiology and Prevention; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Peripheral Vascular Disease; Council on Quality of Care and Outcomes Research; and Stroke Council

Health literacy, the degree to which an individual can access, process, and comprehend basic health information and services in order to inform and participate in health decisions,¹ has a pivotal, decisive role in healthcare delivery and outcomes. Limited health literacy is an invisible barrier to healthcare delivery that has profound costs for individual and public health. Health literacy has been associated with limited knowledge of health conditions²⁻⁴ and medications,⁵ poorer overall health status,^{6,7} higher healthcare costs,^{8,9} and increased likelihood of rehospitalization¹⁰ and mortality.¹¹⁻¹³ Awareness of health literacy, its implications, and relevance to individual and public health is fundamental to achieving the American Heart Association (AHA) 2020 Impact Goals to improve cardiovascular health by 20% for all Americans.¹⁴ The rationale for this statement is to address the relevance of health literacy to cardiovascular disease (CVD) management, prevention, and public health.

The overall objective of this statement is to clarify the central relevance of health literacy to cardiovascular health. The Institute of Medicine's landmark 2004 report *Health Literacy: A Prescription to End Confusion* emphasized that health literacy operates within the "health concept," recognized as the broad social fabric in which institutional, public, and private health occurs.¹ Over the course of the past 1 to 2

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decades, the discourse has progressed: Abundant and consistent scholarship has shown that health literacy is a barrier to healthcare access, physician-patient communication, adherence, and effective healthcare use and that organizational factors have a major role in easing or complicating health for people with limited health literacy. Likewise, patient- and family-centered care and patient/family engagement have emerged as priorities for addressing health literacy. Limited health literacy prevents individuals and families from developing the knowledge, skills, and confidence necessary to engage in their care in an empowered fashion. The effects of limited health literacy extend beyond the individual health encounter, given that health literacy is a shared function of social, cultural, and individual factors. Therefore, it structures opportunities for health and mediates and exacerbates disparities in cardiovascular care and treatment. This statement affirms the commitment of the authors and the AHA to addressing these challenges.^{1,15}

Programmatic initiatives from the American Medical Association, the American College of Physicians,¹⁶ and The Joint Commission¹⁷ have advocated for incorporating health literacy into healthcare delivery and services. The Agency for Health Research and Quality (AHRQ) has promoted the Universal Precautions Toolkit to improve communication and implementation of health care.¹⁸ The authors of this statement embrace the “universal precautions” approach, which advocates for standardized communication, accessible at any level of health literacy. Understanding health literacy is critical for delivering health care, developing prevention initiatives, and addressing public health. This statement appreciates health literacy as systematically permeating how patients interact with the medical system, including their self-care, activation, and participation in decision making. Limited health literacy prevents individuals and families from developing the knowledge, skills, and confidence necessary to engage or participate in their care. The summary objective of this statement is to clarify the central relevance of health literacy and its importance in cardiovascular health and the health of the individual, the family, and our society.

The commitment of the AHA to this statement stems from the recognition of the widespread prevalence of limited health literacy in US adults¹⁹; the associations of health literacy with increased patient morbidity, mortality, healthcare use, and costs^{7,8,20}; and the increasing complexity of understanding and navigating healthcare material and documentation provided to patients, including the use of electronic patient portals and other Internet-based health tools.²¹

The objectives of this statement are 5-fold. The first objective is to inform healthcare professionals’ knowledge of the prevalence of limited health literacy as it relates to cardiovascular health within and across healthcare encounters. Second, the statement establishes the

importance of health literacy to health care in general and CVD treatment and prevention specifically by summarizing the association of health literacy across a spectrum of cardiovascular risk factors, diseases, and treatments. Third, this statement describes established and promising strategies that mitigate barriers imposed by limited health literacy to CVD management and prevention. The fourth objective is to articulate the interface of health literacy with social determinants of health and thereby demonstrate how limited health literacy perpetuates health disparities. Finally, this statement suggests future directions for integrating health literacy in cardiovascular research and health with the goal of improving patient care and public health initiatives.

METHODS: COMMITTEE COMPOSITION AND APPROACH TO THE LITERATURE

This statement summarizes contemporary studies relevant to health literacy and CVD and situates health literacy as an essential concept for the community of AHA researchers, investigators, and practitioners. This statement is not a systematic review, given the expansive nature of the topics of health literacy and CVD, nor is it a guideline for clinical practice. Rather, the statement is a summary of the contemporary science of CVD and health literacy with the purpose of enhancing the knowledge and awareness of healthcare professionals. The studies presented are a synthesis of the existing literature, informed by existing systematic reviews and the diverse perspectives of the experts on the writing group.²² The 10-member writing group for this statement is diverse in its demographic composition, disciplinary perspectives, and context expertise. It consists of 4 women, includes 2 underrepresented minorities, and comprises clinicians (internal medicine, cardiovascular physicians, and nurses) and clinician scientists engaged in health services research, epidemiology, health education, and behavioral health interventions. The committee is further enhanced by individuals with expertise in social determinants of health (including health literacy) and cardiovascular health disparities affecting racial/ethnic minorities and rural populations and the development and evaluation of community-based interventions and strategies to promote health.

HEALTH LITERACY: DEFINITIONS AND DIMENSIONS

Measuring Literacy in the United States

In 1992, the US Department of Education initiated the first population-based, in-person assessment of adult literacy with the National Adult Literacy Survey.²³ The

survey characterized 46% to 51% of participants as being in the 2 lowest quintiles of literacy. From this study, as many as 90 million Americans ≥ 16 years old were estimated to have significantly limited reading and quantitative skills. In 2003, the US Department of Education conducted the National Assessment of Adult Literacy Survey,²⁴ which specifically included health literacy, in contrast to the measurement of general literacy by the National Adult Literacy Survey. The National Assessment of Adult Literacy Survey determined that 36% of US adults had basic or below-basic health literacy and identified significant differences in health literacy across sex, age, and race/ethnicity categories.²⁵ Twelve percent of women were classified in the lowest literacy category, below basic, compared with 16% of men. Older adults (categorized as ≥ 65 years of age) had worse health literacy than individuals in younger age categories in that 59% were measured at or below basic health literacy. There were substantive racial and ethnic differences: 9% of non-Hispanic whites had below-basic health literacy compared with 25% of American Indian/Alaskan Native, 24% of non-Hispanic black, and 41% of white Hispanic adults. Health literacy was positively correlated with educational attainment. Of individuals without a high school education, 49% were categorized as having below-basic health literacy compared with 3% to 5% of those with some college education.²⁵

The more contemporary Programme for the International Assessment of Adult Competencies surveyed $>160\,000$ adults 16 to 65 years of age in 24 countries and subnational regions to assess literacy and numeracy in a technology-rich environment. Literacy and numeracy levels were ranked from 1, the lowest level, to 5, the highest level, across participating countries.²⁶ In the United States, 5010 adults participated in the administration of the survey in 2011 to 2012. The majority of US participants (54.3%) were categorized as having level 2 or lower literacy. In terms of numeracy proficiency, 65.6% of participants were classified as having level 2 or lower proficiency.²⁷ These data indicate the ongoing challenge of adult literacy in contemporary US society.

Dimensions of Health Literacy

Continued scholarship in health literacy has broadened the definition and constituent components of the topic. The definition of health literacy has expanded to encompass skills requisite for successful functioning in an information-based, electronic society.²⁸ There is a current appreciation that health literacy extends beyond proficiency in reading, writing, and numeracy and involves interpretation of images, oral communication, facility with technology, and social networking.²⁹ Health literacy has further been considered fundamental to abstract skills such as evaluating and weighing treatment considerations and engaging in medical decision mak-

Table 1. Taxonomy of Health Literacy Skills and the Specific Domains of Their Competencies

Skill	Constituent Competency and Ability
Literacy	Perform basic reading tasks
Interaction	Engage in communication about health
Comprehension	Understand varied sources of information
Numeracy	Engage in basic numerical and arithmetic tasks and operations
Information seeking	Seek and obtain health-related information
Application/function	Process and use current and evolving health-related information
Decision making/critical thinking	Engage in informed health-related decision making
Evaluation	Filter, interpret, and evaluate information
Responsibility	Take responsibility for health and health-related decision making
Confidence	Have sufficient confidence to improve personal and community health
Navigation	Navigate society and health systems for successful self-care

Data derived from Sørensen et al³³ and Haun et al.³⁴

ing; how patients navigate the electronic, geographic, and administrative components of health care; and how individuals implement health-related information and engage in self-care.^{30–32} The net result is an understanding of health literacy as spanning multiple cognitive and social domains that interface with the technological and community environments. A content analysis identified 11 fundamental, interrelated skills that make up and define health literacy.³³ These skills and their definitions are summarized in Table 1.

