Health Literacy: Past, Present, and Future: Workshop Summary

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Joe Alper, Rapporteur; Roundtable on Health Literacy; Board on Population Health and Public Health Practice; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine

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Health Literacy

Past, Present, and Future

Workshop Summary

Joe Alper, *Rapporteur*

Roundtable on Health Literacy

Board on Population Health and Public Health Practice

Institute of Medicine

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

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[1] Institute of Medicine planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published workshop summary rests with the workshop rapporteur and the institution.

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This workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this workshop summary:

Jennifer Dillaha, Arkansas Department of Health
Alice Horowitz, University of Maryland
Terri Ann Parnell, Health Literacy Partners, LLC
Carol Teutsch, Health Care Institute

Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the workshop summary before its release. The review of this workshop summary was overseen by **Harold J. Fallon,** School of Medicine, University of Alabama at Birmingham. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this workshop summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this workshop summary rests entirely with the rapporteur and the institution.

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The Roundtable wishes to express its appreciation to the following speakers at the workshop for their interesting and stimulating presentations: Terry Davis, Victor Dzau, Betsy Humphreys, George Isham, Howard Koh, Gerald McEvoy, Theresa Michele, Michael Paasche-Orlow, Ruth Parker, Scott Ratzan, Lindsey Robinson, Russell Rothman, Rima Rudd, Barbara Schuster, Steven Teutsch, Michael Wolf, Winston Wong, and Victor Wu.

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Acronyms and Abbreviations

ACA	Patient Protection and Affordable Care Act (Affordable Care Act)
ACGME	Accreditation Council for Graduate Medical Education
ACO	accountable care organization
ACP	American College of Physicians
ADA	American Dental Association
AHRQ	Agency for Healthcare Research and Quality
ASHP	American Society of Health-System Pharmacists
CAMBRA	Caries Management by Risk Assessment
CDA	California Dental Association
CDC	Centers for Disease Control and Prevention
CMI	Consumer Medication Information
CMS	Centers for Medicare & Medicaid Services
DOE	U.S. Department of Education
EHR	electronic health record
FDA	U.S. Food and Drug Administration
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration

IHA	Institute for Healthcare Advancement
IOM	Institute of Medicine
LCME	Liaison Committee for Medical Education
LGBTQ	lesbian, gay, bisexual, transgender, and queer
NCPDP	National Council for Prescription Drug Programs
NICHD	National Institute of Child Health and Human Development
NLM	National Library of Medicine
NSURE	Nonprescription Safe Use Regulatory Expansion
OTC	over-the-counter (such as medications)
PCORI	Patient-Centered Outcomes Research Institute
PMI	Patient Medical Information document
UMS	Universal Medication Schedule
USP	U.S. Pharmacopeia

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Introduction[1]

George Isham, senior advisor at HealthPartners and senior fellow at the HealthPartners Institute for Education and Research, opened the workshop with a brief history. In 2004, the Institute of Medicine (IOM) released *Health Literacy: A Prescription to End Confusion*, a report on the then-underappreciated challenge of "enabling patients to comprehend their condition and treatment, to make the best decisions for their care, and to take the right medications at the right time in the intended dose" (IOM, 2004, p. xi). In that report, the IOM's Committee on Health Literacy documented the problems, origins, and consequences of the fact that tens of millions of U.S. adults are unable to read complex texts, including many health-related materials, and it proposed possible solutions to those problems. The committee stated the importance of health literacy—the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions—and it laid out a comprehensive strategy to improve health literacy in America.

In that same year, the Agency for Healthcare Research and Quality (AHRQ) published a systematic review and analysis of evidence about the relationship between health literacy and health outcomes and the effective-

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[1] The planning committee's role was limited to planning the workshop, and this summary has been prepared by the workshop rapporteur as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants, and are not necessarily endorsed or verified by the IOM, nor should they be construed as reflecting any group consensus.

ness of interventions to mitigate the impact of low literacy (AHRQ, 2004). In that same year, the National Institutes of Health (NIH) and AHRQ announced the availability of funding for research on health literacy concepts, theory and interventions as they related to the U.S. Department of Health and Human Services (HHS) and public health priorities.

One outcome from newfound attention being paid to health literacy was the IOM's decision in 2006 to create the Roundtable on Health Literacy as a means of holding ongoing, regular discussions on the challenges facing health literacy research and practice, and identifying approaches to promote health literacy through mechanisms and partnerships in both the public and private sectors. To commemorate the anniversary of the release of the report that led to its inception, the Roundtable convened a 1-day public workshop to assess the progress made in the field of health literacy over the past decade, the current state of the field, and the future of health literacy at the local, national, and international levels (see Box 1-1). Isham noted, "The field has moved a considerable amount in this last decade, some of it as a result of our activity. It is very appropriate for us to pause and take note, see where we have come, and to reflect upon on what we hear today and talk about the future challenges and future opportunities."

Victor Dzau, the recently inaugurated president of the IOM, remarked from his perspective as a cardiologist and the former chancellor for health affairs at Duke University and the president and chief executive officer (CEO) of the Duke University Health System, how important health literacy is for addressing the social determinants of health and the health disparities that exist in the U.S. health care system. He also pointed out that the lack of health literacy costs the United States more than $100 billion annually and that efforts to reduce this astounding number must focus not just on helping patients learn more, but also on aligning health systems so that they communicate information in a health-literate manner. "We need to make sure that we respect people's skills, abilities, and values so they can maximize the learning they can have and understand the choices they need to make," said Dzau.

Research, he added, has illuminated the nature of the relationship between health literacy and health outcomes. He observed that U.S. health care organizations have responded to the challenge of increasing health literacy, thanks in part to the efforts of the Roundtable to increase awareness of these issues. He noted that in the 10 years since the release of the IOM's report on health literacy that drug and food labels have improved, that health professionals have been exploring creative ways of communicating with patients, and that academic medical centers are increasing their focus on health literacy, particularly in the way they train health professionals. He also cited how technology is now being used to measure and assess whether patients are processing health information.

BOX 1-1
Workshop Statement of Task

An ad hoc committee will plan and conduct a public workshop to commemorate the 2004 release of the Institute of Medicine report *Health Literacy: A Prescription to End Confusion*. The workshop will feature invited presentations and discussions of the field of health literacy since the release of the report. The topics may include the progress made in the field of health literacy in the past 10 years, the current state of the field, and the future of health literacy at the local, national, and international level. The committee will define the specific topics to be addressed, develop the agenda, select and invite speakers and other participants, and moderate the discussions. An individually authored summary of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

Examples of the topics the workshop covered included health literacy at HHS and the U.S. Food and Drug Administration (FDA); the progress made and challenges remaining with regard to creating health-literate health care delivery and medication orders; the role of education in health literacy; the impact of the Affordable Care Act (ACA) on health literacy; and the future of health literacy. In planning and convening this workshop, the Roundtable hoped to expand the network of those involved in health literacy research and practice and to explore areas in which the nation needs to redouble its efforts to making all communications between health care professionals and their patients and families understandable and actionable.

ORGANIZATION OF THE SUMMARY

The workshop (see Appendix A for the agenda) was organized by an independent planning committee in accordance with the procedures of the National Academy of Sciences. The planning committee included Luis Bravo from the Office of the Commissioner at FDA and designated federal officer on the Risk Communication Advisory Committee; Terry Davis, professor of medicine and pediatrics at the Louisiana State University Health Sciences Center in Shreveport; George Isham; Michael Paasche-Orlow, associate professor of medicine at the Boston University School of Medicine; Scott Ratzan, vice president for global corporate affairs at Anheuser-Busch InBev; Rima Rudd, senior lecturer on health literacy, education, and policy at the Harvard School of Public Health; and Winston Wong, medical director for Community Benefit and director of Disparities Improvement and Quality Initiatives at Kaiser Permanente. This publication summarizes the discussions that occurred throughout the workshop, highlighting the key lessons presented, practical strategies, and the needs and opportunities for improving health literacy in the United States. Chapter 2 provides an overview of health literacy activities at HHS. Chapter 3 discusses health literacy and medications; Chapter 4 discusses the role that health literacy plays in delivering high-quality, patient-centered health care; and Chapter 5 reviews what has been happening in the area of education and health literacy. Chapter 6 recounts the panel discussion that looked at the future of health literacy, and Chapter 7 covers the Roundtable's discussions of where the field of health literacy needs to go and its reflections on the key lessons learned at this workshop.

In accordance with the policies of the IOM, the workshop did not attempt to establish any conclusions or recommendations about needs and future directions, focusing instead on issues identified by the speakers and workshop participants. In addition, the organizing committee's role was limited to planning the workshop. The workshop summary has been prepared by workshop rapporteur Joe Alper as a factual summary of what occurred at the workshop.

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Health Literacy at the U.S. Department of Health and Human Services: Progress and Possibilities[1]

The workshop opened with a plenary presentation by Howard Koh, professor of the practice of public health leadership at the Harvard School of Public Health and former Assistant Secretary of HHS. He reviewed the progress that HHS has made in health literacy over the past decade despite what he characterized as the giant obstacles in this arena. "This field is not viewed as glamorous by many," said Koh. "While it may not necessarily attract headlines, it is absolutely at the core of everything we do as health care and public health professionals." He noted his friend, the late Reverend William Sloane Coffin, once said, "Giant obstacles are brilliant opportunities, brilliantly disguised as giant obstacles," which is relevant to what has transpired over the past decade of health literacy work in the United States. He also acknowledged the work of his former colleagues in the HHS Health Literacy Group, specifically Cynthia Baur, Cindy Brach, and Linda Harris.

As the son of Korean immigrant parents and one who wanted to be a physician from a young age, Koh has had a long interest in health literacy. He noted how his family would ask him health questions from the time he was in medical school and later relied on him to help them navigate the health care system. "At a very early age, on a personal level I encountered all of the barriers to good communication and health literacy in the health system," said Koh. He also commented on the fact that ongoing demo-

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[1] This section is a summary of the presentation by Howard Koh, professor of the practice of public health leadership at the Harvard School of Public Health and former HHS Assistant Secretary, and the statements are not endorsed or verified by the IOM.

graphic changes project that by 2043 the United States will become a so-called majority/minority nation—one in which a majority of the population will be a member of a racial or ethnic minority. He cited the statement by Reverend Martin Luther King, Jr., that "we may have all come on different ships, but we're in the same boat now" as to why these demographics are important to the topic of health literacy.

A major gap looms between what providers intend to convey and what patients and families understand, said Koh. "The central question is, what does it take to have the capacity to process and understand health information in order to make appropriate health decisions? That is the heart of health literacy." He said there are so many dimensions to this question given the many avenues of communication that exist between doctor and patient, including reading ability, verbal language skills, and numeracy. He realized early in his medical career that simply asking patients if they understood his explanations of a cancer diagnosis and possible treatments was the wrong way to approach a doctor/patient encounter.

A better approach, he learned, was to first assess a patient's understanding of their condition before providing any additional information. Some patients would reply they had read everything conceivable about their cancer, that they knew about all of the treatment options and had decided on the one that was most appropriate for them. Others would say they felt scared and paralyzed by all of that information, and wanted to rely on his advice on which treatment option was best. Then there are the patients who would say they are not physicians, that they did not want to hear any information and they would simply follow whatever course he would lay out for them. "That is a tremendous spectrum," he said, and over time he came to respect that spectrum of knowledge and understanding and to start the dialogue by understanding where the patient was. "In hindsight, this was my own way of discovering what all now know as the teach-back method," said Koh. "That method represents the future for health literacy."

Health literacy took on added importance for Koh when he became Assistant Secretary for HHS in 2009. It was then that he first became aware of the growing body of evidence showing that limited health literacy leads to a cascade of suboptimal outcomes. At that time he came to appreciate that health literacy can be viewed through many lenses, whether it is in terms of specific areas such as understanding prescription drug labels and medication adherence, or broader areas such as disease category, cultural and linguistic barriers, and how health literacy affects children or seniors. One of his suggestions for the future is to take an even broader view and move the health literacy discussion into the community, into public health and population health.

As an example of how health literacy has an impact beyond the clinic, he cited how the nation and the world are struggling with the most recent outbreak of Ebola. "When we hear the term 'quarantine,' what does that mean to you? Does it mean confinement in a hospital or in a tent on hospital grounds, as happened to the nurse in New Jersey? Does it mean confinement at home? Does it mean you have limited movements, but you can move around with freedom as long as you do not mingle with large crowds in public?" asked Koh. How someone interprets the word quarantine can influence how they protect their own health and the health of their families, he explained.

Over the past decade, Koh said he believes there have been at least two major paradigm shifts in the field. The first shift has been to view health literacy not simply as a problem for individuals, but rather as a systems issue. "If we are going to make further progress on health literacy, we must embrace the concept of organizational responsibility for health literacy," said Koh. "In addition to training individuals and providers, for example, we need to get organizational heads to underscore the importance of health-literate organizations." It will be critical to promote systems change for all health care organizations. The second paradigm shift, which has been called universal precautions, has been to stop assuming that people understand health information but instead assume that people are at risk for not understanding unless proven otherwise. In this time of health reform, insurance terms like "medical loss ratio" can lead to confusion for almost all Americans.

To make progress going forward, he said, we can engage as many partners as possible in this conversation, including non-traditional partners, and integrate the health literacy theme into all health care and public health discussions. "That way, health literacy comes alive and we gain more supporters for this very important cause," said Koh. Today, for example, leaders from hospitals and health organizations, as well as from government, academia, foundations, and patient and consumer groups, have joined this conversation. More needs to be done, however, to involve leaders of health plans and public insurance programs, as well as those of accrediting bodies, and to reach out beyond the health care sector into fields such as adult education and child care.

Health literacy has long been of interest at HHS, said Koh, as witnessed by its inclusion in the *Healthy People 2010* report, which was released in 1999, as an important goal for the nation. The most recent *Healthy People 2020* report includes a number of goals and objectives related to health literacy, particularly regarding metrics for assessing how many providers make their instructions to patients easy to understand, how many are using the teach-back method, and how many are involved in the commitment to shared decision making with their patients. He noted that HHS has worked closely with the U.S. Department of Education (DOE). A key national assessment of adult literacy conducted in 2006 showed that 36 percent of U.S. adults had basic or below basic health literacy.

Other HHS activities of note include AHRQ's annual research conference on health literacy and its inclusion of health literacy questions in the Consumer Assessment of Healthcare Providers Surveys; the use of health literacy principles to create the health and prevention information available on the HHS website http://www.healthfinder.gov; and the 2010 release of a national strategy for health literacy (HHS ODPHP, 2010), which Koh said is still the only publicly available strategic document on health literacy goals and strategies. Among the seven goals listed in the strategic plan are those that link health literacy with child care, English-language instruction activities, and adult education, all of which reach out beyond the health sector and take a social determinants approach to health. The plan explicitly addresses the need for culturally and linguistically appropriate services, and Koh noted that the HHS Office of Minority Health has for the past 13 years put forward what is known as the CLAS Standard, a set of culturally and linguistically appropriate services standards. These standards are aimed at getting organizations to take a systems approach to thinking about reducing health disparities and increasing health equity (Koh et al., 2014).

In 2010, AHRQ released the Universal Precautions Toolkit (DeWalt et al., 2010), building on the paradigm change of assuming that people are at risk for *not* understanding health information unless proven otherwise. The Toolkit contains 20 specific steps for implementing universal precautions across a health care system and includes concrete suggestions such as focusing on teach-back and ensuring a brown-bag medication review for patients so they understand what prescription drugs they are taking and how to take it. Koh noted that the Toolkit's emphasis of creating health-literate organizations owes much to the pioneering work of the IOM and the Roundtable.

Another accomplishment that Koh noted is the Plain Writing Act of 2010 that President Obama announced. "I remember that each agency was asked to appoint a lead person to assure that federal documents were written more understandably," said Koh. He added that at HHS, the Executive Secretary, the person responsible for all of the department's written correspondence, was put in charge of that effort. Koh also noted a 2012 paper published in the journal *Health Affairs* that highlighted the role that federal policies can play in boosting health literacy and reducing the cost of health care (Koh et al., 2012).

With regard to the transformative ACA, Koh said it is unclear how much the public understands the opportunities that the Act affords them to get insurance coverage and how well people understand basic insurance terms such as "deductible" and "copay." He noted that the Centers for Medicare & Medicaid Services (CMS) launched an outreach effort in the summer of 2014 to inform the 10 million newly insured Americans about the dimensions of their new coverage and how having insurance can benefit their health. CMS has developed easy-to-understand pictures and graphs to better explain insurance coverage benefits. He also commented on the results of polls conducted by organizations such as the Kaiser Family Foundation showing the overwhelming popularity of section 2715 of the ACA, which calls for standard definitions and uniform explanations of coverage benefits for all plans.

One tremendous opportunity for improving health literacy is in the ACA's focus on improving quality through new models of care and prevention, such as accountable care organizations (ACOs) and patient-centered medical homes. An initiative called the Community-Based Care Transitions links patients being discharged from the hospital to providers in the community to reduce the chances of being readmitted to the hospital. Koh also mentioned the opportunity for cost savings and quality improvement through bundled payments and through better management and coordination of care for patients who are eligible for both Medicare and Medicaid. CMS's innovation grants foster new ways for teams to test new strategies to improve care quality and lower costs. "Health literacy should be a major theme in all of these efforts," said Koh. Not paying attention to health literacy wastes money and leads to adverse outcomes and lives lost. With that in mind, the health literacy community should promote efforts to build a strong business case for the field that will capture the attention of policy makers, Koh said.

As a final note, Koh described the cycle of crisis care that can result when health literacy is ignored. In a typical scenario, Mrs. Jones is without insurance and on a fixed income, and she suffers from diabetes and heart failure. She arrives a half-hour late for her appointment because the hospital signage confused her. Her confusion increases when she cannot understand the pile of forms the receptionist hands her. It rises even further in the examination room when she cannot understand the medical jargon that her provider uses. At that point, she is too overwhelmed to ask any questions and the doctor leaves her with a handful of prescriptions that she does not understand and referrals for laboratory work that she cannot quite comprehend. Not surprisingly, she fails to obtain the laboratory tests and some of her prescriptions go unfilled. Eventually, she ends up being hospitalized, treated, and discharged, again with little understanding of what she is supposed to do to best care for herself.

"We have all been through this as doctors, as patients, and as public health professionals," said Koh. "We have to move toward a system that is better in supporting the patient every step of the way." One way to do so is to follow what Koh and his former colleagues at HHS called the Health Literate Care Model based on the Care Model pioneered by Edward Wagner. This model provides a means for changing systems to provide improved care for patients. It argues for looking at ways of connecting decision support and clinical information systems to the community.

The Health Literate Care Model that the HHS team proposed calls for leveraging systems change to create health-literate care organizations. In this updated scenario Mrs. Jones would receive a call prior to her appointment telling to bring all of her medications to her appointment. A health-literate organization would provide her with forms that she can understand and help her fill them out if she has questions. A medical assistant would review medications with her and make sure she truly understands how to take them. Her physician would present treatment options in a way that would enable the two of them to create a care plan that Mrs. Jones could explain in her own words. When she got home, she would be connected to a diabetes peer support group near her home that would help her practice prevention. "That is the vision for the future," said Koh. "If we can do that for all patients, all consumers in health care and in public health, and if we can build these better systems and make the best business case possible with the best data we have, then we can certainly make much more progress for health literacy in the future," said Koh in closing.

DISCUSSION

During the brief discussion period following Koh's presentation, Lindsey Robinson, a practicing dentist and trustee for the American Dental Association, asked Koh how oral health fits into the discussion within the federal government, both about health literacy but also as part of the bigger issues of health care reform. Koh replied that traditionally, oral health was seen as something separate from the rest of health care and public health, but that attitude is changing. Today, he said, HHS has an oral health working group that spans the entire department, just as is seen with health literacy. He also noted the coordination that is occurring nationwide thanks to the work of the National Oral Health Alliance, of which Robinson happens to be a board member. As one example of the concrete progress that has been made at integrating oral health into the bigger scope of health care, Koh cited the community health centers. "Well over 50 percent of them are now providing oral health services on site," said Koh.

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Health Literacy and Medications

The workshop's first panel session featured three presentations addressing progress in the field of health literacy and medications. Ruth Parker, professor of medicine, pediatrics, and public health at the Emory University School of Medicine, provided an overview of the field's progress. Gerald McEvoy, assistant vice president of drug information at the American Society of Health-System Pharmacists, discussed the progress that has been made creating a standard and best practices for medication prescription labels. Theresa Michele, director of the Division of Nonprescription Clinical Evaluations at FDA, then described the efforts that her agency has made in the health literacy area. An open discussion moderated by George Isham followed the presentations.

OVERVIEW[1]

To begin her presentation, Parker recalled that when the committee that produced the 2004 report first met in 2002, approximately 10,000 prescription drugs and more than 300,000 over-the-counter (OTC) products were on the market. At the time, prescription drugs accounted for 10 percent of U.S. health care expenditures, which was double the level in 1980. The average American over age 65 was taking six or more medications prescribed by multiple doctors. "It was confusing, puzzling, and if you

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[1] This section is based on the presentation by Ruth Parker, professor of medicine, pediatrics, and public health at the Emory University School of Medicine, and the statements are not endorsed or verified by the IOM.

will, frustrating to patients," said Parker. "A lot of folks knew that things could be better."

Parker looked at this problem of health literacy as it applies to medications as a puzzle, with pieces of this puzzle represented by patients, prescribers, pharmacists and pharmacies, research, the timing of an increased focus on quality, the development of collaboratives, those who influence policy and public behavior, and the IOM. Starting with patients, she recounted collaborating with colleagues to listen to more than 35 hours of videotaped interviews of patients describing their struggles with understanding drug labels, and she remembered thinking at the time that "if we can get the word 'twice' [as in twice daily] off of every pill bottle, I am going to retire." Ten years later, she's still hoping for that to happen.

The variability in the way medication directions were given on drug labels was overwhelming despite the work of FDA and a system it had put in place to standardize the contents on labels. "From a patient standpoint, it was a non-system. It was broken," said Parker, and the result was that patients were getting different content from different sources, whether it was the drug label itself, the pharmacist, or the prescribing physician. Physicians, for example, used different terms, sometimes even on the same prescription sheet, for "take one tablet twice daily," and even today they still use Latin terms when ordering medication for their patients. Ten years ago, those Latin orders would often end up on the label on the pill bottle, though there were pharmacies and health care systems even then that were starting to change that practice and trying to figure out how to provide more consistent and easy-to-understand information for patients.

As far as what constitutes label information that patients might receive, there is the actual container label, the Consumer Medication Information (CMI) sheet that gets stapled to the bag, the package insert, and medication guide. Parker said that 10 years ago, it was not clear what kind of information was included in the CMI and whether it was even evidence based. There were also questions about the real purpose and clarity of the package inserts and the medication guides, which were and still are approved by FDA. "Are they really for the patient, or are they for the prescriber?" said Parker. She also noted that the pill bottles themselves are often cluttered with warning stickers (see Figure 3-1). "I remember Alistair Wood[2] saying a pill bottle looked like a Christmas tree, with precious little real estate with all of those colorful little sticky things on it," said Parker, "and when you really got down to it, there wasn't a lot of evidence driving the content that was taking up this very precious real estate."

Research became a piece of the puzzle when investigators started looking at the information consumers receive about medications and trying to

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[2] Dr. Wood developed a uniform medication schedule that standardized dosing times.

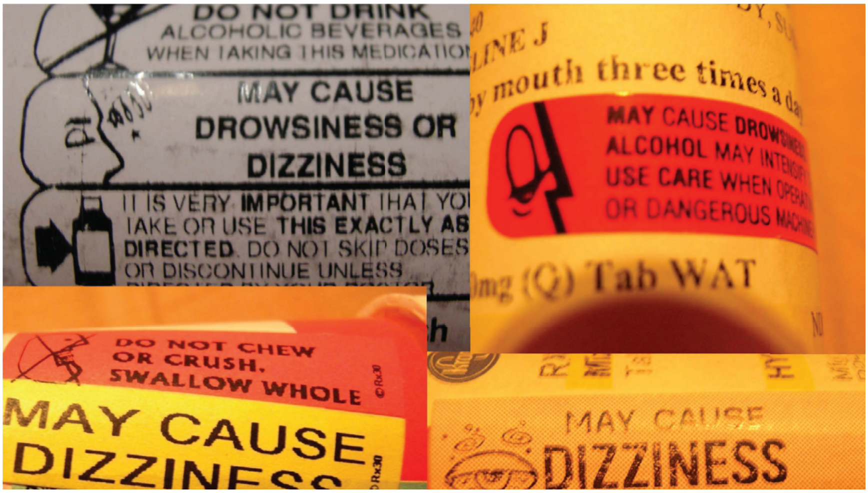


FIGURE 3-1 Examples of the confusing array of warning labels on prescription pill bottles.
SOURCE: Parker, 2014.

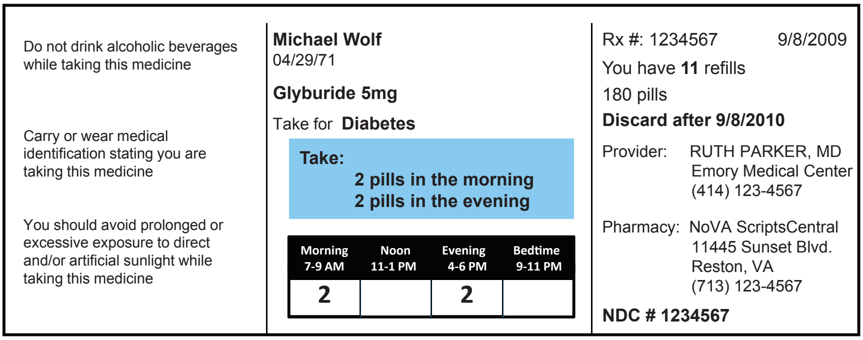
figure out what patients get from this information and how it was presented to them. She recounted a study that she and her colleagues conducted that found that prescriptions written during one 8-hour period in one health system used 53 different phrases for "take one tablet a day" and that the translations of those phrases varied significantly (Bailey et al., 2009). One lesson from this study was that while drug container labels look simple, they are not clear. "The ability to read them doesn't mean that you can actually interpret them or safely and effectively take the drug, which is what FDA wants to make sure you are able to do," said Parker.

Mistakes were also common and increased with the number of drugs a patient took. They were also more frequent in individuals with low health literacy. Studies such as this one led to the conclusion that variability in dosing instructions is a root cause of some of the confusion patients experience with regard to their medications. Parker said one of the biggest lessons from the field of health literacy is that patients are actually experts on what they need in terms of drug information, and that partnering with them is important if the difficult challenge of making drug information understandable and actionable is going to be solved.

Over the past decade, a framework for health literacy has been developed that puts health literacy at the intersection of skills and abilities with demands and complexities, Parker explained, and it was the paradigm shift that Koh described of aligning demands and complexities with skills and abilities that enabled the field to start making progress in creating health-literate drug information. One thing this paradigm shift led to was the development of consolidated medication regimens consisting of a small number of uniformly defined time intervals, rather than random intervals spread across the day (Wolf et al., 2011a). Parker and others have been developing reprogrammed medication labels (see Figure 3-2) that are more systematic and consistent in the way they present information to the patient, and as a result, are more likely to be correctly interpreted compared with standard instructions (Wolf et al., 2011b). In addition, they are developing instruction sheets that reduce the cognitive load on patients by using plain language, sequencing information in an order that makes sense to the patient, and only using visual aids that are meaningful (see Figure 3-3). Drop-down menus in electronic prescribing modules that use simplified and consistent pharmacy signature codes are also proving useful for creating labels and instruction sheets with standardizing language.

Instructions for pediatric liquid medications need improving, too. Dosing instruments, concentrations, and units of measures vary greatly, leading to confusion about how to give drugs to children. During the H1N1 influenza outbreak in 2009, for example, parents were instructed to give their children a dose of three quarters of a teaspoon of Tamiflu oral suspension, but the syringe included with the prescribed drug package was marked in a unit of milligrams, not fractions of a teaspoon (Parker et al., 2009). This confusing dosing information led FDA and the Centers for Disease Control and Prevention (CDC) to issue a warning (Budnitz et al., 2009).

Perhaps the most important shifts occurred when health literacy become framed as an issue of patient safety, and again when health literacy became linked with self-management as one of the priorities for



Do not drink alcoholic beverages while taking this medicine

Carry or wear medical identification stating you are taking this medicine

You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine

Michael Wolf
04/29/71

Glyburide 5mg

Take for **Diabetes**

Take:
2 pills in the morning
2 pills in the evening

Morning 7-9 AM	Noon 11-1 PM	Evening 4-6 PM	Bedtime 9-11 PM
2		2	

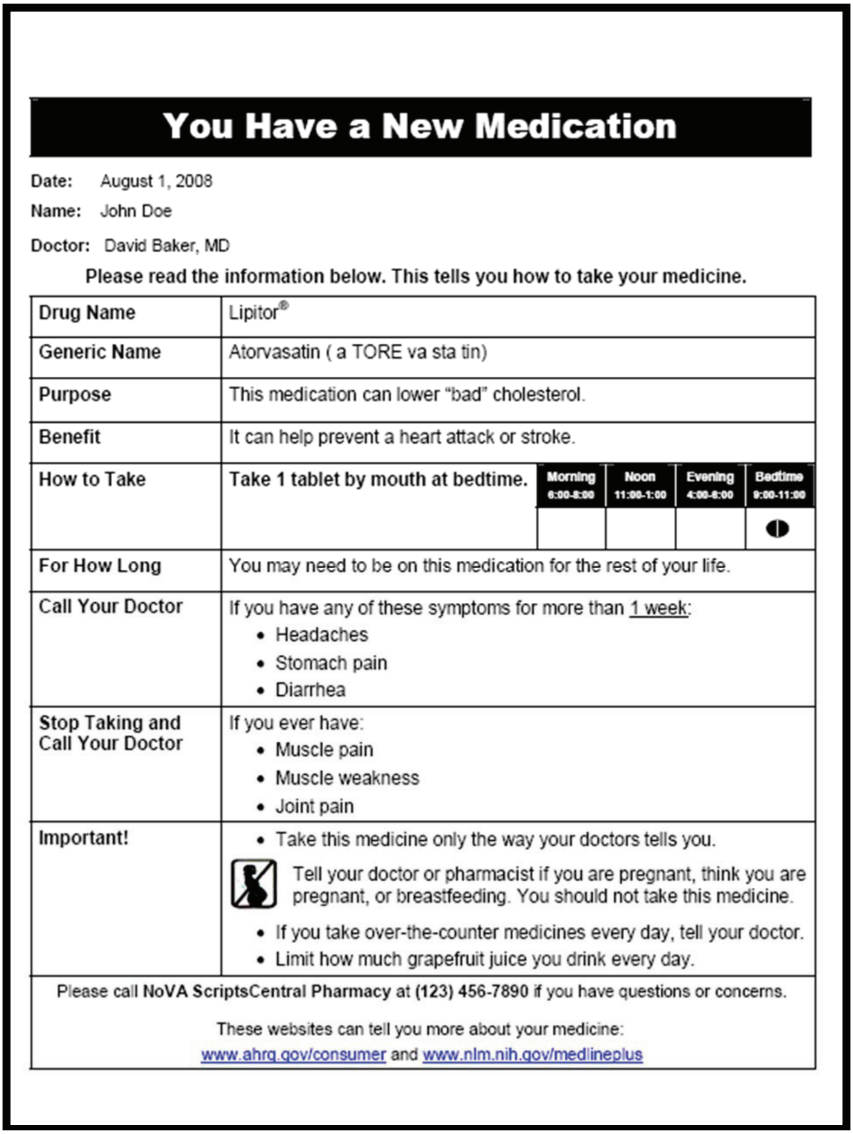
Rx #: 1234567 9/8/2009
You have **11** refills
180 pills
Discard after 9/8/2010

Provider: RUTH PARKER, MD
Emory Medical Center
(414) 123-4567

Pharmacy: NoVA ScriptsCentral
11445 Sunset Blvd.
Reston, VA
(713) 123-4567

NDC # 1234567

FIGURE 3-2 A reprogrammed prescription label.
SOURCE: Parker, 2014.