Multiple and diverse measures have been implemented for quantifying and characterizing individuals' health literacy. Table 2 summarizes select, widely used health literacy measures, their fundamental characteristics, and the health literacy dimensions assessed by the measures. The most recent comprehensive review of the dimensions and psychometric properties of the measures was published in 2014,³⁴ which at that time identified 51 tools for health literacy measurement. The tools were characterized as general assessments ($n=26$), disease or condition specific ($n=15$), or targeted to a population ($n=10$). The Boston University Health Literacy Tool Shed maintains a database of health literacy measures.⁴⁷ Items are categorized by health literacy domain, instrument context (such as condition or disease), number of items, instrument language, and administration time. The database also contains a psychometric evaluation for the various instruments that includes the sample size used for validation, cohort age, and the measure style as characterized by the predominant measurement tools for health literacy assessment. More than 125 such instruments are now cataloged by the Health Literacy Tool Shed.^{34,47}

Table 2. Health Literacy Measures and Descriptive Characteristics

Measure	Constructs Measured	Year Published	Available in Spanish	Number of Items	Time to Administer, min	Remote Administration (Phone, E-Mail)
Rapid Estimate of Adult Literacy in Medicine ³⁵	Recognition and pronunciation of medical terminology	1991 (LV) 1993 (SV)	No	66 (LV) 7 (SV)	3–7 (LV) 1 (SV)	No
Test of Functional Health Literacy in Adults ^{36,37}	Reading comprehension, numeracy	1995 (LV) 1999 (SV)	Yes	67 (LV) 36 (SV)	22 (LV) 7 (SV)	No
Three-Item Health Literacy Screening, ³⁸ Brief Health Literacy Screening Tool ³⁹	Reading and verbal comprehension, need for assistance, confidence	2004, 2009	Yes	4	1–2	Yes
Short Assessment of Health Literacy for Spanish-Speaking Adults ⁴⁰	Recognition of medical terms	2006 (LV) 2010 (SV)	Yes	50 18	3–6 (LV) 2–3 (SV)	No
Newest Vital Sign ⁴¹	Reading, comprehension of a nutrition label	2005	Yes	6	3–4	No
Medical Term Recognition Test ⁴²	Recognition of medical terms	2010	No	70	2–3	Yes
Functional Health Literacy Test ⁴³	Reading comprehension	2009	No	21	3	No
Health Literacy Skills Instrument ^{44,45}	Prose, document, quantitative, oral and Internet information seeking	2010 (LV) 2012 (SV)	No	25 10	>10 (LV) 5–10 (SV)	Yes
Health Literacy Assessment Using Talking Touchscreen Technology ⁴⁶	Prose, document, quantitative	2011	Yes	30	18	Yes

LV indicates long version; and SV, short version.

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HEALTH LITERACY AND SOCIAL DETERMINANTS OF HEALTH

Health literacy extends beyond the clinic- or hospital-based environment where health care is delivered to encompass how individuals approach and navigate self-care and health-related experiences. Social determinants of health are defined by the World Health Organization as “the circumstances in which people are born, grow, live, work, and age, and the systems put in place to deal with illness.”⁴⁸ Limited health literacy is more prevalent among racial and ethnic minorities, older adults, and individuals with less education.^{19,24} Likewise, health literacy is strongly related to socioeconomic position, English language proficiency, and the

development of general literacy.⁴⁹ The relationship between health literacy and social determinants of health is portrayed in Figure 1. This figure further indicates the shared associations among health literacy, social determinants, and intermediate and long-term health outcomes.

Health literacy may be contextualized in the context of the life course model of risk factors and disease.^{50–52} Language is critical for self-expression beginning in infancy and is shaped by early childhood exposure to verbal expression, diction, and linguistic content in the home and social arenas. Children of low-income families experience deficits in language exposure and acquisition (described as the “30-million-word gap”) from early infancy.⁵³ In addition, pa-

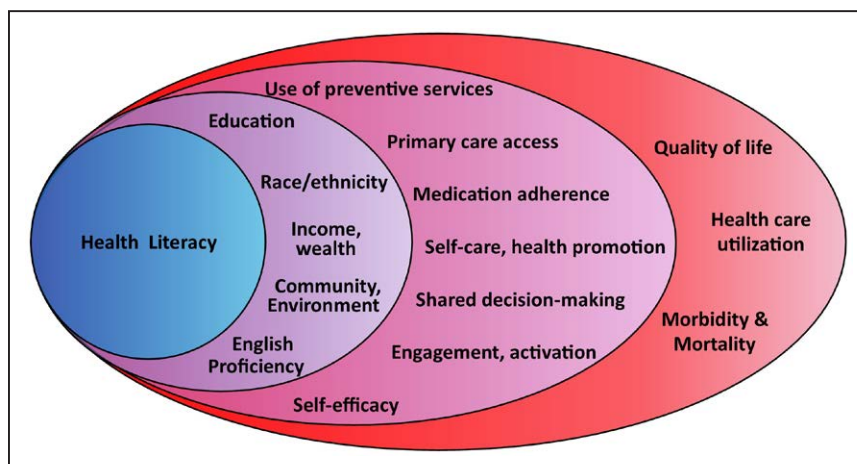


Figure 1. Health literacy nested within social determinants of health (education, race/ethnicity, income and wealth, community and environment, and English proficiency), which in turn are associated with a range of intermediate- and long-term health-care outcomes.

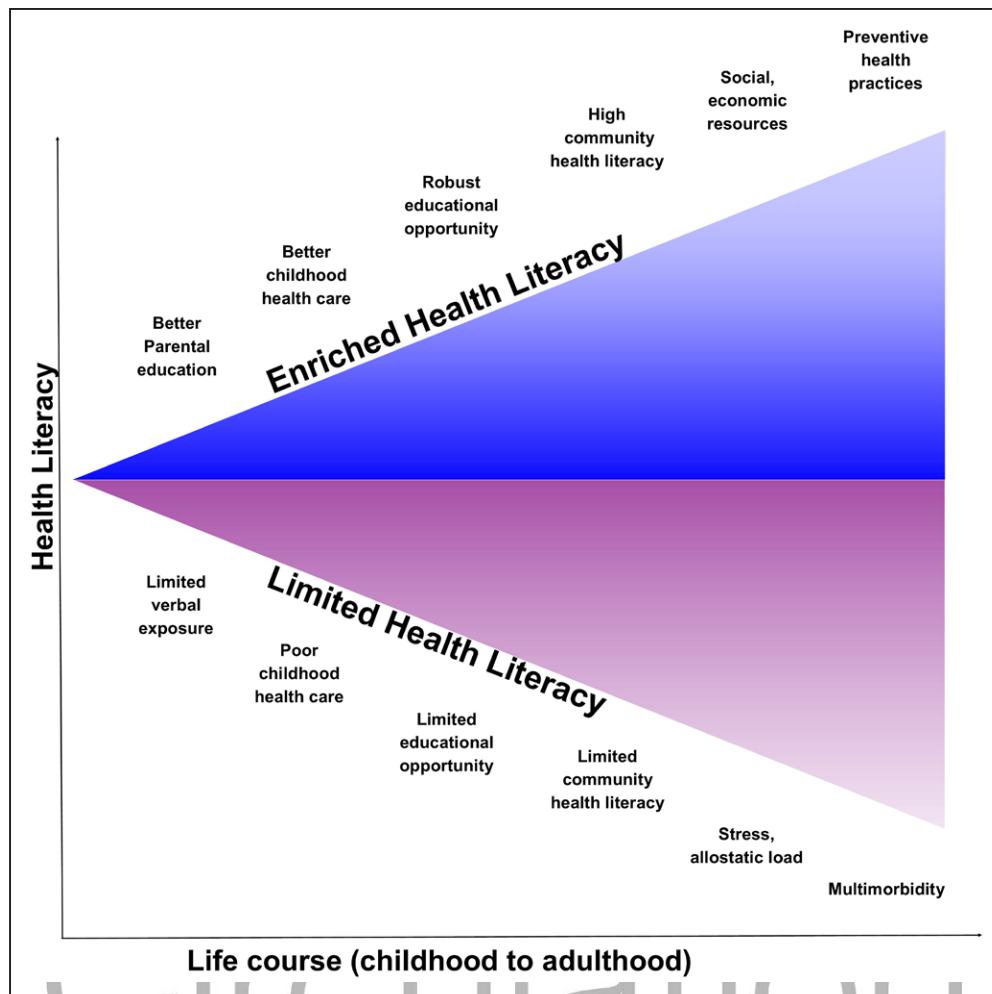


Figure 2. Health literacy presented as a life course trait.

Opportunities exist for the enfranchisement or impoverishment of health literacy beginning in infancy and spanning across the life course. Health literacy as encountered in adults reflects myriad familial, community and environmental, and educational influences. This statement emphasizes the overall goal as not correcting health literacy challenges in an individual but implementing approaches toward healthcare communication and delivery that are universally accessible.

rental health literacy directly affects the preventive care that children receive,^{54,55} having a direct impact on both childhood health and orientation toward preventive health care.⁵⁶ Children of parents with limited literacy have been shown to have worse health outcomes. At least 1 in 3 adolescents and young adults has limited health literacy,⁵⁴ and children with limited literacy tend to exhibit worse health behaviors.⁵⁷ Older adults have increased risk for limited health literacy for multiple reasons that may include social norms and expectations about health or decline in cognitive function with aging. More important, limited generational opportunities for education may impair general literacy early and throughout life; older adults bear the effects of the absence of standardization in education and the historical racial segregation of the educational environment.⁵² Educational disenfranchisement in older adults similarly clusters with income and socioeconomic position, both correlated with

health literacy. Thus, health literacy both is related to and perpetuates the disparities associated with social determinants of health. Figure 2 presents opportunities for challenges and gains in health literacy across the life course.

The Challenge of Limited Health Literacy

Obstacles to optimal health care for people with limited health literacy occur at multiple levels in healthcare delivery.⁵⁸ First, individuals with limited health literacy experience challenges in accessing healthcare services. Electronic or paper applications for insurance coverage are complex documents that are not designed for individuals with basic literacy skills. Successfully completing such documentation may be challenging. The details of insurance coverage and accompanying administrative bureaucracy demand a high level of literacy to grasp. The Affordable Care Act and its constituent mandates

were critiqued as challenging for many to understand, which may have affected enrollment.⁵⁹

Second, as consistently documented by an extensive body of literature, all manner of health-related materials exceeds the reading ability of the average US adult.¹ Educational brochures and instructions routinely include technical language and complicated explanations of pathophysiology or do not include comprehensible illustrations, making them hard to understand. Despite hundreds of publications about the readability of informed consent documents and patient education materials, most patients cannot read documents intended to empower them. Individuals with limited health literacy may have less access to reliable Internet-based health education materials.^{60–65}

A third challenge for individuals with limited health literacy stems from physician-patient communication. Physicians frequently use medical terminology in their written and oral communication that exceeds the understanding of even highly educated individuals.^{66,67} Overcoming patient-provider communication barriers remains challenging, particularly for patients with limited health literacy, despite the growing emphasis on improving communication skills in medical school and resident curricula.⁶⁸ Furthermore, individuals with limited health literacy may not ask fundamental questions or seek to clarify ambiguity^{69,70}; they may have had stigmatizing experiences resulting from limited literacy and have shame about their level of understanding.^{71,72} A universal precautions approach advocates screening for comprehension of the clinical plan and tailoring treatment to enhance and verify patient understanding.^{73,74} Such an approach mitigates shaming of individuals with limited literacy and improves healthcare communication by placing responsibility for successful communication with the provider.⁷⁵

Fourth, patients with limited health literacy must use oral and written communication, integrate complex information, and use numeracy and quantitative skills. For example, medication adherence frequently requires understanding complex scheduling and dosing details, as well as information relating to dietary choices and timing, and appropriate vigilance about symptoms and side effects.

Finally, language and cultural barriers may interfere with healthcare delivery. There is extensive literature on health literacy challenges faced by refugees and immigrants, in addition to individuals with limited English proficiency.^{76,77} Such populations are vulnerable to poor communication about health-related services.⁷⁸ Improved access to language-appropriate services is critical. It is also important to understand that overcoming language barriers is simply the first step; mitigating health literacy barriers in interpreted encounters is the next communication challenge to overcome for safe and effective care.

HEALTH LITERACY AND CARDIOVASCULAR RISK AND OUTCOMES

Health literacy has a prominent role in the primary and secondary prevention of CVD. Given the extensive literature, the writing group selected studies that emphasize health literacy in addressing CVD risk and outcomes. Table 3 provides details on studies selected for larger size ($n > 150$, used to focus on larger studies), use of validated measurement of health literacy, and treatment of health literacy as an independent variable that were published from January 2004 through November 2016.

Hypertension and Health Literacy

Health literacy has had robust investigations in hypertension.^{79–81,112} Health literacy is related to recognition and knowledge of hypertension. A cross-sectional study of 402 patients from 2 racially diverse and geographically distinct public, urban healthcare facilities found that the majority (55%) of individuals with inadequate health literacy were not able to recognize a blood pressure of 160/100 mm Hg as abnormal.¹¹³ The finding is particularly relevant in that knowledge of blood pressure targets has been related to effective management of hypertension.¹¹⁴ In urban ambulatory care cohorts, individuals with limited health literacy had a 1.8 to 2.7 times increased risk of not achieving guideline-based blood pressure recommendations.^{80,115} Limited studies have examined the effect of patient-centered interventions integrating health literacy on blood pressure control. A multisite trial (the Heart Healthy Lenoir Study) conducted in 6 primary care practices over 24 months found that a multilevel intervention improved systolic blood pressure among patients across health literacy levels.⁸²

Patient-centered interventions have addressed limited health literacy to improve medication adherence in hypertension. Adherence is a complex, multilevel concept; its constructs and the relevance of social determinants of health, including literacy, to medication adherence in patients with hypertension have been evaluated by a systematic review and meta-analysis.^{116,117} The aim of such interventions is to address patient misunderstanding of prescription instructions and unintentional misuse of medications to which individuals with limited health literacy are particularly vulnerable.^{118,119} A 2-arm multisite trial ($n = 845$) used patient-centered drug labeling, recognized by the study team as an inexpensive and simple modification, to improve adherence to blood pressure and diabetes mellitus medications. The intervention improved adherence in study participants with inadequate literacy 4-fold, by self-report, and 5-fold, by pill count, compared with the standard care

referent cohort.¹²⁰ A small (n=68) study composed predominantly of participants with limited health literacy identified that aids, such as flashcards and smartphone-activated videos, improved medication adherence.¹²¹ These strategies indicate that simplified regimen administration, use of aids, and multilevel interventions can improve blood pressure control in individuals with limited health literacy.

There are continued gaps in the investigation of health literacy and hypertension. Few studies have measured health literacy as a covariate. Inclusion of health literacy as a measure in large, prospective, community-based cohort studies would facilitate exploring the prospective short- and long-term effect of health literacy on hypertension and blood pressure control. Inclusion of health literacy measurement in clinical trials may provide insight into how health literacy may modify adherence in a trial, as well as provide an assessment of generalizability to individuals with limited health literacy who are less likely to participate in clinical trials.

In addition, multidisciplinary and multilevel interventions are needed to improve blood pressure control in individuals with hypertension and limited health literacy. Healthcare providers and health systems should collaborate to provide patient materials and to use strategies that mitigate the effects of limited health literacy.¹²² For example, strategies that promote patient-provider communication⁸² and foster patient empowerment may improve medication adherence.¹²³ Community-based interventions can leverage resources such as neighborhood pharmacies to promote blood pressure screening, monitoring, and adherence. Multifaceted interventions that incorporate patients, providers, and health systems are essential to address health literacy barriers and to promote patient empowerment and success with long-term hypertension management.

Diabetes Mellitus and Health Literacy

Success for the patient with diabetes mellitus requires an array of skills integral to health literacy: interactional, numeracy, information seeking, application/function, decision making, confidence, and navigation. Specific components of diabetes mellitus in which health literacy has been best evaluated are social and cognitive factors, including diabetes mellitus knowledge,¹²⁴ self-efficacy^{125,126} or activation,¹²⁷ and attitudes or beliefs,¹²⁸ and self-care,⁸⁴ spanning the range of activities that relate to diabetes mellitus management, including diet, physical activity, medication and treatment adherence, and problem solving. Health literacy has also been linked to outcomes relevant to diabetes mellitus such as glucose control and microvascular complications.^{129,130} The literature describing these associations between health literacy and diabetes mellitus was well evaluated and summarized in 2014 by Bailey et al.¹³¹ Limited

health literacy has been related to decreased access to healthcare screening and basic services and therefore has been implicated in diabetes mellitus risk.¹³²

Diabetes mellitus is a chronic disease that requires consistent health behaviors guided by specific knowledge of the condition and its treatment.¹²⁸ A systematic review identified consistently strong evidence that health literacy is associated with diabetes mellitus knowledge.¹³⁰ One study (n=2594) characterized Indians and Alaskan Natives as having limited social and economic resources and identified a strong relation between health literacy and diabetes mellitus knowledge that adversely affected dietary behaviors in this vulnerable cohort with significant social and economic challenges.⁸⁷ The study authors concluded that diabetes mellitus knowledge is a central component of addressing diabetes mellitus care in individuals with inadequate health literacy. Conversely, decreased health literacy in a single-center cohort of individuals (n=280) with poorly controlled diabetes mellitus (hemoglobin A_{1c} levels >8%) was related to poor knowledge; individuals in the lowest health literacy tertile were 4-fold more likely to assert that their diabetes mellitus was well controlled, despite a hemoglobin A_{1c} >8.0%, than those in the referent tertile.¹³³ The importance of health literacy as a parental trait is demonstrated by its impact on parents of children with type 1 diabetes mellitus; adults with limited health literacy face the challenge of knowledge gaps in providing care for their children.^{134,135}

Observational studies have related health literacy to diverse and varied behaviors that make up diabetes mellitus self-care,¹³¹ including associations between health literacy and adherence to both diabetes mellitus and nondiabetes mellitus medication.^{84,88} Health literacy has been demonstrated to mediate the racial disparities in adherence to diabetes mellitus medications observed in a biracial (black and white; n=398) cohort.¹³⁶

The electronic patient portal is increasingly used to augment self-care in diabetes mellitus and other chronic diseases. Analysis of a large health maintenance organization found that members with limited health literacy were 1.7 times less likely to use the electronic patient portal for communication and disease management than members with adequate or higher health literacy.¹³⁷ Multiple studies have related health literacy to patient engagement, activation, and self-efficacy,^{3,138,139} with some demonstration that health literacy may facilitate or mediate patient activation and diabetes mellitus management.^{140,141} The range of studies indicates the types of health literacy skills (Table 1) that are needed for self-care among patients with diabetes mellitus.