You Have a New Medication

Date: August 1, 2008
Name: John Doe
Doctor: David Baker, MD

Please read the information below. This tells you how to take your medicine.

<table>
<tr><td>Drug Name</td><td>Lipitor®</td></tr>
<tr><td>Generic Name</td><td>Atorvasatin (a TORE va sta tin)</td></tr>
<tr><td>Purpose</td><td>This medication can lower “bad” cholesterol.</td></tr>
<tr><td>Benefit</td><td>It can help prevent a heart attack or stroke.</td></tr>
<tr><td>How to Take</td><td>Take 1 tablet by mouth at bedtime.
<table>
<tr><th>Morning
6:00-8:00</th><th>Noon
11:00-1:00</th><th>Evening
4:00-6:00</th><th>Bedtime
9:00-11:00</th></tr>
<tr><td></td><td></td><td></td><td>◐</td></tr>
</table></td></tr>
<tr><td>For How Long</td><td>You may need to be on this medication for the rest of your life.</td></tr>
<tr><td>Call Your Doctor</td><td>If you have any of these symptoms for more than <u>1 week</u>:
• Headaches
• Stomach pain
• Diarrhea</td></tr>
<tr><td>Stop Taking and Call Your Doctor</td><td>If you ever have:
• Muscle pain
• Muscle weakness
• Joint pain</td></tr>
<tr><td>Important!</td><td>• Take this medicine only the way your doctors tells you.
Tell your doctor or pharmacist if you are pregnant, think you are pregnant, or breastfeeding. You should not take this medicine.
• If you take over-the-counter medicines every day, tell your doctor.
• Limit how much grapefruit juice you drink every day.</td></tr>
<tr><td colspan="2">Please call NoVA ScriptsCentral Pharmacy at (123) 456-7890 if you have questions or concerns.
These websites can tell you more about your medicine:
www.ahrq.gov/consumer and www.nlm.nih.gov/medlineplus</td></tr>
</table>

FIGURE 3-3 A simpler, more straightforward medication instruction sheet.
SOURCE: Parker, 2014.

transforming the quality of health care in the United States, said Parker. A 2007 Joint Commission on Accreditation of Healthcare Organizations report (Joint Commission, 2007) was particularly important for raising awareness about the link between health literacy and patient safety and for prompting the formation of collaboratives to address the challenges of creating patient-friendly medication information. Parker noted the involvement of a wide range of organizations that have become involved in this effort since it was first raised at an AHRQ conference in 1999, including federal and state legislatures, the U.S. Pharmacopeia (USP), numerous professional medical societies, the Latino Coalition for a Healthy California, the National Consumers League, pharmaceutical manufacturers, and even the mass media. Between 1999 and 2000, for example, the number of references to health literacy on television and radio increased from 7 to 128.

Parker noted the American Medical Association has been holding discussions about health literacy since the late 1990s, and *Healthy People 2010* and *2020* have specifically highlighted the importance of health literacy to achieving national goals for improving the health of the nation. Surgeons Generals have been outspoken about health literacy. For example, Richard Carmona, who was Surgeon General from 2002 to 2006, mentioned health literacy in 200 of his last 260 speeches. She also applauded the work of the IOM, which has held 15 public workshops on health literacy, including workshops on how to align demands and complexities and on FDA's Safe Use Initiative and building better patient-centered outcomes. The IOM's publication of workshop proceedings over the years shows steady growth in efforts to continue to understand, build and support better patient-centered and health literate outcomes

She concluded her remarks by noting that the puzzle is not yet complete. "When the 2004 report came out I think we all felt good about the vision it laid out for a society in which people have the skills they need to obtain, interpret, and use health information effectively and within which a wide variety of systems and institutions do take responsibility for providing clear communication and the support to facilitate health-promoting actions," said Parker. "I think that is still the vision that we share. Once we get that we will actually finish the pieces of the puzzle." As a final note, she recounted a famous quote attributed to many sources: "It is amazing what you can do when you don't care who takes credit."

CREATING A STANDARD AND BEST PRACTICES FOR MEDICATION PRESCRIPTION LABELS[3]

In his presentation, Gerald McEvoy focused on a USP initiative to develop standards for medication labels. He began his remarks by noting the confusing array of information that is included on the standard prescription label (see Figure 3-4), which historically features the name of the pharmacy as the most prominent piece of information. Over time, he noted, that information will become less prominent, and he acknowledged that progress toward creating more patient-friendly labels was being made before USP undertook its current effort and began issuing recommendations. Companies such as CVS and Target and health systems such as the Veterans Health Administration, for example, engaged experts such as Parker and others to assist them in designing labels even before standards became available.

The stimulus for much of this work, McEvoy said, was a white paper—*Improving Prescription Drug Container Labeling in the United States: A Health Literacy and Medication Safety Initiative*—that was commissioned by the American College of Physicians Foundation and presented at an October 2007 IOM Roundtable workshop. Two key findings noted in this white paper were that there was an inadequate understanding of the prescription container by patients that led to poor adherence, and that there were no universal standards for prescription labels. Other key findings in this white paper included

- Evidence-based practices should guide label content and format.
- Prescription instructions are important for patients and should be clear and concise.
- Patient medication information should be an integrated system that extends beyond the container.
- Health care providers are not communicating adequately to patients.
- Research is needed to identify best practices.

McEvoy also listed the following major messages to come out of that IOM workshop:

- The container label is the patient's most tangible source of information about prescribed drugs and how to take them.
- The container label is a crucial line of defense against medication errors and adverse drug effects.

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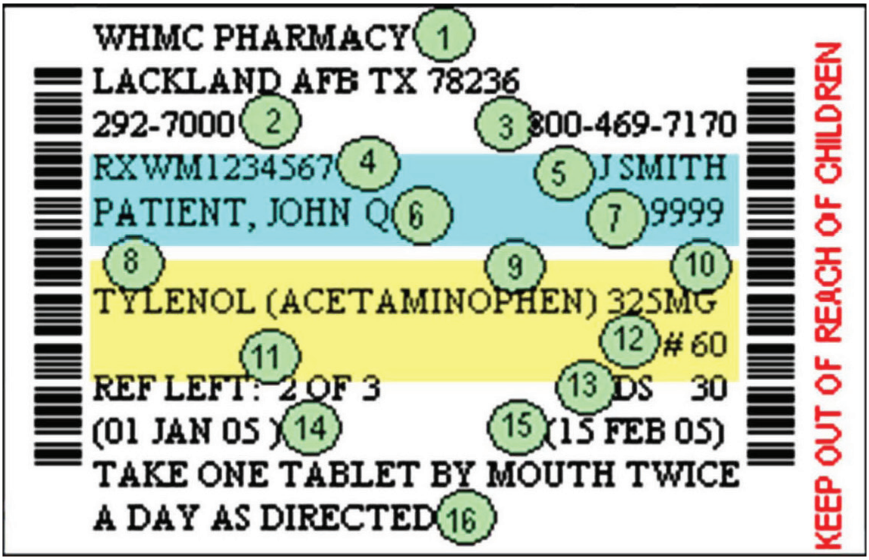
[3] This section is based on the presentation by Gerald McEvoy, assistant vice president of drug information at the American Society of Health-System Pharmacists, and the statements are not endorsed or verified by the IOM.



WHMC PHARMACY①
LACKLAND AFB TX 78236
292-7000② ③800-469-7170
RXWM1234567④ ⑤J SMITH
PATIENT, JOHN Q⑥ ⑦9999
⑧ ⑨ ⑩
TYLENOL (ACETAMINOPHEN) 325MG
⑪ ⑫# 60
REF LEFT: 2 OF 3 ⑬DS 30
(01 JAN 05)⑭ ⑮(15 FEB 05)
TAKE ONE TABLET BY MOUTH TWICE
A DAY AS DIRECTED⑯
KEEP OUT OF REACH OF CHILDREN

FIGURE 3-4 A standard prescription drug label presenting an array of information that is often confusing to patients.
SOURCE: McEvoy, 2014.

- Forty-six percent of patients across all levels of literacy misunderstood one or two dosing instructions.
- Fifty-four percent misunderstood one or more auxiliary warnings.

At that workshop, Alastair Wood presented his concept of the universal medication schedule and Roger Williams (then Chief Executive Officer of USP) offered to have USP convene a neutral, multidisciplinary group to develop prescription container labeling standards, an offer that many workshop participants endorsed. This offer was followed by the USP Safe Medication Use Expert Committee authorizing an advisory panel to determine an optimal prescription label content and format in order to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription instructions and to create universal standards for label format, appearance, content, and language. This advisory panel, which McEvoy and Joanne G. Schwartzberg co-chaired and that included Parker, Cindy Brach, and other health literacy experts, was formed in December 2008 and published the initial draft universal standards in January 2011. The standards became official in May 2013, with draft revisions focusing on visual impairment and patient-centered dosing expected to be posted for comment sometime during 2015. The standards are available for downloading through the USP website.[4]

McEvoy noted that the decision was made to publish the initial set of standards based on top-level principles without waiting for additional evidence to more fully support detailed recommendations because enough things needed to be addressed and corrected in order to organize the information in a patient-centered manner. For example, the name of the pharmacy or its logo are not particularly important to patients, but how to contact the pharmacy with questions is important. In creating the standards, the advisory committee focused on issues such as improving readability, optimizing the label's topography, and simplifying language. Discussions included topics such as whether to include the purpose of the drug—some patients do not want that information on the label for confidentiality reasons, but having that information is particularly important for the elderly, who often take multiple medications. Auxiliary information was a big focus of the advisory committee's work and the ultimate recommendation was to minimize auxiliary information because there often is limited evidence to support that information and because it was distracting to patients.

Today, the standards are at what McEvoy characterized as at a high level, but he expects that over time they will become more specific in terms of how to standardize content and format as published evidence expands and strengthens. Currently, the standards stress that the prescription label be patient centered, that the information must be organized in a way that best reflects how most patients seek out and understand medication instructions, and that prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use. The standards also state that the language on the label should be clear, simplified, concise, familiar, and free of jargon; that it is used in a standardized manner in sentence case; and that it should not use all capital letters. Instructions on the label should clearly separate the dose itself from the timing of each dose and should convey the number of dosage units to be taken, the timing of the doses using specific time periods—morning, noon, evening, and bedtime—and use numerals instead of letters for numbers. The standards note that dosing by precise hours of the day makes it harder for patients to follow.

The standards further state, McEvoy continued, that if the purpose of the medication is included on the prescription, it should be included on the prescription container label, though confidentiality and patient preference may limit inclusion of the purpose on labels. If the purpose is included, it should be in clear, simple terms and not use medical jargon—for example,

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[4] See http://www.usp.org/usp-nf/key-issues/usp-nf-general-chapter-prescription-container-labeling/download-usp-nf-general-chapter-prescription-container (accessed May 11, 2015).

high blood pressure should be used rather than hypertension. When in doubt, those writing the label should refer to the Plain Language Medical Dictionary available at the University of Michigan library website.[5] Readability is important and the standards stress that labels should be designed and formatted with horizontal text so that the need to turn the container to read lines of text is minimized, that critical information is not truncated or abbreviated, and that the number of colors and their use should be minimized.

The important thing to remember about these standards, said McEvoy, is that USP is not a regulatory body and has no regulatory authority for this particular type of activity. Instead, states have to endorse the USP standards if they are to have the force of law because that is where the practice of both pharmacy and medicine are governed, he explained, though standards of practice can still apply when state regulations do not specifically endorse or preclude them. In 2011, California became the first state to require patient-centered labels, and the National Association of Boards of Pharmacy adopted the USP standard in a 2012 resolution that encourages individual states to adopt the standards. New York and Utah and perhaps others have since adopted some supportive language, and some national pharmacy chains have pre-empted state adoption to the extent permitted by state laws.

The Institute for Safe Medication Practice, the National Council for Prescription Drug Programs (NCPDP), and other groups have also voiced support for the standards. NCPDP in particular, said McEvoy, can promote rapid adoption of the standard because it is the group responsible for electronic data standards that apply to medicines. He noted that NCPDP has published a white paper on acetaminophen label best practices (NCPDP, 2013), and these recommendations—including the one to replace APAP with acetaminophen and fully spell-out the ingredient for all combinations—were adopted quickly by the major pharmacy chains. Today, nearly 97 percent of U.S. pharmacies have adopted the recommended changes for acetaminophen-containing medications, including standardized warnings about liver toxicity and avoiding inadvertent concomitant use of multiple acetaminophen-containing products. In addition, the APAP abbreviation has been eliminated from the databases of every major medical publisher.

NCPDP has since released a second white paper containing recommendations and guidance for standardizing dosing designations on prescription container labels of oral liquid medications (NCPDP, 2014). The recommendations in the white paper include using milliliter as the standard unit of measurement and discontinuing the use of household units of measure

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[5] See http://www.lib.umich.edu/taubman-health-sciences-library/plain-language-medical-dictionary (accessed May 11, 2015).

such as teaspoons, providing a dosing device with numeric graduations corresponding to the labeled dose, and always using leading zeros before a decimal point and never use trailing zeros. The white paper also recommends educating patients and caregivers about oral medications and educating pharmacy staff about the importance of using milliliters as the unit of measure for all oral liquids. CDC, FDA, USP, and professional practice groups have all voiced support for these recommendations, as have several large national pharmacy chains. Pharmacy database producers are facilitating easy adoption by converting household units to milliliters, and schools of pharmacy are now being asked to advocate the recommendations, which McEvoy said have received widespread national press coverage.

As far as the future goes, McEvoy reiterated that two proposed revisions will be available for comment. Revisions to address visual impairment incorporate the June 2014 U.S. Access Board Best Practices for the Visually Impaired (U.S. Access Board, 2013), which were authorized by the FDA Safety and Innovation Act signed into law on July 9, 2012. The revisions concerning more specific recommendations about using patient-centered instructions will refer to the Universal Medication Schedule (UMS), which schedules medication taking into four standardized time periods and which is particularly useful for simplifying daily medication regimens that include multiple oral therapies. McEvoy recalled visiting his parents and finding that they put out 10 to 15 cups of pills each day, each for a specific time of day ordered by their doctors. Randomized controlled trials have shown, however, that patient-centered labels using UMS improve understanding in a population that takes an average of five drugs: from 59 percent for standard labeling to 74 percent for UMS. Data also show improved adherence over 3 months from 30 percent for the standard label to 49 percent for UMS (Wolf et al., 2011b).

HEALTH LITERACY AT THE FOOD AND DRUG ADMINISTRATION[6]

In the final presentation of this panel session, Theresa Michele decided to eschew speaking about what has transpired over the past decade at FDA and instead talk about ongoing agency projects, both for prescription and OTC medications. She noted that none of this work would have been possible without the advances and paradigm shifts that the prior speakers discussed.

One of the things that concerns FDA about prescription drugs is that

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[6] This section is based on the presentation by Theresa Michele, director of the Division of Nonprescription Clinical Evaluations at FDA, and the statements are not endorsed or verified by the IOM.

there are "too many cooks in the kitchen," said Michele, meaning that patients are receiving prescription drug information from too many different sources that may be duplicative, incomplete, or difficult to understand. When patients pick up their drugs from the pharmacy, they receive medication guides and patient package inserts that are developed in collaboration with FDA, but they also receive consumer medication information that is not vetted by the agency. As a result, FDA is now considering a new regulation to require that all prescription drugs have a single, standardized Patient Medication Information (PMI) document. "They will get one piece of paper when they leave the pharmacy, and that would be for every prescription," explained Michele. She stressed that this information will not replace patient counseling, which she said is absolutely crucial for reinforcing physician orders. Most importantly, the source of information in the PMI would be the FDA-approved professional labeling information.

Since it started this effort in September 2010, the agency has held a variety of expert meetings and public workshops to solicit input regarding the content and form of the PMI. For the most part, this idea has been well received, said Michele. The most recent of these workshops, held in July 2014, explored lessons learned from health literacy researchers engaged in the PMI projects and the role of stakeholders who regularly interface with the PMI in moving the initiative forward. FDA is now working on developing a framework for the PMI that is being informed by research and input from stakeholders. Some of the principles that the agency is considering in the development of the PMI framework include

- The agency will take a surveillance approach that includes reviewing and approving manufacturer-authored PMI;
- All information in the PMI will be based on FDA-approved professional labeling;
- The PMI will undergo consumer testing for comprehension, as is now done for OTC medications; and
- The PMI will be updated when certain changes are made to the professional labeling.

Another effort in the prescription drug area comes out of the FDA Safety and Innovation Act of 2012, and in particular Section 907, addressing issues related to demographic subgroups in clinical trials. The FDA Action Plan focuses on three key priorities, said Michele: quality in terms of improving the completeness and quality of demographic subgroup data collection, reporting, and analysis; participation with regard to identifying and breaking down barriers to subgroup enrollment in clinical trials; and transparency as far as making demographic subgroup data more available and transparent to physicians and consumers who might benefit from those data. FDA is developing a website with a standardized consumer-friendly format that will be online soon, she said. These data are now available, but they are hard to find and are not useful to the general public.

Turning to the subject of OTC medications, Michele explained that the main focus of FDA's activities is with the Nonprescription Safe Use Regulatory Expansion (NSURE), which would allow the use of innovative technologies or other conditions of safe use to expand which drug products can be considered nonprescription. To better explain what is involved in this effort, she first discussed some of the issues with the current system of regulating OTC drug products. In general, she said, OTC products have a few defining characteristics. They can be adequately labeled so that the consumer can self-diagnose, self-treat, and self-manage the condition being treated, and they can be used safely and effectively without input from a health practitioner. In addition, OTC products have low potential for misuse and abuse and they have a safety margin such that the benefits of OTC availability outweigh any risks associated with the product.

OTC drug candidates are tested to make sure they have these characteristics, typically using consumer studies. Michele explained that FDA requires a variety of consumer studies that look at label comprehension, self-selection, and actual use by patients. "These studies have evolved significantly over time to become much more sophisticated and much more in line with what we would expect for Phase III trials in prescription drugs," said Michele. Currently, though, information to the consumer is limited to the small space on the drug facts portion of the product label, and FDA wants to ensure that OTC drugs gain wider use because of the difficulty that some patients have gaining access to the health care system. "We want to help patients take charge of their own health," she explained.

Michele acknowledged that there were many misconceptions about what NSURE was trying to accomplish. Some stakeholders, for example, thought NSURE was trying to eliminate doctor visits, which is not the intention. Rather, NSURE aims to help people who are sitting in the pharmacy without seeing a doctor, not to stop those who want to see a doctor from doing so. Another concern FDA heard from stakeholders was that FDA was going to create a third class of drugs, but the agency has no intention of doing that, and NSURE is not designed to give prescribing powers to pharmacists. The latter, in fact, is regulated by the states. "What we are trying to do is expand the pie a little bit for those products that could be non-prescription if people had the health literacy abilities to understand how to use them," said Michele in closing.

DISCUSSION

Betsy Humphreys, deputy director of the National Library of Medicine (NLM), started the discussion by noting that NLM appreciates the collaboration it has with FDA in terms of making approved drug labels available through the DailyMed website and for helping keep prescription standard terminology up to date. She then asked about the use of the PMI in cases where a patient has other comorbidities that would alter how they use a particular drug or where there are other factors that conflict with the standard information in the PMI. Michele replied that every great idea comes with stumbling blocks, and it is important to address as many as possible ahead of time, which is what FDA is doing with the PMI. She reminded the workshop that the PMI is not meant to replace individualized counseling or the special instructions that come with certain medications, such as those that use metered-dose inhalers or an auto-injector.

McEvoy continued on this theme by asking about off-label use, which is more common and more important for many drugs. As an example, he noted that methotrexate was used off-label to treat arthritis long before it was approved for that specific use. "Imagine the patient who got a PMI that only talked about cancer as the use for that particular drug. That is an important issue," said McEvoy. Parker added that part of the vision for the future of the medication label is to develop a more standard approach to the instructions on the label, which, as she put it, is where the rubber meets the road for the actual patient. "We want to see that become a piece of the clinical trial that brings a medication to the market, where the data from the trial actually reflect the reality of what it is that ends up on the label and what ends up happening with the actual person consuming the products," said Parker.

Humphreys then asked about the challenges of providing demographic breakdown data given that some of these data are not too accurate and wondered about the level of expertise that would be needed to assess the data. Michele said she could not agree more that it would not be useful to report on a tiny subgroup, and that additional feedback from the field will help FDA determine what kinds of data are useful and how they can best be presented.

Laurie Myers, lead of the Healthcare Disparities and Health Literacy Strategy group at Merck & Co., Inc., then asked Michele if she had any idea about the timing of the PMI framework and its implementation given that it has been in the works for a number of years. Michele responded that she could not say that anyone other than FDA is working on it, particularly with regard to meeting the needs of patients with low health literacy. Isham commented that the widespread availability of cell phones and other technologies may provide some opportunities for addressing some challenges that come with low health literacy. Michele noted that FDA is considering all options as part of the NSURE Initiative, and has asked the pharmaceutical industry for any creative ideas it may have.

Parker noted that a recent meeting of the IOM Roundtable on Promoting Health Equity and Eliminating Disparities was well attended by technologists; there are now nearly 700 apps available to help with medications. She also remarked that cell phones are particularly popular with some of the underserved populations that might have issues with low health literacy. On the other hand, cell phones are becoming an increasing cause of Health Insurance Portability and Accountability Act (HIPAA) violations when used to communicate with patients. This is particularly true when patients text pictures of their medications when asking for advice. McEvoy added that the Office of the National Coordinator Meaningful Use Stage II Requirements for Electronic Health Records requires that there be patient access to information in context. What that means, he explained, is that if a patient accesses his/her electronic health record (EHR) portal using his/her cell phone to get information about his/her medications, that EHR must provide the in-context access to information about those drugs. "That is already being adopted and the government is stimulating it," said McEvoy.

Thinking about how hard it is sometimes to decide which OTC product to take for a particular self-diagnosed illness, Isham asked the panelists if they had any thoughts about how drug labeling for OTC medications might integrate with a larger system for helping the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Michele replied that that would be a tall order. "I think OTC consumers get their information in a variety of different ways, and we need to reach out to them beyond just what is on the pharmacy shelf," she said. One FDA program, called Medications in Your House, not only reaches out to the adult consumer, but is meant to be used as a middle school curriculum to educate budding adults who will soon need to understand what is on the pharmacy shelf and what is in their medicine cabinet.

"We need to be creative in this space because it's not just about what is on that drug facts label," said Michele. In the prescription drug space, all information should flow from the package insert, which FDA controls tightly even with regard to advertising. "In the OTC space, the drug facts label is just a small part of what the consumer sees," she added, noting that the first thing the consumer sees is what is on the front of the box, which may not even say what the names of the drugs are in the product.

Parker noted that as a health care practitioner, her health literacy has been advanced by being part of FDA Advisory Committees. "I think FDA's willingness to have those of us who are engaged in this field be a part of the conversation to become educated and health literate ourselves about the nuances of a regulatory agency and what it takes to make progress and what to change has really contributed to my lens of what it is about. I am very appreciative of their allowing us to be a part of the table," said Parker. She added that she has come to appreciate the fact that a regulatory agency such as FDA should not move too quickly with regard to issues such as these that are highly nuanced. As an example, McEvoy cited issues having to do with product branding, such as the decision of the maker of the cold product Sudafed to develop a formulation that did not include pseudoephedrine, which had been relegated to behind-the-counter status because of its potential use in making illicit drugs, and call it Sudafed PE. "This may not seem important but it really is," said McEvoy. "Patients will draw their conclusions about what that product is intended for because of the history they have with that brand, so how do we balance the importance to the manufacturer of the brand versus solving that particular issue?" He also cited acetaminophen as another example because the United States is the only country where the generic name for that drug is not paracetamol. With the large number of immigrants in this country, it is important that acetaminophen also be identified as paracetamol to prevent accidental overdosing by someone who is not familiar with the U.S. name for this drug.

Isham concluded the discussion, noting that it illustrated a few important points, including the facts that (1) very capable individuals are addressing these issues, and (2) the need of consumers to treat themselves and the need to do it safely is a complex interface. Finally, he said the discussion has demonstrated the progress the field has made and drawn a clear line to some of the activities of the Roundtable, yet at the same time it points out that much more progress needs to be made to solve the issues of health literacy and medication safety.

4

Use and Delivery of Health Care

The workshop's second panel session included four speakers. Michael Paasche-Orlow, associate professor of medicine at the Boston University School of Medicine, opened the session by reviewing the progress that the health care delivery enterprise has made over the past decade at incorporating the concepts of health literacy into its interactions with patients. George Isham, senior advisor at HealthPartners, then discussed the link between health literacy and quality of care, and Russell Rothman, director of the Center for Health Services Research at Vanderbilt University, described ongoing efforts to create health-literate health care delivery. Victor Wu, managing director for clinical transformation at Evolent Health, provided some insights into the effects of the ACA on the health literacy field. An open discussion moderated by incoming roundtable chair Bernard Rosof, CEO of the Quality in Healthcare Advisory Group, followed the three presentations.

OVERVIEW[1]

Before providing an overview of the progress that has been made over the past decade incorporating the concepts of health literacy into the use and delivery of health care, Paasche-Orlow noted the tremendous amount of social capital present at the workshop. He also noted the vast amount of

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[1] This section is based on the presentation by Michael Paasche-Orlow, associate professor of medicine at the Boston University School of Medicine, and the statements are not endorsed or verified by the IOM.

educational privilege in the room and the responsibility to use that privilege, as those present at the workshop have demonstrated that they are committed to working to create a system that cares about the most vulnerable populations.

In thinking about the topic of use, it is important to remember that there is no use without access, said Paasche-Orlow, and he pointed out that over the past decade, there has been improvement with regard to access in those states that have taken the necessary steps. He also remarked, though, that access will once again become a problem because of a limited capacity of the health care system to absorb more patients given the looming shortage of primary care physicians.

One of the lessons that comes from reviewing the literature that has evolved over the past decade, he said, is that when talking about access, use, and delivery of health care, it is important to use the lens of health literacy to do so. As the literature shows, health literacy is a significant mediator in the nexus between the relationship between individuals and systems, between the use side and the delivery side of health care. Health literacy is clearly an important core value for increasing equity, addressing disparities, promoting patient-centeredness, improving outcomes and quality, and reducing costs. “It is financially perilous to ignore the effects of health literacy,” said Paasche-Orlow.

Over the past decade, there has been a move from primarily observational work toward interventional work, though this evolution of the field is still in its early stages. There has also been a move from local exploration toward some examples of broader implementation, and he commented that the implementation of quality findings in health care in general is itself an emerging science that has developed over the past decade and is still developing. The incorporation of health literacy principles into training standards is also just beginning, and he added that, “you can build a workforce, but you also have to train providers to communicate effectively and this will require cultural transformation.” Paasche-Orlow said that the inclusion of core health literacy concepts such as universal precautions and teach-back that Howard Koh mentioned in his presentation are an important part of this cultural transformation, one that all clinicians are going to have to endorse and embrace and see as part of their mission.

Paasche-Orlow said there is still a great deal that this field needs to accomplish in the years ahead, and he listed three specific areas that need work. There is going to need to be a massive increase in education and support for patients, families, and social networks to understand and use health care effectively. Health care systems have to be activated and empowered to deliver a decent product while greatly reducing unnecessary complexity in every aspect of their interactions with patients, along the lines of the discussions in the previous panel about creating health-literate organizations.

Finally, while policy is starting to emerge that will advance health literacy and access in some areas, "policy that actually has teeth will have a bigger impact than just unfunded mandates. Figuring out where to put additional leverage points to promote health literacy behavior up and down the spectrum is going to be critical," said Paasche-Orlow.

Closing on an optimistic note, he recounted the days when he would go to the heads of his hospital and talk about reducing readmission rates, they would tell him to leave, that their job was to keep hospital beds full. Today, this is no longer true; he credited policies with teeth for this cultural transformation. What he would like to see next are high-stakes testing policies that not only require new doctors to know how a kidney works but also to have to demonstrate the communication skills needed to confirm understanding. "In the end, that is going to end up moving the needle," he said.

HEALTH LITERACY AND QUALITY[2]

George Isham began his presentation by reiterating Koh's remarks that it is important to move the conversation about health literacy from the clinical domain into the broader scope of health and public health. He then commented that there is some confusion about the definitions that those in the health literacy field use and about whether the field's target is health care services or the outcome of health itself, which is affected by factors beyond health care services.

Several decades ago, said Isham, the IOM defined the quality of health services as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. To this definition, he would add interventions broader than health services and that the professions the definition refers to go beyond just doctors and nurses to include those professionals who interact with the community beyond health care delivery in ways that affect health more broadly. The Health Resources and Services Administration (HRSA) quality toolbox website defines quality improvement as the systematic and continuous improvement in health services or health care services and the health status of targeted patient groups. Finally, there is the IOM definition of health literacy, which is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

In practice, health literacy is the place where skills and abilities meet the demands and complexity of health systems. There are opportunities on both sides of this equation, said Isham, and the field is now recogniz-

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[2] This section is based on the presentation by George Isham, senior advisor at HealthPartners, and the statements are not endorsed or verified by the IOM.

ing the impact of demands and complexity as a complement to addressing individual skills and abilities. In terms of how broad the definition of health services should be, he referred to data from the University of Wisconsin's county health rankings and noted how much factors beyond clinical care impact health (see Figure 4-1). He recounted how even just a couple of decades ago, factors such as tobacco use, diet, and exercise were not even on the radar screen of health care delivery systems. Today, with the advent of the ACA and the increasing stress on community-wide efforts to improve health, the definition of health services needs to include other socioeconomic factors such as culture, education, and employment.

As an example, Isham remarked that his organization has an emphasis on children's health that goes far beyond clinical care to include how to work with other agencies in the community around education and early childhood development. This broader focus, he explained, was stimulated by research findings as well as from thinking about the relationship between health and the physical environment.

Turning to the subject of health and quality improvement, Isham said it is important to have good focus when trying to improve quality, whether it is quality of health more broadly or quality of health care services. He

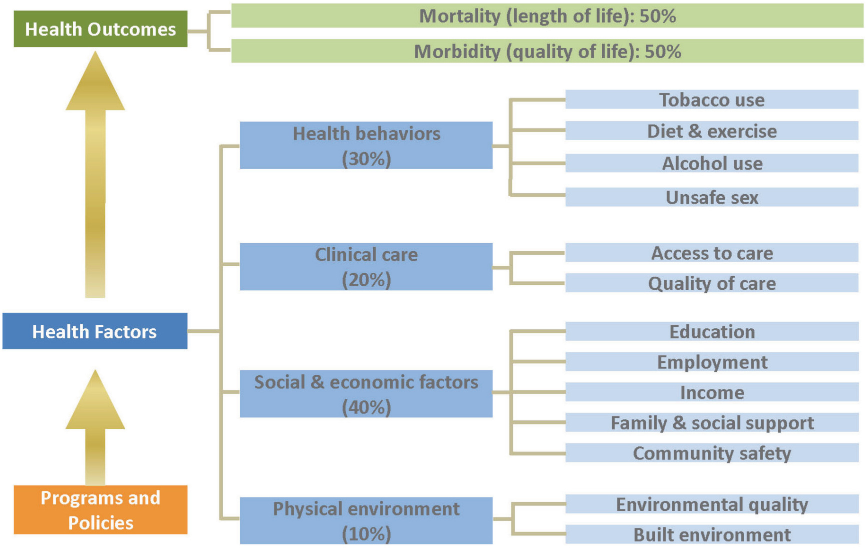

FIGURE 4-1 Many factors beyond those provided in the clinic impact health outcomes.
SOURCE: County Health Rankings, 2013.

noted that it is also important to consider that quality improvement work is about focusing on systems and processes and how they impact individuals. The basic framework for quality improvement work is to consider the available resources—people, infrastructure, materials, information, technology, and the like—what is done with those resources and how they are used, and what their impact will be in terms of the services delivered and on the satisfaction of patients, or more broadly that of individuals outside of the doctor's influence (Donabedian, 1980).