Evidence about the relation of health literacy and glycemic control is mixed, which may be explained by variation in how potential confounders are handled

Table 3. Summary of Selected Studies of Health Literacy and Cardiovascular Risk Factors and Outcomes

Disease	Authors	Study Design, Setting	N	HL Assessment	Setting
Hypertension	Aboumatar et al ⁷⁰	Observational, cross-sectional	275	REALM	Ambulatory
	Willens et al ⁷⁹	Observational, cross-sectional	23 483*	BHLS	Ambulatory
	McNaughton et al ⁸⁰	Observational, cross-sectional	423	REALM	Ambulatory
	McNaughton et al ⁸¹	Observational, cross-sectional	46 263	BHLS	Hospitalization
	Halladay et al ⁸²	RCT	525	S-TOFHLA	Ambulatory
Diabetes mellitus	Morris et al ⁸³	Cross-sectional, observational	1002	S-TOFHLA	Ambulatory
	Cavanaugh et al ⁸⁴	Observational, cross-sectional	398	DNT, REALM	Ambulatory
	Mbaezue et al ⁸⁵	Observational, cross-sectional	189	S-TOFHLA	Ambulatory
	Sarkar et al ⁸⁶	Observational, cross-sectional	14 357	3-Item screener	HMO registry
	Brega et al ⁸⁷	Secondary analysis	2594	Print literacy, numeracy	Ambulatory
	Bauer et al ⁸⁸	Prospective	1366	3-Item screener	HMO claims data
	McNaughton et al ⁸⁹	Cross-sectional, Guyanese ED	228	SILS	ED presentation
Obesity	Geboers et al ⁹⁰	Prospective cohort	3241	BHLS	Ambulatory
	Lassetter et al ⁹¹	Observational, cross-sectional	364	NVS	Enrolled at primary care visit
	Lam and Yang ⁹²	Observational, cross-sectional	1035	S-TOFHLA	Community-based adolescents
	Joshi et al ⁹³	Observational, cross-sectional	739	HL Management Scale	Mail-based survey
	Chari et al ⁹⁴	Observational, cross-sectional	239	NVS	Ambulatory
Coronary disease	Bailey et al ⁹⁵	Retrospective	696	NVS, S-TOFHLA, REALM	Hospitalization
	Gazmararian et al ⁹⁶	Prospective cohort	1549	S-TOFHLA	Ambulatory
	Kripalani et al ⁹⁷	Retrospective	434	REALM	Ambulatory
	McManus et al ⁹⁸	Retrospective cohort	804	Single-item screen	Hospitalization, ACS registry
ACS and HF	Bell et al ⁹⁹	RCT	851	S-TOFHLA	Hospitalization
HF	Laramee et al ¹⁰⁰	Cross-sectional, observational	998	S-TOFHLA	Ambulatory
	Murray et al ¹⁰¹	Prospective	192	S-TOFHLA	Ambulatory, inpatient
	Macabasco-O'Connell et al ¹⁰²	Cross-sectional, observational	585	S-TOFHLA	Multicenter, ambulatory
	Chaudhry et al ¹⁰³	RCT, secondary analysis	1464	REALM-R	Ambulatory
	Peterson et al ¹⁰⁴	Retrospective cohort	1494	BHLS	Outpatient survey
	Noureldin et al ¹⁰⁵	RCT, secondary analysis	281	S-TOFHLA	Hospitalization
	Dewalt et al ¹⁰⁶	Multisite RCT	605	S-TOFHLA	Ambulatory

(Continued)

Table 3. Continued

Intervention and/or Main Outcomes	Follow-Up	Essential Finding, Primary Outcome
Involvement, communication, trust, satisfaction	NA	No difference in medical decision making by HL; communication behaviors differed by HL status in asking medical questions.
BP control	NA	No difference in SBP control by HL; lower HL, median SBP, 130 (IQR 120–142) mm Hg; higher HL, SBP 131 (120–142) mm Hg. Difference in DBP by HL: lower HL, 70 (64–79) mm Hg; higher HL, 74 (67–82) mm Hg.
BP control	NA	Limited HL associated with increased risk of uncontrolled BP (OR, 1.75; 95% CI, 1.06–2.87).
BP control	NA	Lower HL: OR, 1.06 (95% CI, 1.01–1.12) compared with higher HL.
BP control	2 y	Mean SBP decrease at 12 mo: lower HL, 6.6 mm Hg; higher HL, 5.3 mm Hg. At 24 mo: lower HL, 8.1 mm Hg; higher HL, 4.6 mm Hg. Between-group difference not significant at 12 or 24 mo.
HbA _{1c} , cholesterol, BP	NA	HL not associated with glycemic control (β , 0.001; 95% CI, –0.01 to 0.01), systolic (β , 0.08; 95% CI, –0.10 to 0.26) or diastolic (β , –0.03; 95% CI, –0.12 to 0.07) BP, or low-density lipoprotein (β , 0.04; 95% CI, –0.27 to 0.36).
Glycemic control	NA	Limited HL, less diabetes mellitus knowledge (DNT: median, 40% vs adequate HL, 74%). DNT weakly associated with glycemic control.
Blood glucose self-monitoring	NA	HL not associated with self-monitoring (OR, 1.50; 95% CI, 0.57–3.94).
Hypoglycemia	NA	Limited literacy associated with 1.3- to 1.4-fold (95% CI, 1.1–1.7) risk of hypoglycemia.
Mediation analysis, glycemic control	1 y	Greater HL associated with glycemic control (standardized parameter estimate, –0.070; CI not provided), mediated by multiple factors.
Adherence to antidepressant medications	1 y	Inadequate HL increased early (<180 d) and later (\geq 180–365 d) adherence to antidepressant medications after index prescription date.
HbA _{1c}	NA	Limited HL: OR, 2.2 (95% CI, 1.2–3.8); HbA _{1c} \geq 48 mmol/mol, consistent with undiagnosed diabetes mellitus.
Obesity, health-related behaviors	1 y	Limited HL, greater obesity risk (OR, 1.35; 95% CI, 1.11–1.63) vs higher HL, limited HL associated significantly with limited physical activity, diet, and alcohol.
Obesity	NA	Lower NVS associated with increased BMI ($r=-0.12$).
Obesity	NA	Low HL increased obesity risk (OR, 1.84; 95% CI, 1.13–2.99).
Obesity	NA	Limited HL increased likelihood of self-reported obesity (OR, 1.86; 95% CI, 1.36–2.54) vs higher HL.
Childhood obesity	NA	Higher parent NVS associated with decreased odds of obese child (OR, 0.75; 95% CI, 0.56–1.00).
Readmission	30 d	After adjustment for demographic and clinical characteristics, the risk of 30-d readmission was 12% lower ($P=0.03$) and the incidence rate was 16% lower ($P<0.01$) for patients with above-basic literacy.
Medication adherence	1 y	Limited HL not related to low refill adherence (OR, 1.23; 95% CI, 0.92–1.64).
Medication adherence	6 mo	Limited HL increased risk of low adherence (OR, 1.7; 95% CI, 1.0–3.1) defined by cumulative medication gap.
Readmission	30 d	Limited HL increased readmission risk (OR, 1.75; 95% CI, 1.14–2.69).
ED, readmission	30 d	Pharmacy intervention reduced event risk in low HL (HR, 0.41; 95% CI, 0.17–1.00).
Association of HF to HL	NA	HF associated with limited HL (OR, 1.55; 95% CI, 1.00–2.41).
ED visit, hospitalization	1 y	Adequate HL, lower risk of HF hospitalization (IRR, 0.34; 95% CI, 0.15–0.76).
HF QOL	NA	Adequate and limited HL, significant differences in HF QOL, knowledge, self-care, and self-efficacy.
Association of HF to HL by race	NA	Black race associated with worse HL (OR, 2.13; 95% CI, 1.46–3.10), 1.6- to 1.8-fold risk of barriers to care relative to white race.
Hospitalization, mortality	Median, 1.2 (IQR, 0.25–1.25) y	Limited HL, hospitalization HR of 1.04 (95% CI, 0.79–1.37) and mortality HR of 1.61 (95% CI, 1.06–2.43).
Adherence intervention	9 mo	Differences in adherence in usual care (15.2%; 95% CI, 6.04–24.3) and pharmacy intervention (12.0%; 95% CI, –0.3 to 24.4) by HL.
Single session vs multisession patient support	12 mo	Limited HL, trial participants had adjusted IRR of 0.73 (95% CI, 0.39–1.36) favoring multisession vs single-session group.

(Continued)

Table 3. Continued

Disease	Authors	Study Design, Setting	N	HL Assessment	Setting
HF (Continued)	Wu et al ¹⁰⁷	Multisite RCT	595	S-TOFHLA	Ambulatory
	Mixon et al ¹⁰⁸	Prospective cohort	471	S-TOFHLA	Hospitalization
	McNaughton et al ¹⁰⁹	Retrospective, hospital-based	1379	BHLS	Hospitalization
	Moser et al ¹¹⁰	Prospective cohort	575	S-TOFHLA	Hospitalization or ambulatory
	Wu et al ¹¹¹	Secondary analysis, RCT	575	S-TOFHLA	Hospitalization or ambulatory

(Continued)

in analysis. Similarly, health literacy has had varied associations with cardiovascular risk factors and clinical outcomes specific to diabetes mellitus. In a large cross-sectional study, health literacy was not associated with cardiovascular risk factors (systolic and diastolic blood pressures and low-density lipoprotein) or self-reported complications (retinopathy, nephropathy, CVD) in individuals with diabetes mellitus.⁸³ However, in an urban patient cohort, individuals with inadequate health literacy had a 2-fold increased risk of retinopathy, as determined by self-report and confirmed by administrative data.¹²⁹ The committee is not aware of studies examining the association of health literacy with adjudicated cardiovascular outcomes such as coronary or other cardiovascular events in individuals with diabetes mellitus. Understanding health literacy and prospective, long-term complications associated with diabetes mellitus would be enhanced by introducing health literacy assessments to established, well-characterized community-based cohort studies.

Health literacy has been incorporated into a range of interventions to improve outcomes in individuals with diabetes mellitus, particularly those with educational, social, and economic vulnerabilities.^{142–145} Strengths have been the outreach to economically and socially disadvantaged individuals, particularly Spanish-speaking adults, and 12-month follow-up to assess for sustained improvements in outcomes relevant to diabetes mellitus. Swavely et al¹⁴³ reported improvement in diabetes mellitus knowledge and limited but statistically significant 12-month improvement in hemoglobin A_{1c} (7.98±1.4% to 7.43±1.4%). A randomized trial used multidisciplinary care with enhanced, individualized communication targeting comprehension of diabetes mellitus knowledge and self-care.¹⁴⁴ Of individuals with limited health literacy, those receiving the intervention had significant success in achieving diabetes mellitus control, defined as reaching a target hemoglobin A_{1c} ≤7.0% (42% vs 15% of those receiving standard care). In contrast, individuals with higher health literacy receiving the intervention showed rates of success comparable to those receiving standard care. An educa-

tional intervention tailored for low-income Latinos with diabetes mellitus demonstrated a 4-month improvement in glycemic control.¹⁴⁵ Of note, the improvement was not sustained at 12 months. These results suggest that multidisciplinary and culturally appropriate interventions that mitigate health literacy-related barriers are needed to achieve sustainable results.

Health literacy in individuals with limited English proficiency and immigrant cohorts has received increased focus.¹⁴⁶ Selected studies have examined health literacy using qualitative and quantitative methods to investigate the relationship between health literacy and diabetes mellitus knowledge, acculturation, and access to care.^{147–150} However, interventions that improve access to language-appropriate services and health literacy support for patients with limited English proficiency are needed.¹⁵¹

Obesity, Diet, and Health Literacy

Health literacy informs health-related knowledge and self-efficacy, which are essential for the promotion of healthy behaviors such as physical activity and general health maintenance.¹⁵² The literature consistently demonstrates the association between health literacy and obesity, dietary choices, and exercise.^{153–155} In Spanish-speaking individuals in the United States with limited English proficiency, higher health literacy has been related to increased exercise and fruit and vegetable consumption.¹⁵³ A study of rural, low-income, predominantly black, high school-educated adults identified a significant association between Healthy Eating Index scores and health literacy and an inverse correlation between health literacy and sugar-sweetened beverage intake.¹⁵⁵

Educational programs aimed at dietary changes for individuals with limited health literacy have been demonstrated to affect caloric consumption significantly. A 6-month educational intervention used health literacy-focused strategies to decrease consumption of sugar-sweetened beverages (227 kcal/d) and show an improvement in body mass index in a medically under-

Table 3. Continued

Intervention and/or Main Outcomes	Follow-Up	Essential Finding, Primary Outcome
Hospitalization, mortality	12 mo	Limited HL, all-cause hospitalization and mortality IRR of 1.43 (95% CI, 1.00–2.05).
Medication errors	NA	Higher HL (OR, 0.84; 95% CI, 0.74–0.95) and subjective numeracy (OR, 0.77; 95% CI, 0.63–0.95) reduced medication error.
ED visit, hospitalization, mortality	20.7 (12.8–29.6) mo	Limited HL, HR, 1.32 (95% CI, 1.05–1.66) for mortality vs higher HL; no association between HL and ED visit or hospitalization.
HF hospitalization, mortality	2 y	Inadequate HL, HR, 1.66 (95% CI, 1.16–2.39) combined outcome relative to adequate HL.
Mediation by HL for age and hospitalization, cardiac death	2 y	Older (≥ 65 y) individuals 3 times more likely to have limited HL; HL mediates age and outcomes in HF.

Studies were selected for size ($n > 150$), use of validated HL assessments, treatment of HL as an independent variable, and publication from January 2014 through November 2016. ACS indicates acute coronary syndrome; BHLS, Brief Health Literacy Survey; BMI, body mass index; BP, blood pressure; CI, confidence interval; CVD, cardiovascular disease; DBP, diastolic blood pressure; DNT, Diabetes Numeracy Test; ED, emergency department; HbA_{1c}, glycated hemoglobin; HF, heart failure; HL, health literacy; HMO, health maintenance organization; HR, hazard ratio; IQR, interquartile range; IRR, incidence rate ratio; NA, not available; NLS, Nutritional Literacy Scale; NVS, Newest Vital Sign; OR, odds ratio; QOL, quality of life; *r*, correlation coefficient; RCT, randomized controlled trial; REALM, Rapid Estimate of Adult Literacy in Medicine; REALM-R, Rapid Estimate of Adult Literacy in Medicine–Revised; SBP, systolic blood pressure; SILS, Single-Item Literacy Screener; and S-TOFHLA, Short Test of Functional Health Literacy in Adults.

*Indicates 23 483 encounters in 10 644 individuals.

served lower-income community.¹⁵⁶ It remains unknown how mobile and electronic technologies can best support dietary and exercise interventions in individuals with limited health literacy.¹⁵⁷

In elementary school-aged children, limited parental health literacy is associated with a 25% increased risk of obesity.⁹⁴ Parents with limited health literacy are twice as likely to perceive their overweight child as being normal weight, and obesity in adolescents correlates with the adolescent's health literacy.⁹⁴ Health literacy may constitute a barrier to childhood physical activity.¹⁵⁸ Community-based interventions such as the Greenlight program have been designed to address the role of health literacy in childhood obesity and nutrition.¹⁵⁹

There are significant opportunities for developing programs to address health literacy challenges in relation to obesity and diet. Community- and school-based educational programs provide avenues for educating youth in communities vulnerable to limited health literacy. The life course impact of limited health literacy on obesity merits examination. Making weight loss, exercise, and diet education programs accessible and available to individuals with limited health literacy is essential. Interventions and programs that incorporate mobile health offer novel opportunities but must be developed so that health literacy is not a barrier for participation.

Tobacco Use and Health Literacy

The interrelation of health literacy, socioeconomic and demographic factors, and tobacco use and cessation is complex.¹⁶⁰ In an urban, multiracial cohort ($n=402$), limited health literacy was related to increased risk of nicotine dependence and decreased knowledge deficits

of smoking-related health risks.¹⁶¹ In the same cohort, researchers found that individuals with limited health literacy were 3.2 times more likely to suffer a relapse in smoking after a cessation program.¹⁶² The number of studies focusing specifically on health literacy and tobacco use is limited. However, the findings demonstrate the relevance of incorporating health literacy into tobacco treatment and cessation programming. These findings are consistent with the overall findings presented in this statement that health literacy is associated with health-related self-care and healthier lifestyle and behaviors.

Coronary Heart Disease and Health Literacy

The authors of this statement identified only a limited number of studies that examined health literacy as an independent variable in relation to cardiovascular risk, incident cardiovascular events, and strategies to improve or augment secondary prevention after cardiac events. Nevertheless, health literacy has been associated with poorer outcomes preceding and following coronary events. In a hospital-based registry of 1967 patients (1197 [60.9%] with acute coronary syndrome), limited health literacy and numeracy proficiency were associated with decreased adherence to medications preceding admission.¹⁶³ Health literacy has likewise been associated with 30-day readmission after acute coronary syndromes.⁹⁵ Medicare enrollees with literacy levels determined as above basic had a 12% reduced risk of readmission than those with basic or below-basic literacy.

To date, interventions addressing health literacy in individuals with CVD have focused primarily on medication adherence, including pharmacy-led interven-

tions that prompt medication refills and graphic illustrations that promote accurate and timely medication taking.^{164,165} One systematic review¹⁶⁶ found that the use of pictorial aids may enhance patients' understanding of how to take medications, especially when combined with other patient education, either written or oral. However, results are mixed. The IMAGE-CHD study¹⁶⁵ (Improving Medication Adherence Through Graphically Enhanced Interventions in Coronary Heart Disease) compared the effects of 2 low-literacy interventions (illustrated medication schedules and refill reminder postcards) on medication adherence in an underserved population with CVD (n=435; mean age, 63.7 years; 91% black; 78% reading below the ninth-grade level). Subjects were randomly assigned to refill reminder postcards, illustrated medication schedules, both interventions, or usual care for 1 year. Post hoc subgroup analyses suggested that illustrated medication schedules may be a useful approach among patients with low medication self-efficacy, polypharmacy, or baseline nonadherence. In the multisite PILL-CVD trial⁹⁹ (Pharmacist Intervention for Low Literacy in Cardiovascular Disease), the effects of a pharmacist-assisted intervention focused on medication reconciliation, inpatient pharmacist counseling, low-literacy adherence aids, and tailored telephone follow-up after discharge from healthcare use were examined in a sample of 851 patients with acute coronary syndrome and decompensated heart failure. The intervention had benefit in individuals with inadequate health literacy, reducing 30-day risk of healthcare use by 59% in the intervention cohort (hazard ratio, 0.41; 95% confidence interval [CI], 0.17–1.00). The results suggest that a multifaceted approach targeting individuals with limited health literacy may be useful in improving healthcare outcomes.

Few studies have addressed the complexity of CVD treatment regimens for patients with limited health literacy; the authors of this statement found crucial gaps in the literature. Studies examining health literacy and CVD outcomes beyond 30-day readmission are essential. Multicenter trials with longer periods of follow-up are needed to clarify how interventions incorporating health literacy are associated with CVD events. Furthermore, studies in individuals of limited English proficiency are needed, given the multiple challenges of adherence, knowledge, self-care, and activation. Finally, health literacy can be evaluated as part of programs aiming to reduce CVD risk and to improve secondary prevention. For example, limited health literacy may be 1 factor that influences dropout rates in cardiac rehabilitation.¹⁶⁶ Individuals with limited health literacy may experience barriers to referral to, engagement with, and participation in cardiac rehabilitation services and thus miss the physiological and nonphysiological benefits after coronary events.