Isham then referred to the Institute for Healthcare Improvement's model for improvement, which talks about aims, measures, tests of change, implementing change, and spreading change (Langley et al., 2009). He commented that there is still a long way to go in terms of developing measures of health literacy and how they are applied, and how the Plan, Study, Do, Act principle of testing and scale-up applies to any quality improvement effort. He then focused on the National Quality Strategy, a product of the ACA, and its three big areas of emphasis related to the triple aim of better care, affordable care, and healthy people and communities. Better care means improving the overall quality of care by making health care more patient-centered, reliable, accessible, and safe, while the focus on healthy people and communities aims to improve population health by supporting proven interventions to address behavioral, social, and environmental determinants of health, in addition to delivering higher quality care. The effort to provide affordable care aims to reduce the cost of quality health care for individuals, families, employers, and government.

One piece of the National Quality Strategy is the National Action Plan to Improve Health Literacy, which includes the following goals:

- Develop and disseminate health and safety information that is accurate, accessible, and actionable.
- Promote changes in the health care system that improve health information, communication, informed decision making, and access to health services.
- Incorporate accurate, standards-based, and developmentally appropriate health and science information and curricula in child care and education through the university level.
- Support and expand local efforts to provide adult education, English-language instruction, and culturally and linguistically appropriate health information services in the community.
- Build partnerships, develop guidance, and change policies.
- Increase basic research and the development, implementation, and evaluation of practices and interventions to improve health literacy.
- Increase the dissemination and use of evidence-based health literacy practices and interventions.

Brach and colleagues (2012) identified 10 attributes of a health-literate organization (see Figure 4-2). These attributes could be areas that the field could look at in terms of activities that influence health quality. "If we changed these features, it might result in a more health-literate result and better outcomes for our patients," said Isham.

The basic strategy for improvement, said Isham, is the universal precaution strategy, which emphasizes structuring the delivery of care as if everyone may have limited health literacy. This strategy also recognizes that higher literacy skills in general do not necessarily equal better understanding, that health literacy is a state rather than a trait, and that everyone benefits from clear communication regardless of their health literacy status. AHRQ, Isham added, has developed the health literacy Universal Precautions Toolkit, which includes 20 tools, a quick start guide, a path to improvement, and more than 25 resources such as sample forms, PowerPoint presentations, and worksheets (DeWalt et al., 2010). "We have a number of elements for quality improvement as it relates to health literacy already in place," said Isham, who noted that quality improvement in health care is a powerful tool in and of itself. He said that since it was introduced in the late 1980s by a number of large organizations, it has produced substantial improvements in health care that have impacted millions of people. Now, with the advent of the ACA and the development of ACOs, the infrastructure is being put into place to broaden that impact even more.

Isham then referred to an article by Koh and his colleagues (2012) that raises several important points. First, despite its importance, health literacy has until recently been relegated to the sidelines of health care improvement efforts aimed at increasing access, improving quality, and better managing costs. However, recent federal policy initiatives have brought health literacy to a tipping point. As a result, if public and private organizations make it a priority to become health literate, the nation's health literacy can be advanced to the point at which it will play a major role in improving health care and health for all Americans. The key, said Isham, is indeed making health literacy a priority.

Isham concluded his presentation with some suggestions on how to move forward with quality improvement efforts that include health literacy. They included

- Link quality of care with improving broader health and health literacy. The concepts need improved clarity and definition.
- Systems need to make health literacy a priority.
- The issue would be more salient locally if the health literacy problem could be described contemporaneously and regularly in regional, state, and community populations.

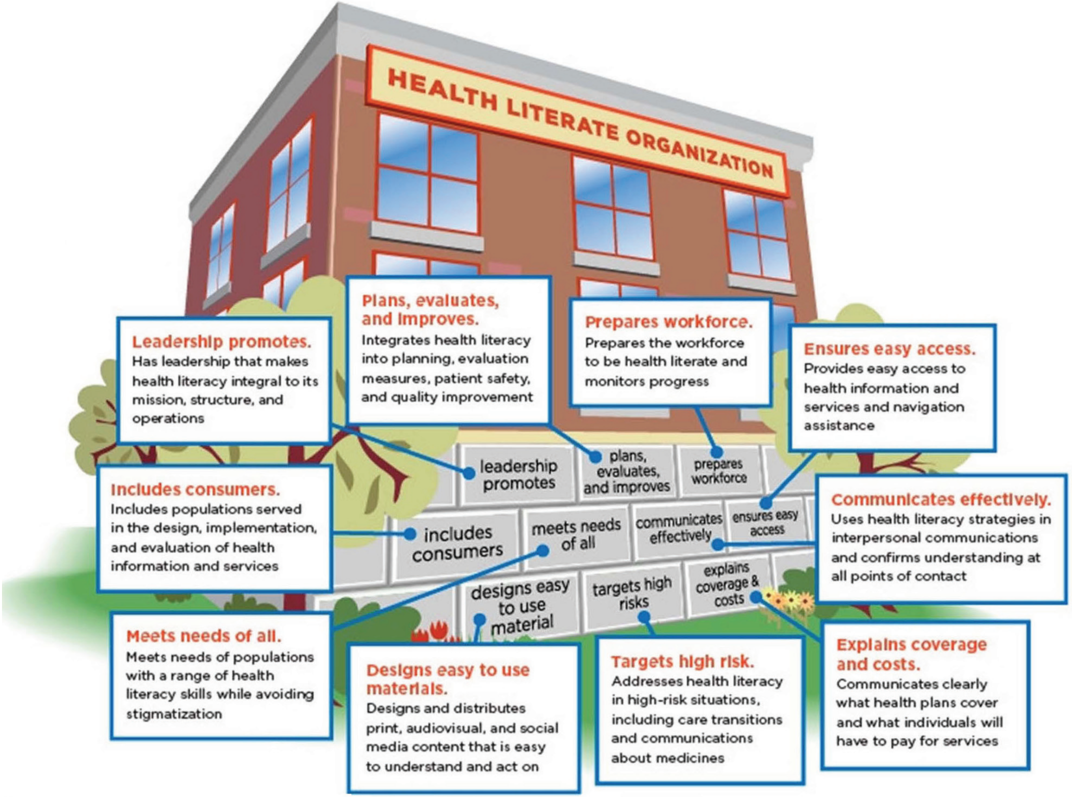

FIGURE 4-2 Ten attributes of a health-literate organization.
SOURCE: IOM, 2012, p. 5.

- The established link between limited health literacy and poor outcomes needs repetitive communication and linkage to system's emerging accountabilities and risk for population outcomes.
- The issue would be more visible on local health system agendas if they had the tools to personalize the issue to local enrolled, or patient, or ACO populations.
- The lack of valid, reliable, useful, and affordable practical public accountability and improvement health literacy performance measures are a relative barrier to action and accountability for that action.
- More examples of local action using evidence-based health literacy interventions to improve outcomes are needed.
- Accreditation programs for health organizations should include more items directly related to health literacy, such as the 10 attributes enumerated in a paper published by the IOM (Brach et al., 2012).
- Financial and non-financial incentives need to be developed and deployed to motivate action.

CREATING HEALTH-LITERATE HEALTH CARE DELIVERY[3]

The subject of Russell Rothman's presentation was the 10 attributes of a health-literate organization that Isham mentioned in his presentation (see Figure 4-2) and a paper commissioned by the Roundtable that he and his colleagues at the Vanderbilt Center for Effective Health Communication authored (Kripalani et al., 2014). He noted the many studies to date in health literacy that have demonstrated that patients with lower health literacy can have poor knowledge and self-care, and even worse self-outcomes. The majority of these studies, he explained, focused only on individual health literacy or patient-provider communication and did not consider larger system-level challenges related to health literacy despite the paradigm shift that Koh referred to regarding the need to think about health literacy at the health system or organizational level. "When a patient interacts with a health care system, yes they are communicating directly with a provider, but there are many other facets of that organization that are at play and that impact the patient's health," said Rothman.

Patients, he explained, may interact with support services such as translators or patient navigators. They may be getting something in the mail to tell them about their appointment and they have to understand that

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[3] This section is based on the presentation by Russell Rothman, director of the Center for Health Services Research at Vanderbilt University, and the statements are not endorsed or verified by the IOM.

to know when to come to their appointment and how to get there. When they arrive at their appointment, they receive a clipboard of materials, such as HIPAA disclosures and permission to bill insurance companies, that they need to sign. Eventually, they see their provider, but they may also see nurses, dieticians, and other health care team members. Then they go home and may deal with billing statements and insurance benefits statements. "There really is a system level of activities going on that patients or families need to navigate that can impact their understanding of their health, their ability to perform self-care activities and have good health outcomes," Rothman explained. The result, he added, is that the health literacy field needs to think about what is going on at the organizational level and whether or not an organization has policies in place, appropriate staff training, and understandable materials available for their patients so they can have the optimal experience that best benefits their health.

After recounting the definition of a health-literate organization as one that makes it easier for people to navigate, understand, and use information and services to take care of their health (Brach et al., 2012), Rothman listed the following 10 attributes of a health-literate organization:

1. Has leadership that makes health literacy integral to its mission, structure, and operations;
2. Integrates health literacy into planning, evaluation measures, patient safety, and quality improvement;
3. Prepares the workforce to be health-literate and monitors progress;
4. Includes populations served in the design, implementation, and evaluation of health information and services;
5. Meets the needs of populations with a range of health literacy skills while avoiding stigmatization;
6. Uses health literacy strategies in interpersonal communications and confirms understanding at all points of contact;
7. Provides easy access to health information and services and navigation assistance;
8. Designs and distributes print, audiovisual, and social media content that is easy to understand and follow;
9. Addresses health literacy in high-risk situations, including care transitions and communications about medicines; and
10. Communicates clearly what health plans cover and what individuals will have to pay for services.

The aim of the work that the Roundtable commissioned was to identify and evaluate current measures for assessing organizational health literacy, and to try to reach out to health care organizations to understand how they are measuring and addressing organizational health literacy. Toward that end, Rothman and his colleagues performed a systematic review to identify measures of organizational health literacy. The first conducted a MEDLINE search for abstracts and articles in which researchers were trying to measure organizational health literacy. This search included all English-language articles from January 2004 to February 2014 and focused on measures of health literacy at the organizational level, excluding those papers and abstracts that looked at measures of individual health literacy and review articles. Recognizing that this is a young field, the Vanderbilt team also searched the so-called gray literature using Google search and by reaching out to experts in the field using listservs and a snowball sampling process to try to identify additional measures that organizations might be using.

Once Rothman and his colleagues identified potential measures, one member of the team reviewed all of the abstracts and papers to identify eligible measures, which were then reviewed by two team members to see how well these measures addressed the 10 attributes of organizational health literacy and to see what kind of work had been done to validate the measure that was developed. Reviewers also looked at whether the measure was being used and how it was being used by organizations. A third member of the team was brought in when needed to reach consensus, said Rothman. The team also used snowball sampling to try to understand how organizations would use these measures in the real world.

The team reviewed 1,926 articles and 59 other sources of information that the team received through the snowball sampling and gray literature. From that initial pool, the team identified 68 measures that were addressing organizational health literacy in some capacity. They considered 12 of the measures as very comprehensive, addressing 5 or more of the 10 attributes (see Figure 4-3), with 2 of them addressing all 10 attributes. Another 27 measures addressed between 2 and 4 of the attributes and 29 more measures focused on just one attribute, usually interpersonal communication. Rothman pointed out that only 3 of the measures addressed attribute 10, which has to do with how patients understand cost or billing information related to their health, an issue that is becoming more important as patients are being asked to pay for a greater share of their health care. He commented, too, that there is a growing demand for transparency in cost, yet the billing forms that a patient receives are often far from understandable. “There are huge opportunities to look at what organizations are doing around explaining cost issues,” he said.

The Enliven tool, one of the more robust measures the team identified, addresses all 10 of the attributes. Consisting of 85 items, it is basically a checklist to ask an organization if it is addressing the 10 attributes. It is designed to be completed by an organization, Rothman explained. For example, a checklist of 15 items is used to measure attribute one—whether

Measure name	# Items	Setting/Context	How administered	Respondent	Relevant attributes									
					1	2	3	4	5	6	7	8	9	10
Enliven Health Literacy Audit Resource	85	Designed for health and social service institutes to assess and guide health literacy appropriateness within their organizations.	Checklist	Organization	X	X	X	X	X	X	X	X	X	X
AHRQ Health Literacy Universal Precautions Toolkit	>100	Designed to address literacy issues for health care organizations, particularly primary care practices.	Toolkit: Surveys, checklists, materials	Organization	X	X	X	X	X	X	X	X	X	X
Communication Climate Assessment Toolkit (CCAT)	>100	Designed to gather data from patients, providers, and leaders to assess patient-centered communication.	Survey	Organization	X	X	X	X	X	X	X	X	X	
Health Literacy Environment of Hospitals and Health Centers	>100	Guides an organization through assessment, interpretation and improvement of the health literacy environment of an institution.	Survey, Checklist, Guidance	Organization	X	X	X	X	X	X	X	X		
Joint Commission Roadmap for Hospitals	>100	Includes checklists to assess effective communication, cultural competence, and patient- and family-centered care in hospitals.	Checklist	Organization	X	X	X	X	X	X	X		X	
Pharmacy Health Literacy Assessment Tool	61	Designed to assess health literacy issues for pharmacies and pharmacy patients.	Observation	Providers, Patients	X		X	X	X	X	X	X	X	
Literacy Alberta: Health Literacy Audit Tool	>100	Designed to assess health organization patient services.	Toolkit; checklist	Organization, staff	X		X	X	X	X	X	X		
Health Plan Organizational Assessment of Health Literacy Activities	>100	Designed by America's Health Insurance Plans (AHIP) to assess health literacy appropriateness of insurance materials provided to patients.	Survey	Organization			X		X	X	X	X		X
NCQA Patient Centered Medical Home (PCMH) surveys	>100	Designed to guide organizations toward PCMH certification.	Checklist	Organization			X	X	X		X	X	X	
CAHPS health literacy supplementary items	31	Designed specifically to target health literacy and provider communication from a patient's perspective.	Survey	Patient					X	X	X	X	X	
HCAHPS health literacy supplementary items	58	These items capture patient experiences of communication with their hospital.	Survey						X	X	X	X	X	
NALA Literacy Audit for HC settings Ireland	57	Designed to inform, assess, and improve the health literacy appropriateness in health care settings.	Toolkit: surveys, education, checklist	Providers, Staff		X			X	X	X	X		

FIGURE 4-3 Measures with five or more attributes of a health-literate organization.
SOURCE: Kripalani et al., 2014.

the organization has leadership that makes health literacy integral to its mission, structure, and operations (see Figure 4-4).