Congestive Heart Failure and Health Literacy

Limited health literacy is highly prevalent in individuals with heart failure, and the relation of health literacy to heart failure outcomes has been confirmed in diverse studies. A systematic review of 20 unique studies of health literacy and heart failure identified the average prevalence of limited health literacy as 39% across all studies (range, 19%–61%).¹⁶⁸ In individuals with heart failure, limited health literacy has been associated with 1.3- to 2-fold higher all-cause mortality in hospital and community-based cohorts.^{104,109} In individuals with heart failure presenting to the emergency room, limited numeracy has been related to 40% greater likelihood of returning to the hospital within 30 days.¹⁶⁹ These data indicate that health literacy strongly contributes to adverse outcomes in heart failure.¹⁷⁰

Health literacy has likewise been identified as a barrier to successful self-care in heart failure. Matsuoka et al¹⁷¹ identified “critical” health literacy (ie, health literacy challenges related to the cognitive ability to evaluate and process information¹⁷²) as related to symptom monitoring and management for self-care in individuals with heart failure. Individuals with limited health literacy have less heart failure knowledge and decreased capacity for the self-care activities essential for heart failure.¹⁰² Health literacy is likewise an independent determinant of successful self-care behaviors used to assess treatment options and to make decisions.¹⁷¹

Interventions to improve health literacy in individuals with heart failure have been diverse and varied. Strategies have included use of low-literacy and standardized materials and implementation of clinician follow-up.^{173–175} One program used graphic illustrations to provide education and targeted symptom monitoring.¹⁷⁶ Pictures included common avenues for patient engagement in heart failure self-assessment such as monitoring for weight gain and assessing for ankle edema. An intervention (n=123) using a self-management program designed for individuals with limited literacy reported a reduced rate of all-cause hospitalization; however, differences in hospitalization for heart failure and quality of life did not reach statistical significance when the intervention group was compared with control cohorts at the 12-month follow-up.¹⁷⁷ A multisite comparative effectiveness trial (n=605) evaluated single-session versus multisession telephone-based intervention and found an effect by literacy status for the secondary outcome of all-cause hospitalization: Individuals with limited health literacy receiving the multisession intervention were less likely to require hospitalization (incidence rate ratio, 0.48; 95% CI, 0.24–0.92).¹⁰⁶

A common theme is that education may improve behaviors such as adherence, dietary choices, and lifestyle modification; enhance monitoring for symptoms;

and avoid clinical decompensation.¹⁷⁸ Health literacy is integral to clinical education about patient monitoring and self-assessment. Interventions that incorporate health literacy as a risk factor for adverse outcomes and a barrier to dietary and medication adherence may benefit from multidisciplinary strategies.^{173,179} A critical next step is implementation research to learn how to bring the benefits of patient education and empowerment for self-care among patients with heart failure to broader populations.

Stroke and Health Literacy

Health literacy related to stroke includes knowledge of risk factors for stroke prevention and recognition of warning signs for acute stroke therapy. Stroke preparedness is the timely recognition of stroke symptoms and onset. Population-based studies have identified racial disparities in stroke preparedness,¹⁸⁰ but how health literacy contributes to disparities in stroke recognition and knowledge has had limited examination. Because rapid intervention is essential for improved outcomes in stroke treatment, initiatives have focused on improving stroke literacy. Examples include the TLL Temple Foundation Stroke Project, a rural behavioral intervention¹⁸¹; the Cincinnati, OH, efforts, based in beauty parlors, to convey culturally meaningful stroke education¹⁸²; Hip Hop Stroke, targeting black elementary school children by incorporating culturally relevant music¹⁸³; and a community-based trial targeting Mexican American middle school-aged children in which students who received the intervention demonstrated greater stroke literacy than a referent cohort who did not.¹⁸⁴

Health literacy related to stroke symptoms and signs remains poor, with low recognition of cardinal stroke symptoms and awareness of acute treatments.^{185–187} Interventions developed for individuals of limited health literacy have consistently shown improvement in knowledge and recognition of stroke signs and symptoms.^{182,188–190} A community-based intervention conducted in churches reported that stroke knowledge and behavioral response were improved with presentation of stroke vignettes.¹⁹¹ The studies cited here demonstrate the opportunities for enhanced stroke education that is delivered with culturally appropriate vehicles. The interventions target families and children to empower and prompt rapid action for stroke recognition. Moving forward, programs to prevent stroke and improve stroke preparedness should promote awareness that stroke is imminently preventable and treatable.

Atrial Fibrillation and Health Literacy

Treatment of the complex syndrome of atrial fibrillation (AF) involves education, decision making, and long-term adherence. Health literacy is correlated with

education and socioeconomic position, and these factors may be associated with medication and behavioral adherence, communication about symptoms, health-related quality of life, access to and experience of care, and outcomes relevant to AF (hospitalization, stroke, heart failure, cognitive and physical decline).

Individuals with limited health literacy are particularly vulnerable to having a limited knowledge of AF and its treatments. In an international survey of physicians (11 countries, n=810), 46% described their patients as unable to explain what AF is and indicated that more than half of their patients needed more information about the condition.¹⁹² In a health maintenance organization, individuals with AF and inadequate health literacy, as assessed by a 3-item screening instrument, were shown to have decreased awareness of AF (prevalence ratio, 0.96; 95% CI, 0.94–0.98).¹⁹³ Knowledge about AF was shown to be directly correlated with level of education in a single-center cohort.¹⁹⁴ Only <10% of those receiving care (n=183) were able to report the indication for anticoagulation; those with inadequate health literacy had a 5-fold increased risk of not understanding the indication for warfarin.¹⁹⁵

Unfortunately, one-off educational sessions as an intervention may have limited impact on patient knowledge, given that retention has been reported as poor.^{196,197} Cochrane analyses identified a small number of studies (n=8–11) evaluating the effect of educational and behavioral interventions on anticoagulation as measured by improvement in time in therapeutic range and did not identify sufficient evidence that such interventions affect time in therapeutic range in individuals with AF.^{198,199} However, a subsequent, limited-size (n=97) multimodality intervention demonstrated a 6-month improvement in time in therapeutic range that was not sustained to 12 months.²⁰⁰ A large clinical trial showed 12-month improvement in adherence to guidelines-based care and reduced hospitalization by implementing a nurse-led, multidisciplinary intervention.²⁰¹ Consistent with other CVD risk factors and outcomes discussed here, multidisciplinary approaches may provide opportunities for continued reinforcement of educational programming to facilitate improved AF care. By necessity, to succeed, such interventions must adopt the universal precautions approach to be accessible across the health literacy spectrum.

Ongoing challenges in evaluating health literacy and AF are multiple. There has been limited investigation into how health literacy may influence evaluation and treatment in AF. For the individual, the AHA/American College of Cardiology/Heart Rhythm Society guideline on treatment of AF emphasizes the recognition and treatment of symptoms.²⁰² The extent to which health literacy may influence how individuals report and monitor symptoms requires further examination. Shared decision making has relevance for AF because of the mul-

multiple decision points that may significantly influence the course of treatment,²⁰³ but tools and strategies need to be accessible across the spectrum of health literacy. Community- and institution-based cohorts can further our understanding of health literacy and its relation to adverse outcomes in AF. Individuals with limited health literacy and AF may experience worse outcomes and have decreased access to treatments and specialized care. Rather than seeking to tailor treatment by health literacy level, centers or hubs of AF care should adapt strategies that facilitate access to care and patient support regardless of health literacy level. The ongoing challenge for institutions is to develop as health-literate organizations in their care for those with AF and other cardiovascular conditions.²⁰⁴

INTEGRATING HEALTH LITERACY INTO CARDIOVASCULAR RISK TREATMENT AND PREVENTION PROGRAMS

Integrating the AHRQ Universal Precautions Toolkit into Cardiovascular Care

The AHRQ Universal Precautions Toolkit for Health Literacy,¹⁸ or Toolkit, is a publicly available document focused on improving quality of care. The Toolkit advocates an orientation to health literacy consistent with the universal precautions approach: best practices, instituted without exception, to provide a uniform, coherent standard of care.^{73–75} Consequently, the goal is not to tailor patient instructions, teaching, approach to care, or shared decision making according to individual patients' level of health literacy. Rather, the objective is to develop and maintain a best practices approach—universal precautions—in written and oral encounters with patients. To emphasize, the objective of the Toolkit and health literacy advocacy is to provide practical approaches for clear oral and written communication to help patients better understand their health information.

The Toolkit includes a 21-step approach to implement a health literacy improvement plan that is scalable for healthcare delivery of any size and context. Fundamentally, healthcare providers who listen, speak slowly, use nonmedical language, encourage questions, apply teach-back methods, and integrate the use of graphics or models are creating a culture of patient care that is sensitive to health literacy. Table 4 presents the components of the AHRQ Toolkit with examples for their implementation in cardiovascular care, including primary and secondary prevention. The authors of this statement advocate the systematic adoption of the Toolkit as a resource for integrating health literacy in CVD prevention and management.

Table 4. AHRQ Health Literacy Universal Precautions Toolkit¹⁸ Components and Modification for Integrating Health Literacy Into Cardiovascular Care

Tool	Title	Applications for Cardiovascular Prevention and Management
1	Form a Team	Develop a team of multidisciplinary stakeholders (eg, primary care, geriatric, and cardiology representatives) to promote best practices for HL
2	Create a Health Literacy Improvement Plan	Construct a plan with explicit short- and long-term goals for addressing HL challenges in the care of CVD
3	Raise Awareness	Educate staff about HL and challenges of HL relevant to CVD
4	Communicate Clearly	Use plain language, avoiding jargon; review consents for reading level; adopt the patient's words; integrate pictures to teach about testing, disease states
5	Use the Teach-Back Method	Document teach-back and use to demonstrate quality improvement in patient engagement and education
6	Follow-Up With Patients	Involve patient in monitoring (eg, symptoms and adherence tracking)
7	Improve Telephone Access	Implement universal precautions to facilitate patient-centered communications
8	Conduct Brown Bag Medicine Reviews	Review all medications as a standard for quality patient care; develop logs to assess adherence routinely with patients; implement pharmacist collaborators
9	Address Language Differences	Conduct education, assessments, and testing with a trained interpreter
10	Consider Culture, Customs, and Beliefs	Receive training in cultural competence; remember the patient's expertise in the intersection of culture and beliefs with CVD and other medical care
11	Assess, Select, and Create Easy-to-Understand Materials	Evaluate forms, informed consents, procedural brochures for readability
12	Use Health Education Material Effectively	Create information order sets or collected materials on CVD treatment options
13	Welcome Patients: Helpful Attitude, Signs, and More	Use the environment to promote questions and medication review
14	Encourage Questions	Invite questions routinely on CVD, patients' experience with disease and treatments
15	Make Action Plans	Have patients choose realizable goals (eg, medication adherence, or addressing risk factors for AF, such as smoking, physical activity, blood pressure control)
16	Help Patients Remember How and When to Take Their Medicine	Facilitate tools to support medication use; educate patients on systems for tracking medication; anticipate errors; provide tools such as pill boxes

(Continued)

Table 4. Continued

Tool	Title	Applications for Cardiovascular Prevention and Management
17	Get Patient Feedback	Use patient expertise on being a patient through surveys and suggestions
18	Link Patients to Non-Medical Support	Use community-based resources
19	Direct Patients to Medicine Resources	Review insurance coverage and verify eligibility; integrate case management
20	Connect Patients With Literacy and Math Resources	Discern how HL affects patients' lives and experience; identify and integrate community resources
21	Make Referrals Easy	Make sure the patient understands the referral rationale; provide timely and relevant feedback when consulting

AF indicates atrial fibrillation; AHRQ, Agency for Healthcare Research and Quality; CVD, cardiovascular disease; and HL, health literacy.

Integrating Toolkit principles of being attentive to health literacy is practical and sensible. Cardiovascular centers can create health literacy-sensitive educational and consent materials; provide health literacy-appropriate education materials in waiting rooms and websites; and teach health literacy-attentive communication to practices.²⁰⁵

Impact of Health Literacy on Cardiovascular Treatment and Care

Individuals with CVD are expected to adhere to complex medication and dietary regimens and to make decisions about how to respond to symptoms.²⁰⁶ The current literature has explored the association of health literacy and self-care of CVDs, which encompasses treatment adherence and symptom monitoring, and early response to symptoms when they occur.¹⁷⁸ In general, adequate self-care has been shown to improve cardiovascular outcomes, including improved quality of life and symptom burden and reductions in hospitalizations and mortality.^{178,207–209} However, despite the availability of patient education, self-care remains especially challenging for those with limited health literacy.²¹⁰

Health literacy in individuals with CVD includes the ability to understand medication instructions, discharge and appointment forms, and education materials (eg, dietary instructions), as well as the ability to negotiate complex healthcare systems.²¹¹ People with cardiovascular risk factors and CVD are aided by skills in reading, listening, analytical thinking, and decision making, as well as the ability to apply these skills to their specific health situation.¹ Finding ways to support people who do not have advanced skills in these areas is the challenge posed by the field of health literacy because this literature shows the injustice of designing complex

systems that work only for people with high levels of education and empowerment.²¹² Inattention to the unneeded complexities in our jargon-filled communications is not a safe or particularly effective approach to patient care and contributes to health disparities.

Adequate health literacy is associated with a higher level of understanding of medications and lifestyle modifications in populations with diabetes mellitus and congestive heart failure. This effect may be mediated by self-efficacy, which allows patients to take ownership of their treatment when they understand the rationale for each strategy. Adequate health literacy also allows patients to avoid medication errors and manage polypharmacy, to understand which symptoms may be caused by CVD and initiate timely response as instructed, and to report side effects that could affect outcomes. Furthermore, self-efficacy, patient engagement, and shared decision making have been increasingly promoted as approaches to enhance care. The writing group for this statement recognizes that work is needed to refine intervention models to attain sustained and generalizable results.

Health Literacy and Participation in Clinical Research

A basic tenet outlined in bioethics principles of clinical research and codified in the Belmont report is respect for individuals with the associated requirement that patients are adequately informed about the nature of research and the voluntary nature of participation.²¹³ For multiple reasons, limited health literacy has been strongly associated with lower participation rates in clinical research.²¹⁴ Limited health literacy may be associated with researchers not offering participation in studies because of a perception of lower understanding of the risks and benefits of research or a concern that follow-up or adherence could be compromised. The nature of the informed consent document may be such that the complexity of the language could be a barrier to participation, and distrust of the healthcare system may play an important role. Alternatively, when individuals with limited health literacy are informed about the nature of research in a culturally tailored manner and given the opportunity to participate, their enrollment rates may be similar to those of individuals with higher health literacy.

The study by Ownby et al²¹⁵ evaluated the association between health literacy and understanding orally presented informed consent information in a sample of 334 English- or Spanish-speaking participants. Health literacy, numeracy, education, and the interaction of health literacy and education accounted for 29% of the variability in performance scores. This suggests that other demographics (eg, race, ethnicity, sex) may not be as important as health literacy and education.

The problem of health literacy and informed consent is highlighted by the cross-sectional study by Paasche-Orlow et al²¹⁶ that examined the Institutional Review Board (IRB) readability standards and informed consent form templates of 114 US medical schools. Using documents accessed from the schools' websites, the study reported that readability varied widely from the 5th to 10th grade (mean, 10.6; 95% CI, 10.3–10.8). The mean Flesch-Kincaid score, a commonly used measure of readability,²¹⁷ for sample text provided by IRBs exceeded stated standards by 2.8 (95% CI, 2.4–3.2) grade levels, illustrating that typical informed consent material likely challenges those with limited health literacy. In 2013, Paasche-Orlow et al²¹⁸ updated the analysis of informed consent form templates (sample n=109) and reported a mean readability level of 9.8 (95% CI, 9.4–10.2), representing a significant improvement from or lower mean readability level ($P<0.0001$) compared with the earlier study. Similarly, there was a slight improvement in consistency of the sample text with IRB standards (mean improvement, 2.2 grade levels; 95% CI, 1.7–2.8). However, most of the Health Insurance Portability and Accountability Act sample content did not reach IRB standards, exceeding the targeted standard by a mean of 4.2 (95% CI, 3.4–5.0) grade levels.

There are several recommendations to address the informed consent challenges faced by those with limited health literacy. First, informed consent documents should meet IRB readability standards, especially the most complex portions like the Health Insurance Portability and Accountability Act material. For many individuals, these standards may still be challenging, so tailoring the informed consent to participants' health literacy level is recommended.²¹⁵ Alternative strategies for ensuring confirmability of informed consent include the teach to goal approach²¹⁹ and the Brief Informed Consent Evaluation Protocol, which uses a telephone interview after consent process.²²⁰ Results of the ePRISM study²²¹ (Patient Risk Information Services Manager), which generated personalized consent forms that were based on a patient's specific clinical risk, suggest that a personalized consent document can improve the patient's understanding of the purpose and risks of procedures, engage patients in shared decision making, and thus improve process of informed consent.

Strategies and Future Directions for Incorporating Health Literacy for Vulnerable Populations

Improving health literacy among those at highest risk and with the lowest economic resources poses a unique challenge. The use of health information technology, including mobile apps to improve self-care behaviors in patients with CVD and to prevent CVD risk by promot-

ing healthy behaviors, is on the rise²²² and may be beneficial in individuals with limited health literacy. However, for individuals who cannot afford a smartphone or who have inconsistent Internet connections, those benefits are unlikely to permeate. Use of mobile health platforms may present an attractive option for patient-oriented education, text messages, and social networking to help with chronic disease management. However, a mobile health intervention study found that those least engaged with text messaging and automated calls were racial or ethnic minorities, older adults, and those with limited health literacy.²²³ This result suggests that reliance on mobile health solutions to mitigate health literacy concerns has the potential to exacerbate disparities in vulnerable populations; the "health literacy divide" may reinforce what has been described as the "digital divide."²¹

Several investigators have explored novel mechanisms for improving CVD-related health literacy. An important component of these interventions is that an understanding of limited health literacy does not exist in isolation with poverty but that other barriers to communication exist, including language and culturally appropriate messaging.²²⁴ For example, promising avenues for improving knowledge of stroke signs and symptoms have involved the use of hairstylists to deliver health messages in predominantly black populations,¹⁸² houses of worship for Spanish-speaking patients,²²⁵ and hip-hop music to educate urban, school-aged children.^{189,226} The use of novel avenues of communication such as case vignettes of possible patients reflective of the community may also be an additional culturally tailored approach.¹⁹¹

Multidisciplinary interventions have incorporated nonmedical providers such as pharmacists and community health workers to address health literacy challenges in CVD, with successful improvement in outcomes.^{227–230} Common themes emerge in several of these interventions, which hold the potential for generalizability to other settings. First, such interventions are community centered and address barriers to care that are specific to individual communities. Such insight may provide a starting point for launching broader interventions that account for health literacy as a barrier to improved CVD screening, prevention, and management. Second, interventions that incorporate health literacy tend to be further enriched by accounting for other social determinants of health: the economic, cultural, language, and other social barriers that obstruct public health implementation.

Toward a Health-Literate Cardiovascular Organization and Program

This statement has articulated how limited health literacy may contribute to increased risk for a range of

Domains	Challenges	Solutions
Organization	Health literacy not an institutional value Lack of health literacy champions Fractured, isolated health literacy efforts	Make health literacy integral to mission Prepare & train a health literate workforce Integrate health literacy into evaluation, safety, & quality
Physician & Provider	Use of jargon & complex terminology Patient instructions, consent, & materials at excessive grade level	Develop health literacy sensitive materials & communication Adopt health literacy communication strategies
Community	Absence of culturally appropriate materials & communication Health literacy absent from patient care & communication agenda	Develop community-centered health messaging Make health information & services accessible
Family & Patient	Absence of community health programming and facilities Limited health screening, preventive care	Place individual in family & community context Adopt "universal precautions" for consent, prescriptions, & teaching materials

Figure 3. Multilevel domains of health literacy and challenges and solutions for achieving a health-literate organization.