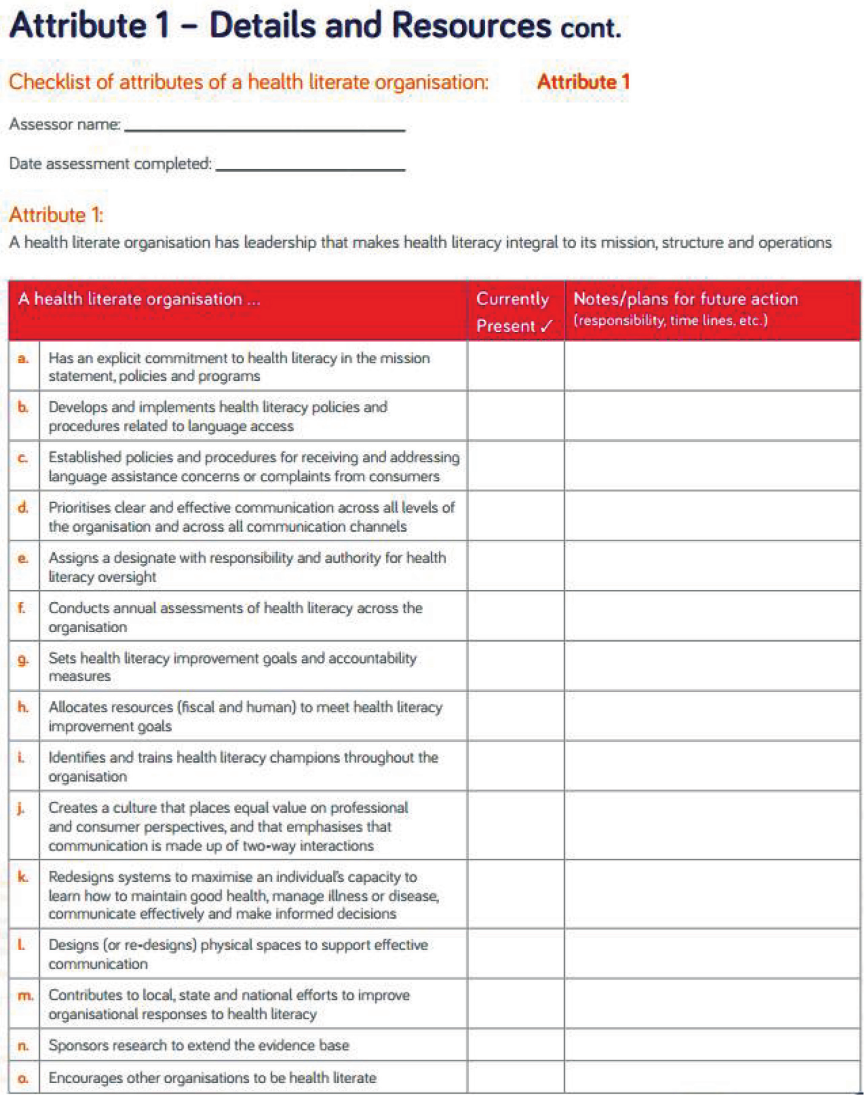
Another robust tool measuring all 10 attributes is the AHRQ Universal Toolkit. This 227-page compendium of more than 20 tools and measures is designed to be completed by staff and the organization. Within the toolkit is a 49-item health literacy assessment questionnaire that covers whether an organization is addressing spoken communication (see Figure 4-5), written communication, self-management, and empowerment in support of systems.

The Communication Climate Assessment Toolkit, developed by a team at the American Medical Association, measures all but the 10th attribute and is referred to as a 360-degree measure because it has different forms for different participants. The forms can be completed by organizational leaders, physicians and other providers, and patients. The toolkit is available in 11 languages and can be administered in person, online, or via phone. Rothman noted that the team that developed this toolkit has done some research demonstrating that it has some good construct validity with positive correlations between performance on the tool or the measurement scale and patient-reported quality of care and trust in the health care system. The researchers also demonstrated that the toolkit has good internal reliability.

The Health Literacy Environment of Hospital and Health Centers Toolkit, developed by Rima Rudd and her colleagues, has been field tested in hospitals, clinics, and other health care organizations in the United States, as well as in Australia, Europe, and New Zealand. This toolkit includes assessments for navigation, print communication, oral exchange, availability of patient facing technologies, policies and protocols, the use of plain language, and other measures of health literacy.

Rothman said that the 12 robust measures for addressing organizational health literacy are more than he expected to find when he and his colleagues started this project. "Several of the measures were developed specifically to address organizational health literacy, but others were originally developed to try to address how patient-centered an organization was or whether or not an organization was meeting criteria for patient-centered medical home. In that process, they were also addressing a lot of the attributes related to organizational health literacy," said Rothman. He added that most of the measures they identified have good content validity, meaning that they seem to be measuring the right things, but that there has been limited work to date to truly assess the construct validity or reliability of these tools. "There has not been a lot of robust work to see if they have utility in predicting health outcomes over time," Rothman added.

The second aim of this project was to determine how organizations are using these measures and specifically if they were using them for reporting, accountability, management, quality improvement, and research. He said



Attribute 1 – Details and Resources cont.

Checklist of attributes of a health literate organisation: **Attribute 1**

Assessor name: ______________________

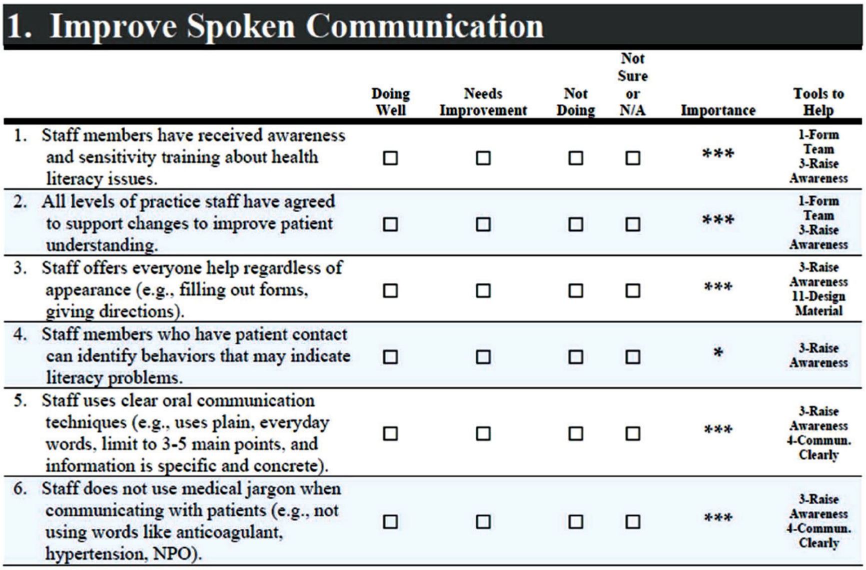
Date assessment completed: ______________

Attribute 1:

A health literate organisation has leadership that makes health literacy integral to its mission, structure and operations

	A health literate organisation ...	Currently Present ✓	Notes/plans for future action (responsibility, time lines, etc.)
a.	Has an explicit commitment to health literacy in the mission statement, policies and programs		
b.	Develops and implements health literacy policies and procedures related to language access		
c.	Established policies and procedures for receiving and addressing language assistance concerns or complaints from consumers		
d.	Prioritises clear and effective communication across all levels of the organisation and across all communication channels		
e.	Assigns a designate with responsibility and authority for health literacy oversight		
f.	Conducts annual assessments of health literacy across the organisation		
g.	Sets health literacy improvement goals and accountability measures		
h.	Allocates resources (fiscal and human) to meet health literacy improvement goals		
i.	Identifies and trains health literacy champions throughout the organisation		
j.	Creates a culture that places equal value on professional and consumer perspectives, and that emphasises that communication is made up of two-way interactions		
k.	Redesigns systems to maximise an individual's capacity to learn how to maintain good health, manage illness or disease, communicate effectively and make informed decisions		
l.	Designs (or re-designs) physical spaces to support effective communication		
m.	Contributes to local, state and national efforts to improve organisational responses to health literacy		
n.	Sponsors research to extend the evidence base		
o.	Encourages other organisations to be health literate		

FIGURE 4-4 The Enliven tool's checklist measuring whether an organization is meeting the definition of attribute one.
SOURCE: Thomacos and Zazryn, 2013.



1. Improve Spoken Communication

	Doing Well	Needs Improvement	Not Doing	Not Sure or N/A	Importance	Tools to Help
1. Staff members have received awareness and sensitivity training about health literacy issues.	☐	☐	☐	☐	***	1-Form Team 3-Raise Awareness
2. All levels of practice staff have agreed to support changes to improve patient understanding.	☐	☐	☐	☐	***	1-Form Team 3-Raise Awareness
3. Staff offers everyone help regardless of appearance (e.g., filling out forms, giving directions).	☐	☐	☐	☐	***	3-Raise Awareness 11-Design Material
4. Staff members who have patient contact can identify behaviors that may indicate literacy problems.	☐	☐	☐	☐	*	3-Raise Awareness
5. Staff uses clear oral communication techniques (e.g., uses plain, everyday words, limit to 3-5 main points, and information is specific and concrete).	☐	☐	☐	☐	***	3-Raise Awareness 4-Commun. Clearly
6. Staff does not use medical jargon when communicating with patients (e.g., not using words like anticoagulant, hypertension, NPO).	☐	☐	☐	☐	***	3-Raise Awareness 4-Commun. Clearly

FIGURE 4-5 One component of a health literacy assessment in the Agency for Healthcare Research and Quality Universal Toolkit.
SOURCE: AHRQ, 2010.

that at this point, not much has been published about how organizations are using them, but he added that he believes these measures can be used for reporting, accountability, management, quality improvement, and research. "Actually, we would really encourage that. We think there are fantastic opportunities for organizations to use the measures that are out there to apply it to their system to improve how they assess health literacy in all of these different areas," said Rothman.

Some of these measures have been widely distributed. The Joint Commission Roadmap for Hospitals, for example, has been downloaded more than 40,000 times, and the Health Literacy Environment of Hospitals and Health Centers, as he had mentioned, has been used both nationally and internationally. The Communication Climate Assessment Tool has been accessed widely and the Health Plan Organizational Assessment of Health Literacy, which was developed by American Health Insurance Plans, has also been distributed nationally. This assessment tool was developed by a health literacy task force drawn from the organization's 65 member plans to look at how health plans address health literacy. The organization has been able to push this tool out to their health plans and encourage its use as a way to assess how they are addressing health literacy and try to drive improvement in this space.

From their snowball sampling, the Vanderbilt team concluded that many health care systems are trying to address organizational health literacy in some way, but that they are early on in the process. They may have gotten a tool or a few tools or they may have pulled together some questions from several different tools, explained Rothman. Most of these organizations are starting to assess health literacy, but they may not yet have taken action to address health literacy or validate the tools they are using. Many groups are, however, starting to hire staff in the patient education, patient engagement, or patient experience sections of their health systems to start addressing organization health literacy, which he characterized as very encouraging.

Sutter Healthcare in California is just one example of an organization that mixed and matched measures, taking some materials from the AHRQ Universal Precautions Toolkit and adapting other materials from the IOM paper on the 10 attributes as well as some measures from the Consumer Assessment of Health Providers and Systems (CAHPS) health literacy supplementary items. Sutter Healthcare is now using this amalgam to try to measure how it is addressing organizational health literacy to help drive organizational change. Other examples include Novant Health and Carolinas HealthCare System, both of which are using the AHRQ Universal Precautions Toolkit and the CAHPS measures to try to assess health literacy at their organizations and make changes in their organizations to address it.

In conclusion, Rothman said that he and his colleagues found a robust array of measures that are now available that could be used or adapted for use by organizations. While many of these measures are meant to be completed by the organizations, he said his personal belief is that the measures that try to address organizational health literacy from all perspectives—the organization's, the provider's, and the patient's perspective—are going to be the most useful and the most robust measures. He also said that these measures can and should be used today for measurement, for accountability, and for quality improvement even though the current data on the validity and reliability of these tools is still somewhat limited.

Rothman also commented on the limitations of this study, noting that the team relied on identification of measures that were published or referred to them and on those written in English. He acknowledged, too, that it can be difficult to assign the individual measurement items to the specific attributes. He also cautioned against picking measures from different instruments or toolkits because that reduces validity. The ideal situation, he said, would be to have a unified adopted measure that was used by many different organizations at the same time and over time to look at what the variation is and how organizations are addressing health literacy, both in the United States and internationally. This ideal situation would also allow the tool to be validated in terms of how well it predicted health outcomes over time.

"I do feel we are at a crossroads here," said Rothman, "given the opportunities created by the Affordable Care Act's focus on population health, the wave of individuals getting insurance coverage for the first time, and the large and growing number of organizations and groups that understand the importance of patient-centered care and patient-centeredness." As a result, he added, there is a tremendous opportunity to push organizations to measure and address organizational health literacy, and he hoped the Roundtable can continue to lead that effort.

HEALTH LITERACY AND THE AFFORDABLE CARE ACT[4]

In this session's final presentation, Victor Wu focused on the impact of the ACA on vulnerable populations, particularly with regard to how the concept of health literacy is being brought to bear to address the demands and complexities of health insurance enrollment. The ACA, he noted, has transformed access to health insurance, which comes as no surprise given all of the attention devoted to trying to enroll individuals who had previously been locked out of the health insurance marketplace. As a result, the number of Americans without health insurance is now at a historic low (Sommers et al., 2014). Some 8.5 million new individuals accessed and purchased health insurance through federal and state insurance exchanges, and there are another 5 million or so enrollees in Medicaid and the Children's Health Insurance Program.

Wu explained that vulnerable populations are overrepresented among the newly enrolled, just as they were disproportionately represented in the uninsured population. After the first open enrollment period, two out of three of the newly insured who enrolled through the marketplaces reported that they had difficulty understanding terms such as provider network, deductible, and premium. He added that of those who bought insurance through the marketplaces, 6 of 10 were previously uninsured and 8 of 10 were eligible for tax credits.

To better understand the challenges facing these individuals, Wu and colleagues Ruth Parker and Kavita Patel interviewed organizations across the country at the local, state, and national levels who have had direct contact with new enrollees through assisters, navigators, certified application counselors, and others who work on the frontlines with those applying for health insurance for the first time. In particular, he and his collaborators have focused on identifying success strategies for hard-to-

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[4] This section is based on the presentation by Victor Wu, Evolent Health, and the statements are not endorsed or verified by the IOM.

reach or vulnerable populations as defined by the organizations themselves. These populations included, but were not limited to, those with limited English proficiency; African Americans, Hispanics, Asian Americans, and Pacific Islanders; immigrants; lesbian, gay, bisexual, transgender, and queer (LGBTQ) populations and homeless and run-away youth; and low-income populations.

Before discussing the strategies these organizations used to reach these vulnerable populations, Wu provided some anecdotal examples. For example, the best assisters for the LGBTQ community were, perhaps not surprisingly, individuals who identified as LGBTQ. Similarly, in some groups the head female in the household was the health decision maker, but that was not the case in the Asian American and Pacific Islander community. These organizations reported that there was no substitute for an in-person encounter with someone who spoke the potential enrollee's language. Some organizations also reported that having data about the communities they were trying to reach was key, and others noted that even after successfully signing up individuals and families for insurance they were contacted several times with questions on how to use it. Several organizations reported that their communities needed multiple "touches" before being ready to sign up for insurance.

Based on these interviews, Wu said that a new framework for thinking about health insurance enrollment is in order. Rather than dividing the process into two components of outreach and enrollment, there should be three components: outreach and education, sign-up, and then use. These three are interconnected and integrated in many ways, Wu explained (see Figure 4-6). The consumer needs to become comfortable with one component before moving to the next. Thinking about the enrollment process as an integrated system means that those who work in outreach need to think about how to get people ready for the next step, sign up, and similarly, those who help people actually fill out the enrollment forms need to get their clients ready to ask questions about how to use their new insurance, find a provider in their network, and use health services that will improve their health.

Underlying all three of these bins, Wu continued, are issues related to language and culture, and to the tone and attitude of those people in the health insurance system and health system with whom these new enrollees interact. These four underlying inputs drive the ways in which people navigate and go through what is broadly called health insurance enrollment. In addition, there are what Wu called inputs and activities, the organizations and people that interact with the uninsured and the plan of attack that they use to reach those individuals and bring them into the system. Finally, said Wu, a framework for health insurance enrollment should also include measurement and evaluation that provides helpful, meaningful, and actionable information to improve the entire enrollment process.