Health literacy is operative in the healthcare organization, physician and provider, family and community, and individual patient. The organization has the chief responsibility and capacity for implementing strategies for effective healthcare delivery that address health literacy challenges.



cardiovascular risk factors and conditions. Individuals with limited health literacy face challenges in accessing and navigating health care, and such obstacles may be exacerbated by family, community, and social factors. Health literacy is a ubiquitous challenge throughout any healthcare system, particularly because only 12% of US adults have the health literacy skills to navigate its complexity successfully.²⁴ Health literacy interfaces with the electronic portal, the physical layout and use of signage for directions, patient instructions, informed consent, the discharge plan, and the complex multitude of communication with patients and their families. The systemic challenge is, therefore, to develop healthcare systems that are accessible and for which health literacy is not an obstacle.

The concept of the health-literate organization has emerged in response to the challenges.²³¹ The concept of the health-literate organization has a 3-fold intent. First, it asserts that health literacy as a problem belongs to the institution, not the individual patient, and declares health literacy as a basic condition and standard for health care. Patients cannot be expected, for instance, to adapt their literacy to meet the complex demands of medical care. As stated, "Being a health literate organization should not be seen as a luxury.... Rather, it is a necessary prerequisite to assuring patient safety, promoting adherence, enhancing self-efficacy, and improving patient outcomes."²⁰⁴ Second, it provides a standard for development as a health-literate organization. Ten attributes of a health-literate organi-

zation²³¹ have been articulated, and they provide substantive guidance for cardiovascular centers and organizations to make it easier for their constituencies and patients to seek and receive health care. The attributes of such an organization may be used to design road maps for institutional growth to become a health-literate organization. The 10 attributes span an attention to health literacy from healthcare institutional leadership, organization framework, and care delivery. Finally, the declaration of a health-literate organization emphasizes the need for a comprehensive program. Health literacy is not the bailiwick of a few individuals; the responsibility for pursuing a health-literate organization belongs to every individual who associates with patients, starting at the front desk and extending to the examination room, hospital ward, and executive boardroom. In Figure 3, we summarize critical domains and their relevant challenges and solutions for addressing health literacy.

FUTURE DIRECTIONS FOR HEALTH LITERACY AND CVD

Health literacy has dynamic and important interfaces with CVD prevention, recognition, management, and treatment. The authors of this statement recognize that links between inadequate health literacy and cardiovascular outcomes can be confounded by substantial overlap with other social determinants of health, including social and economic position, educational attainment, access to care, and cultural affiliations. We

conclude that the relations between health literacy and CVD risk and outcomes described in this statement are independent, valid, and significant. Inadequate health literacy is a barrier that will need to be overcome to fulfill the mission of cardiovascular health across the spectrum of prevention, screening, and treatment. The public health effectiveness of cardiovascular treatments that have demonstrated efficacy in clinical trials cannot be realized without managing the issue of health literacy. Further work on health literacy in patients with or at risk for CVD should therefore focus on effectively addressing the adverse health impact of limited health literacy. The authors of this statement note the following questions as priorities:

1. How can healthcare organizations mitigate the effects of inadequate health literacy on CVD risk and outcomes? Addressing health literacy is an institutional mandate; decreasing health literacy barriers is the responsibility of healthcare organizations. Individuals, centers, departments, and institutions can collaborate for multilevel strategies that incorporate and address health literacy by removing unneeded complexity, thus advancing patient empowerment and education to improve healthcare delivery. Although many aspects of the AHRQ Toolkit can be readily implemented by healthcare organizations, opportunities to further establish promote health-literate organizations are evident.
 - In terms of preventive cardiology, interventions at the organizational level focused on hypertension, diabetes mellitus, diet, and exercise that are effective and scalable should be disseminated. Appropriate incentives for healthcare organizations to use such interventions should be considered.
 - In terms of treatment of established CVDs such as acute coronary syndromes, heart failure, stroke, and AF, interventions that can be recommended with confidence are less widely available. Tools that support shared decision making for complex preference-sensitive procedures such as percutaneous coronary interventions and radiofrequency ablation need to be validated and disseminated.
 - Any and all resources provided to patients should be usable and empowering for people across the spectrum of health literacy. Assessment of readability is paramount and may identify text that is obviously too complex. However, readability assessment is not sufficient as a mechanism to determine what material will be understood and effective.
2. How can individual physicians mitigate the effects of inadequate health literacy on CVD? Improving the skills of physicians in understanding the

health literacy challenges of their patients and communicating complex health concepts requires continued attention. Mechanisms to inculcate an approach of universal precautions in which patient comprehension is proactively confirmed need to be further elaborated.

3. How can the AHA as an organization address health literacy? For the AHA, it is imperative to develop a best practices approach to health literacy and to be a leader in promoting massive improvements in patient education and empowerment.
 - Material developed by the AHA can be evaluated and tested by patient stakeholders and individuals with demonstrated content expertise in health literacy, with easily accessible online assessments to determine grade-level readability.
 - The AHA can recognize and legitimize health literacy and its relevance for cardiovascular outcomes. The AHA can incorporate health literacy as part of the curricula of professional meetings, webinars, and professional learning opportunities, as well as in scientific statements. The AHA can include health literacy as a targeted factor in health services research-funding mechanisms. The AHA can encourage council leadership to recognize and address health literacy as an obstacle for optimal cardiovascular health. An integrated, multilevel, cross-disciplinary approach will likely be needed for the AHA to enhance an organizational approach to health literacy.
4. What is the impact of the rise in information technology on those with inadequate health literacy? The increasing reliance on health information via the Internet and social media threatens to exclude individuals with limited health literacy. People may lack access to such resources. However, information technology may emerge as an effective path to mitigating inadequate health literacy through such things as interactive text messaging and graphic or video communication. Technology alone, without adaptation for health literacy challenges, is likely to be inadequate to overcome health literacy challenges.
5. How should awareness of limited health literacy affect the design and conduct of clinical trials? Because of the complexity of informed consent for clinical trials and the lack of standardization across institutional review boards, individuals with inadequate health literacy may inadvertently be excluded from clinical trials. Consequently, the external validity of clinical trials may be limited by the lack of attention to health literacy. Similarly,

without evaluation or measurement of health literacy, imbalances in effect by health literacy cannot be measured. Health literacy measurement should be explored as an important baseline variable in trials.

6. What is the role of communities in mitigating inadequate health literacy in CVD? Because inadequate health literacy often coexists with characteristics such as educational attainment and income, individuals with inadequate health literacy may be segregated by neighborhood and community. Involving community groups in efforts to address health literacy appears to be feasible on the basis of available research and deserves wider study. Community agencies and representatives can provide leadership and participate as stakeholders for programs and interventions.
7. What is the impact of an increasingly complex healthcare financing system on access for those with limited health literacy? Individual responsibility for enrollment in health insurance plans, frequent changes between different health insurance plans, and complex plans with high deductible levels are realities of American health care. Although the evaluation of the impact of health literacy on healthcare access and financing is beyond the scope of this statement, the impacts of health literacy on healthcare access and financing merit investigation. Advocacy for an equitable healthcare system must also incorporate health literacy obstacles in the access to and administration of health care.
8. What are the next steps in health literacy investigation and scholarship? Throughout this statement, the authors have identified knowledge gaps and opportunities for further research that integrates health literacy. Researchers conducting clinical, health services, and outcomes investigations and clinical trialists have multiple opportunities for incorporating health literacy into their studies. Priorities are to include health literacy assessments in cardiovascular studies and trials to assess generalizability and to determine effect modification by health literacy as part of either primary or secondary analyses. Second, study materials for patients should be reviewed with the objective of maintaining the universal precautions approach described in this statement.

Third, multifaceted interventions should be developed that incorporate healthcare systems, providers, and patients. Researchers addressing health literacy should avoid being siloed, that is, developing interventions that are not integrated with the healthcare system, practice, and clinical interface that patients experience. Fourth, inclusion of patient stakeholders with limited health literacy in patient advisory committees and similar bodies is fundamental for patient-centered outcomes research because such individuals will enhance and legitimize the development of patient-centered research. The final and most pressing priority is the examination of the implementation of a universal precautions approach in clinical care. As identified by this statement, the evidence for the significant contribution of health literacy to disparities is well established. Steps forward must study how to improve the process of implementation of literacy sensitive strategies and interventions.

ARTICLE INFORMATION

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

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Disclosures

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Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Jared W. Magnani	University of Pittsburgh	Doris Duke Charitable Foundation*	None	None	None	None	None	None
Herbert D. Aronow	Warren Alpert Medical School of Brown University, Lifespan Cardiovascular Institute	None	None	None	None	None	None	None
Crystal W. Cené	University of North Carolina at Chapel Hill	None	None	None	None	None	None	None
Victoria Vaughan Dickson	New York University College of Nursing	None	None	None	None	None	None	None
Edward Havranek	Denver Health	AHA (investigator)*; AHRQ (principal investigator)*; NIH (investigator)*; PCORI (principal investigator)*	None	None	None	None	None	None
Lewis B. Morgenstern	University of Michigan Medical School	None	None	None	None	None	None	None
Mahasin S. Mujahid	University of California, Berkeley	NIH (co-investigator and investigator on 2 NIH grants)*; Robert Wood Johnson Foundation (co-investigator on a grant)*	None	None	None	None	None	None
Michael K. Paasche-Orlow	Boston University School of Medicine	None	None	None	None	None	None	None
Amy Pollak	Mayo Clinic	None	None	None	None	None	None	None
Joshua Z. Willey	Columbia University	None	None	None	None	None	None	None

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*Significant.

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Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Pamela L. Lutsey	University of Minnesota	None	None	None	None	None	None	None
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*Modest.

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Health Literacy and Cardiovascular Disease: Fundamental Relevance to Primary and Secondary Prevention: A Scientific Statement From the American Heart Association

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