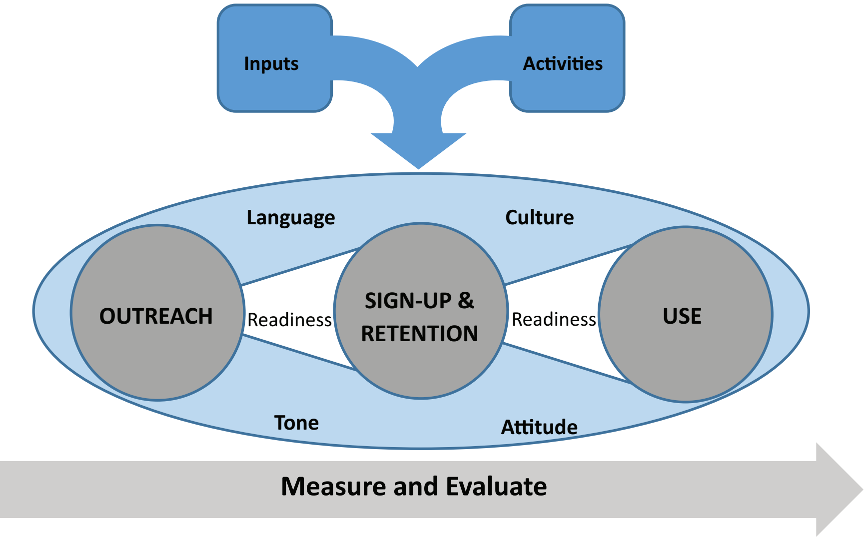

FIGURE 4-6 A model for engaging consumers in getting and using health insurance.
SOURCE: Parker et al., 2015.

One of the high-level strategies that came from the interviews is that three major components in this framework should be integrated into a mutually supportive, iterative process, Wu said. Oftentimes, individuals go back and forth between these bins at different points in the enrollment process until they reach a level of understanding that is meaningful and empowering. One of the strategies that organizations have taken in response to this type of learning behavior is to create opportunities for multiple touch points during the enrollment process, and to go along with that, they establish multiple convenient and consistent times and locations at which individuals can get help. Wu noted that it may take at least four interactions before an individual will sign up and think about using their health insurance, which makes it important for individuals to know where and when in their community they can interact with the enrollment process.

Wu said that another important lesson is that in-person assistance is essential for vulnerable populations. As Wu and colleagues learned from the interviews, those working in the field consider in-person assistance as the gold standard for helping individuals in vulnerable populations navigate through the three components of the enrollment process. Organizations also reported a need for a standardized process for information exchange among local partners and between state and federal officials to share best practices and to collaborate on solving problems that occur on the frontlines of the enrollment process.

The second high-level strategy that successful organizations use is to equip the assisters with information, training, and materials that will enable them to engage in conversations about the value of health insurance, the options available, how to use it, and what it will cost. Assisters need to be prepared to have difficult conversations with anyone who is looking for insurance access for the first time, but in particular those in vulnerable populations. "Comprehensive conversations regarding the cost and affordability of health insurance must be constructed and incorporated to help ensure successful signup and retention," said Wu, who explained that in practice this means equipping the navigators and assisters with the right material for the right consumer at the right encounter.

Diagnosing and filling knowledge gaps to help better approach and meet consumers where they are in terms of their level of understanding is, Wu said, essential. As an example, Wu said that many immigrants come from countries where there may be universal care or where there is no health insurance system at all. "Forget talking about how to use it, forget talking about premiums, and forget talking about deductibles. They are not even familiar with the concept of health insurance," said Wu. Along those lines, it can help to prepare understandable analogies and anecdotes that assisters can use to help explain complex concepts. Cost, for example, is an incredibly complicated and sensitive subject, and organizations that were successful in having conversations about cost found that anecdotes and analogies to which individuals could relate were vital to the process.

The third strategy identified during the interviews was to meet individuals where they live. "We learned that identifying data describing uninsured populations, preferably by zip code, and making those data available to assisters was one of the best strategies to find and target those individuals," said Wu. These geo-coded data also helped frontline workers have the right materials and information available for specific populations. One organization in Florida, for example, found that such data allowed it to target specific groups with materials that reflected culture, ethnicity, language, age, gender, literacy levels, and income.

The fourth strategy involves building trust and to do that by intentionally designing processes that will build trust with targeted populations and provide actionable steps for consumers. It was vital, Wu explained, to identify and use trusted community sources and "unofficial" trusted advisors in outreach efforts. One lesson learned from those working with immigrant populations is that individuals who spoke English well and had connections in the communities were viewed as trusted sources. Using them as extensions into the community and spreading information that was accurate were important factors in boosting enrollment in those communities. For many vulnerable populations, it was also important to choose physical locations that are neutral or trusted sites that help reduce the stigma associated with some terms being used to describe who was eligible for insurance for the first time under the ACA.

The final strategy is to create health-literate materials, which Wu said goes without saying, but is incredibly difficult to do in practice. He noted that while many tools are available for achieving this, there is a need to facilitate the development of culturally sensitive, accurately translated, and actionable health-literate materials for vulnerable populations. For example, there are so many translated documents available for Spanish-speaking individuals that they become confusing because they use different definitions for premiums and deductibles. Having action-oriented materials and checklists was also instrumental for helping people move through the stages of enrollment.

Concluding his presentation, Wu said the projections for 2015 estimate there will be 5 million new enrollees. "We are positive they are going to be even harder to reach," said Wu, noting that the projections suggest these individuals will have an even lower level of education, be concentrated within Spanish-speaking communities, and be geographically concentrated in the southern United States. Wu concluded by saying that, in addition to the outreach efforts that will be needed to reach these populations, it will also be important to retain those who were new enrollees in 2014 and to now provide those individuals with the health-literate materials and information they need to make the best use of their new insurance to benefit their health.

DISCUSSION

Session moderator Bernard Rosof started the discussion by agreeing with Isham that the National Quality Strategy, which encompasses the triple aim of providing better care, improving health care of the community and the population, and making care affordable, depends heavily on health literacy. He also agreed with Rothman that the measures his team identified will be helpful for driving the transformation of systems into health-literate systems, and he wondered if there are metrics to demonstrate whether organizations are improving in that regard and if they are identifying gaps where they can improve. He also wondered if that was something the Roundtable could discuss and catalyze. Rothman replied that the Roundtable should encourage and move forward with pushing for organizations to measure organizational health literacy and to do so in a way that helps organizations make these measurements in a robust way that optimizes the opportunity for evaluation. It would also be important to try to get multiple sites using the same metrics in order to have more power to look at the predictive utility of measuring and addressing health literacy.

Rothman also commented that one of the challenges in doing quality improvement is to not just rush in and start measuring things without a robust evaluation plan in mind, and that perhaps the Roundtable could help organizations think through what they should be measuring at baseline so they can conduct their quality improvement assessments with an improvement plan in mind. Ideally, he added, these measures will be linked to improved patient satisfaction, patient self-care behaviors, and patient health. "Ultimately, we need to make the link that addressing organizational health literacy does ultimately lead to improved patient health outcomes," said Rothman.

Isham remarked that the Vanderbilt group's work and the resulting paper has been helpful in describing where the field is with respect to measurement, and he agreed with Rothman that until there are organizations using a subset of these measures in a way that is consistent and that they can share with one another, the field will not quite be at the point to have broad-scale assessment of organizational health literacy. He noted, though, that many of the tools identified are labor-intensive to deploy within an organization, particularly if they are used repetitively to assess improvement efforts, and that work remains to enable organizations to deploy these measurement tools in a manner that will meet the needs of each specific organization. Reflecting this state of affairs is the fact that there are no measures that are ready for submission to the National Quality Forum or other regulatory or accountability organizations for broad use. "That doesn't mean we should be discouraged, just that we have a long way to go," said Isham.

The other point he raised was that the field needs to be aware that health literacy is an issue in different ways for different populations and different geographies. Although national survey data show how prevalent low health literacy is in the nation and how that is related to outcomes, those data need to be duplicated at local and organizational levels in order to get the attention of those who need to focus on health literacy where it intersects with real people. "Those components of measurement are critical to getting organizations to devote resources and actually improve the situation," said Isham. Paasche-Orlow added that these measurements will eventually have to be made at the individual level as well to really determine if these interventions are having an effect on the disparities that need addressing.

Catina O'Leary, president and chief executive officer of Health Literacy Missouri, asked Rothman for his thoughts about possible internal biases from asking people to evaluate themselves on measures that are sensitive and complicated. Rothman agreed with her concern about bias and said it is an important challenge with some of the organizational health literacy assessment tools that are available, which is why he believes that the tools that measure from multiple perspectives are likely to be more robust.

He acknowledged that there is subjectivity in many of the measures and that there has not been enough work done assessing the validity of those measures. Even when the measures try to be more objective there can be subjectivity, he said. For this example, the question "What percentage of your staff has received health literacy training?" may seem objective, but without a definition for what training is, one organization might consider 20 minutes of training as enough, while another would only consider staff trained with regular classes. Paasche-Orlow added that it is time to engage with an accrediting organization that can serve as outside eyes.

Rima Rudd, senior lecturer on health literacy, education, and policy at the Harvard School of Public Health, noted that many of her colleagues in Europe are moving from patients to consumers to communities in their deployment of measures of health literacy, and perhaps that is something the U.S. research community should consider. Isham remarked that the universal precaution strategy is one way, albeit a blunt one, to address that challenge, but that it can be used to tailor an approach to individuals based on health literacy skills. He also noted that information technologies will be a big help with moving from the individual to the community.

Rudd then brought up what she called the elephant in the room—the lack of assessments for health professionals. While there are fairly robust measures of patient skills or deficits and the link between those and outcomes, there is a need for measures of the communication skills of health professionals and their link to outcomes. "I would venture a guess that we cannot easily move ahead with assessments of institutions until we have those measures and the assessments of the professionals working within the institutions," said Rudd. Isham, Paasche-Orlow, and Rosof all agreed that this was an important point. Rothman said there has been some focus on the communication skills of the physician or key provider in the room, but little if anything has been done with the other members of the health team with whom the patient may interact. "We don't look at it from a full system level. We tend to get down to the one patient, one provider level," said Rothman.

Following up on the point about assessing the entire health care team, Betsy Humphreys said that it is more important to look at the team as a whole rather than ensuring that every member of the team has to be a great communicator.

Parker asked the panelists who they thought might be good partners for attribute 10, the issue of having transparency around cost or what might be considered as making the business case. Rothman said that the most obvious partner is government given that state and federal governments are major payers for health care. In particular, he said, Medicare has started to get involved in making cost transparent, but there is a huge need to improve the clarity of the message around some of these cost issues. He noted that there are private organizations that are moving into the cost space, including one company that he knows of that was founded around transparency of cost for laboratory tests for individuals.

HealthPartners, said Isham, "has been very active in terms of promoting measures of cost of care," and has developed a measure for total cost of care.[5] The reason why there are not many measures available goes beyond the area of health literacy, and there is resistance from a number of sources about making costs transparent. The attitude of many in health care is that the preferred state is one in which there is the freedom to deliver quality care regardless of cost. Because of political pressure, Isham added, the Patient-Centered Outcomes Research Institute is prohibited from looking at cost in its comparative effectiveness research. Some private organizations, such as the National Committee for Quality Assurance and the National Quality Forum, are starting to look at cost transparency and cost measures. There is an emerging appreciation for cost of services, not just performance, thanks to the ACA, Isham added. Rosof said his firm has been active in this space for some time and his opinion is that a public–private partnership would be an obvious approach to take. To the two organizations that Isham listed, he suggested The Brookings Institute or the Robert Wood Johnson Foundation as potential partners in such an effort.

Michael Villaire, CEO of the Institute for Healthcare Advancement, reiterated Wu's point that retention is just as important as enrollment. He added that his organization has developed some best practices that address retention. He also commented that there is an interesting aspect to the issue of informing people how to use their new health insurance, and that has to do with the behaviors that the chronically uninsured have developed and that may be barriers to getting the care they needed. These barriers may include failure to obtain preventive care, lack of a primary care physician, or use of the emergency room for routine care. By understanding these behaviors, it may make it easier to change those behaviors so that these individuals get better care now that they have insurance.

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[5] See http://www.healthpartners.com/tcoc (accessed May 11, 2015).

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Education

The workshop's third panel session included presentations by three speakers. Rima Rudd, senior lecturer on health literacy, education, and policy at the Harvard School of Public Health, provided an overview of where the field started and where it has progressed to in terms of education and health literacy. Barbara Schuster, Campus Dean, Georgia Regents University/University of Georgia Medical Partnership, addressed professional education, and Lindsey Robinson, a practicing dentist and trustee of the American Dental Association, discussed the role of education in oral health literacy. An open discussion moderated by Roundtable Chair George Isham followed.

OVERVIEW[1]

Rudd began her review by reminding the workshop about the clearly articulated recommendations that the IOM offered in the 2004 report *Health Literacy: A Prescription to End Confusion*. These included

- Recommendation 5-1: Accreditation requirements for all public and private educational institutions should require the implementation of the National Health Education Standards (NHES).

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[1] This section is based on the presentation by Rima Rudd, senior lecturer on health literacy, education, and policy at the Harvard School of Public Health, and the statements are not endorsed or verified by the IOM.

- Recommendation 5-2: Educators should take advantage of the opportunity provided by existing reading, writing, oral language skills, and mathematics curriculum to incorporate health-related tasks, materials, and examples into existing lesson plans.
- Recommendation 5-3: HRSA and CDC, in collaboration with the Department of Education (DOE), should fund demonstration projects in each state to attain the NHES and to meet basic literacy requirements as they apply to health literacy.
- Recommendation 5-4: DOE in association with HHS should convene task forces comprised of appropriate education, health, and public policy experts to delineate specific, feasible, and effective actions relevant agencies could take to improve health literacy through the nation's K-12 schools, 2- and 4-year colleges, and universities, and adult and vocational education.
- Recommendation 5-5: The National Science Foundation (NSF), DOE, and National Institute of Child Health and Human Development (NICHD) should fund research designed to assess the effectiveness of different models of combining health literacy with basic literacy and instruction. The interagency Education Research Initiative, should lead this effort.
- Recommendation 5-6: Professional schools and professional continuing education programs in health and related fields, including medicine, dentistry, pharmacy, social work, anthropology, nursing, public health, and journalism, should incorporate health literacy into their curricula and areas of competence.

Of these, only the second and sixth recommendations, to integrate health literacy with literacy skills and that professional schools incorporate health literacy into their curricula, have strong illustrative examples. One example of follow through on the second recommendation was then-Mayor Michael Bloomberg's Health Literacy initiative in New York City. The initiative started with a partnership between Harvard School of Public Health and the Literacy Assistance Center of New York City. Adult education teachers in each of the five boroughs were engaged in a series of half day meetings that enabled them to integrate health literacy skills into their adult education ABE (adult basic education), GED (general education development), and ESOL (English for speakers of other languages) classes. Rudd noted that the tools and materials her team developed were tested in New York and then widely disseminated throughout the United States. Examples of follow-through on the sixth recommendation include health literacy courses that were first developed at the Harvard School of Public Health, the Johns Hopkins School of Hygiene and Public Health, the University of Chicago Medical School, and the University of West Virginia Medical

School. Health Literacy classes and modules and are now increasingly being included in medical schools, dental schools, and pharmacy programs. Sadly, said Rudd, there are still a number of barriers to wider adoption of health literacy coursework, with the main one being the perception that there is no room in the curriculum to add another requirement. One comment she has heard has been that until competency in health literacy becomes a requirement for licensing, nothing much will get done.

In contrast, the non-formal health literacy education has flourished over the past decade, something that Rudd said was not in the IOM's thinking when it developed this recommendation. Nonetheless, health literacy courses are also being included in professional continuing education offerings and are being made available as part of online courses, toolkits, training programs, workshops, and conferences. There has been what she characterized as a wonderful diversity of examples in the non-formal sector, where community education projects were developed. Many of these projects have only appeared in the gray literature given the difficulties in publishing studies that do not have overt links to health outcomes.

Regarding the third recommendation about demonstration projects, she said that the vision turned out be much more expansive than what actually happened, for there was not a regular effort in every state. Neither was much done as far as the development of partnerships between funding agencies. "That is not to say that there have not been incredibly interesting and exploratory work and really wonderful demonstration projects, but they didn't have the impact on the national level that I think the recommendation was really trying to speak to, nor did the partnership work with the National Science Foundation," said Rudd, who added that this is still a worthwhile goal. Much remains to be done in integrating health literacy insights and findings into broad public health efforts. In some ways, she added, global climate change debates and the panic over Ebola represent failures in health literacy.

Rudd said that some may ask why progress has been so slow given that the argument supporting health literacy insights is sound. After all, she said, the links between literacy skills and health outcomes has been well-documented, as have the poor findings of U.S. adult literacy skills, the mismatch between the skills of individuals and the demands of health systems, and the implications of poor health literacy with regard to disparities in health and in care services. Some difficulty can be attributed, Rudd noted, to the evolving concept of health literacy (Chinn, 2011). While Howard Koh spoke about paradigm shifts, there is also a shift under way in our understanding of what constitutes health literacy, what it means, where the locus of responsibility lies, and how contextual issues will be brought into the equation, explained Rudd. It is only recently, she added, that the field broadened its vision of health literacy from its initial focus on the skills and deficits of patients to one that now includes attention to the skills of health professionals and the contextual factors of institutions in health care, public health, and social services. As many speakers at the workshop noted already, there is a new focus on institutions that includes not only their behaviors, but also the culture and norms that shape practice and policies. "It is only when we pay attention to all of these areas that we benefit the patient, the individual, and the community," said Rudd.

She then offered some theory-based analysis to explain why progress has been slow, turning first to Kurt Lewis's work on force field analysis. Force field analysis requires first analyzing the current situation before articulating a vision for change. The current situation in this case refers to the state of the field in 2002 to 2004 when the report was being assembled, and the articulation of change contained in the recommendations in that report. Force field analysis also requires carefully identifying the facilitating forces and the barriers to be removed before change is possible.

The context at the turn of the 21st century was one of excitement given the multiple DOE reports earmarking adult literacy starting in 1992; the *Healthy People 2010* health literacy objective that came out in 2000; the HHS health literacy action plan released in 2003; the 2002 NIH Conference on Education, Literacy, and Cognition; the NLM's preparation of annotated bibliographies on health literacy; The Education Testing Service's population-based Health Literacy Analysis published in 2004; the 2004 American Medical Association report *Understanding Health Literacy*; AHRQ's systematic review of the field in 2004; and the 2004 IOM report, among others. Rudd remarked that her European colleagues are amazed key players pushing the health literacy agenda were from government.

An important facilitating force for individual researchers at the time, Rudd said, was that it was a new field in which young researchers could make their mark. White papers, editorials, dedicated conferences, and workshops provided further incentives for researchers to join this nascent field. In addition, health literacy represented a malleable variable to address disparities and it held the promise for potential cost savings as well. There were also restraining forces, including the fact that health literacy challenged existing norms and common practices of already overburdened health care systems and was an implicit critique of the job that the health care community was doing. There was also little focus on efficacious action, that is, on understanding what to do differently or how to do it differently.

There were also constraining as well as restraining forces. There was a budget crisis then involving cuts and sequestration that included severe cuts to funding for adult education. Even well-designed and -tested health literacy educational programs for staff developed by CDC and the Veterans Health Administration, for example, were never fully deployed because of budget cuts. Social and political distractions were also operating over the past decade, including the passage and subsequent challenges to the ACA.

The strategic action that force field analysis calls for is not only to understand the current state in order to identify a strategy, but action to remove barriers. Rudd wondered if the field might have done better work if everyone had not been so focused on the facilitating factors and had paid more attention to the strategic action of identifying restraining forces.

Another theory that provides insight is Everett Rogers's articulation of Diffusion of Innovation. Diffusion, according to this theory, is the *process* by which an *innovation* is *communicated* through certain *channels* over *time* among *members* of a *social system*. Each of these key components (the processes, the innovation, the types of communication, the channels of communication, time, the various players, and the social system) has characteristics that can support or impede diffusion. A strategic action plan can focus on re-shaping some of the components to help with the spread of ideas and with the adoption process. When health literacy is analyzed as an innovation it offers implications for practice, institutional change, and modification for the way health materials are developed. Analyzing an innovation entails paying attention to relative advantages, compatibility with existing systems and ideas, and its trialability, complexity, and observability. The relative advantages are mixed, she noted, particularly because health literacy can seem bothersome and costly in the short run. "Perhaps we could have paid more attention to some of those difficult elements and changed our approach a bit," said Rudd.

Communication channels have been extraordinarily challenging, she continued. The myriad journals that speak to specific audiences require that the message about the value and importance of health literacy be repeated over and over again in multiple journals, at multiple conferences, and to multiple professional groups. Addressing the vast number of audiences in the health field has been exhausting, said Rudd. She also said that while everyone in the health literacy field feels the urgency of their mission, patience is important for the time it takes for knowledge to spread, for persuasion to take place, and for decision making and action to follow. In many instances, the field is still at the persuasion stage. Furthermore, the social systems involved are just now being addressed as researchers begin looking at the characteristics of institutions in both healthcare and public health.

Rudd said one challenge was that the field in the early days was populated largely by young researchers who did not yet have the gravitas that would get others to listen to them. "Things have changed over time and we have more gravitas to us," said Rudd. The social systems involved are just now being addressed as researchers begin looking at the characteristics of institutions in both health care and public health.

The lessons from diffusion of innovation theory come from analyzing the decision process and the consequences of those decisions. This analysis requires examining carefully the key elements of the innovation and perhaps considering the reinvention and malleability of health literacy to adapt approaches that best fit the core needs of the members of health care and public health systems. "That may be why we didn't resonate with education—a field overburdened by its own set of changes and challenges," said Rudd. For future planning and strategic action, Rudd contended that conducting a diffusion analysis and force field analysis will help the field move ahead with greater precision. "That's not to say that we should not celebrate today for indeed we should celebrate the accomplishments in health literacy education," said Rudd, and the field should certainly celebrate the fact that government agencies and institutions have been incredibly supportive of these efforts. In closing, she noted that the rich array of educational resources and programs that have long been available and are still available for free online, both for health professionals and for institutions to adapt and adopt, thanks to the hardworking people in our government institutions.

HEALTH LITERACY IN PROFESSIONAL EDUCATION[2]

Barbara Schuster began her presentation by reviewing the educational requirements for various health care fields. For medical education, two bodies are involved. The Liaison Committee for Medical Education (LCME) is the accrediting body for allopathic medical schools, which have increased in number over the past decade to 140 schools. LCME's Standard 7.8, Communication Skills, calls for the faculty of a medical school to ensure that the medical curriculum includes specific instruction in communication skills as they relate to communication with patients and their families, colleagues, and other health professionals. She also noted the role of the Accreditation Council for Graduate Medical Education (ACGME), which oversees the allopathic residencies, postgraduate medical education that is required for licensure and specialty certification in the United States. Schuster noted as an aside that by 2020, all osteopathic residencies will also fall under the same jurisdiction. ACGME has six core competencies it requires in graduate medical education and one of them calls for competency in interpersonal and communication skills "that result in effective information exchange and teaming with patients, their families, and other health professionals." ACGME core program requirements also state that "the

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[2] This section is based on the presentation by Barbara Schuster, Campus Dean, Georgia Regents University/University of Georgia Medical Partnership, and the statements are not endorsed or verified by the IOM.

residents are expected to communicate effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds, and to communicate with physicians, other health professionals, and health-related agencies."

There are also communication requirements in pharmacy education. The Accreditation Council for Pharmacy Education Standard 3, Approach to Practice and Care, states that pharmacy programs "must impart to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to solve problems; educate, advocate, and collaborate, working with a broad range of people; recognize social determinants of health; and effectively communicate verbally and non-verbally." Looking at the standards, there is good overlap between what is required in the education of physicians and pharmacists, said Schuster.

The American Association of Colleges of Nursing's Essential Number 7, Clinical Prevention and Population Health, states that "health promotion and disease prevention at the individual and population level are necessary to improve population health and are important components of baccalaureate generalist nursing practice." Sample content could include health literacy. It is not a required component, but nonetheless at least health literacy is mentioned specifically, said Schuster.

Examining these accreditation standards offers several take-away lessons, she said. Each of the accreditation systems lays out the competencies and requirements for educating professionals in their respective fields, but each individual school writes its own competencies and curriculum. The schools then have to demonstrate to the accrediting bodies that their curriculum meets the standards and their stated competencies. "That means that if I want to make health literacy a requirement, I need to write a learning objective in my curriculum, which is going to answer a competency for the school that then answers a standard for the accrediting body," explained Schuster. "You can see how in the national standards, health literacy is almost never actually specifically stated as a requirement or standard."

Nonetheless, the general expectation is that students are taught about health literacy in some form, and most schools would say that they do teach health literacy. Schuster said that she was fortunate when she came to Georgia to start the Athens medical campus, a partnership between the Medical College of Georgia at Georgia Regents University and the University of Georgia (GRU/UGA) because one of the young faculty members was one of Ruth Parker's disciples and had learned the skills needed to conduct health literacy training while an internal medicine resident at Emory. This faculty member does not teach a formal course because Schuster's campus does not offer courses in any subject, but rather has an integrated, facilitated case-based and skills-building curriculum that also includes community outreach and working with community agencies. Core skills building in communication and physical examination is a critical component in this curriculum, and health literacy is an explicit part of this curriculum, which Schuster illustrated by listing the following learning objectives for first year medical students:

- Describe the extent of low health literacy and numeracy in the United States.
- Identify possible outcomes when patients misunderstand issues in clinical care settings.
- Describe ways to present health information to patients to help overcome misunderstandings due to low health literacy and numeracy skills without appearing condescending.
- Practice plain language and the "teach-back" method.
- Evaluate patient handout materials and make suggestions on how to improve them for low health literacy patients.
- Given a case scenario, recognize clues that might suggest a patient has low health literacy and/or numeracy skills.
- Given a case scenario, identify possible misunderstandings that may arise due to low health literacy and numeracy skills.

Not only do the students have to describe what health literacy and numeracy are, but they have to practice how to deliver concepts such as percentages and percentiles and to use teach-back methods that stress plain language. Everything the students write for patients, particularly during their projects in community health, is judged in part on their health literacy. All of their communications with volunteers who serve as "patients" are also judged on clarity and health literacy using a communication assessment tool (see Figure 5-1). For example, assessment item number six asks if the student uses language that patients can understand, and asks what behaviors the student exhibited, such as "uses some language that would be unclear to most patients," "uses some language that may be unclear to many patients," "consistently uses plain language," and "consistently uses plain language and checks understanding as needed." This assessment tool, she noted, continues to emphasizes good communication skills throughout the examination process.

Schuster said that once students leave their educational programs, it is important to continue stressing health literacy, and to illustrate her concerns she spoke about how the American College of Physicians (ACP) Foundation has changed. The ACP Foundation chose health communication as a major program area thanks to the role that Parker played in the formation of the Foundation, and as a result, health literacy was at the core of the Foundation's mission. The ACP Foundation, in fact, helped facilitate some of the IOM's early workshops on health literacy and supported the development

DOMAIN		BEHAVIORS				N/A
1	Allows patient to tell story without unnecessary interruption	Stops open-ended questioning very early OR Frequently interrupts	Stops open-ended questioning prematurely OR Noticeable interruption	Allows adequate open-ended questioning; Minimal interruption	Cultivates complete patient statement through open-ended questioning; No unnecessary interruption	
2	Questions demonstrate listening and attentiveness	Many questions are inappropriately repetitive or ignore interview context	Some questions are inappropriately repetitive or ignore interview context	Questions are not inappropriately repetitive, generally fit interview context	Questions are not inappropriately repetitive, reflect insightful response to context of interview	
3	Facilitates patient expression as appropriate	No or inappropriate: prompting of patient OR attempts to guide interview	Ineffective: prompting of patient OR attempts to guide interview	Effective: prompting of patient OR attempts to guide interview	Tailored, calibrated: prompting of patient OR attempts to guide interview	
4	Treats patient with respect	One or more responses would appear disrespectful to most patients	One or more responses could be interpreted as disrespectful	Consistently shows respect for patient	Clearly displays a high level of respect OR dealt respectfully with difficult subject	
5	Explores patient's perspective of health concern	No or minimal effort at understanding patient's perspective	Asks few or superficial questions about patient's perspective	Adequately explores patient's perspective	Develops full understanding of patient's perspective	
6	Uses language patients can understand	Uses some language which would be unclear to most patients	Uses some language which may be unclear to many patients	Consistently uses plain language	Consistently uses plain language, checks understanding as needed	
7	Student non-verbals communicate respect & interest	Some non-verbals communicate disinterest or disrespect	Some non-verbals could be interpreted as disinterest or disrespect	Non-verbals communicate respect/interest	Non-verbals communicate respect/interest, are adapted to specific moments of interview	

FIGURE 5-1 The Communications Assessment Tool used by the GRU/UGA Medical Partnership.
SOURCE: Schuster, 2014.

of some of the research papers that have helped move the field forward. In 2012, the ACP decided the Foundation would no longer be involved in health literacy, raising the question of who would champion health literacy going forward.

Schuster recounted how in 1975, when she was a third year medical student at the University of Rochester, Dr. John Romano, the chair of the psychiatry department would take every student to the state psychiatric hospital, where he interviewed patients in a very traditional manner. She remembered Romano saying to her and the rest of the students that the reason he took them to the state hospital was that they needed to learn as physicians how to communicate with everyone, from the farmer that grows corn to the engineer who thinks in a black box. "That was very powerful as I sat there and watched this incredible person," said Schuster.

She concluded her comments by noting that one of the big challenges that professional schools face is that they do not have faculty who have the background and skills to teach students about health literacy and to continually stress the need to communicate effectively and clearly to patients and their families. She told the story of a resident she once supervised who complained about a mother who repeatedly brought her child for care to the resident practice with an unresolved chief complaint. Schuster asked the resident to explain why. The resident responded said that he was writing out the instructions for the mother and that the instructions should have been clear. However, the resident had neglected to find out if the mother could read, which turned out to be the reason for the lack of communication and repeated clinic visits. "We need more faculty in nursing, pharmacy, and medicine who can teach these skills," said Schuster. She also commented on the confusion that exists given that the regulations now talk about cultural competency, the use of translators, and communications as a whole, but not about the fine skills that the Roundtable has identified that are specific to health literacy.

There are opportunities. State organizations are now focusing on health literacy, as are interdisciplinary groups, which is important given that professional education is becoming increasingly interdisciplinary. As a last point, she returned to the question of who will champion health literacy. She asked in closing, "Will health literacy go the way of the bio-psychosocial model or evidence-based medicine, or will it become so enmeshed in professional education that there will be no further need for champions?"

EDUCATION IN ORAL HEALTH LITERACY[3]

It is the responsibility of the dental profession and its professional organizations to play a leading role in educating dentists and dental team members—hygienists and dental assistants—on the importance of oral health literacy, said Lindsey Robinson. The vision of the American Dental Association (ADA), she explained, is to be the recognized leader on oral health, and the mission of the California Dental Association (CDA) is a commitment to the success of its members in service to their patients and the public and to improve the health of all Californians by supporting the dental profession in its efforts to meet community needs, she explained.

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[3] This section is based on the presentation by Lindsey Robinson, a practicing dentist and Trustee of the American Dental Association, and the statements are not endorsed or verified by the IOM.

In 2000, the Surgeon General issued a report that put oral health on the map in terms of its importance to overall health and well-being (HHS, 2000). This report highlighted research findings that pointed to the possible associations between periodontal or gum disease, and diabetes, heart and lung diseases, stroke, low birth weight babies, and premature births, and it pointed out that dental caries is the single most common chronic disease of childhood, five times more common than asthma. This report was followed by the 2003 National Call to Action to Promote Oral Health, also from the Surgeon General's Office (HHS, 2003), that stressed the importance of public–private collaboration, and a National Institute of Dental and Craniofacial Research report on oral health literacy released in 2004 (HHS, 2005). Research on oral health literacy also began appearing in the literature, particularly from groups headed by Jessica Lee and Gary Rozier at the University of North Carolina (Lee et al., 2013) and Alice Horowitz at the University of Maryland (Horowitz and Kleinman, 2008; Rozier et al., 2011). Since 2001, health literacy has been included in the annual sessions of most major dental organizations and government-sponsored meetings, Robinson added.

Other important developments raising the profile of oral health literacy included the adoption of a definition for health literacy in dentistry and a policy statement affirming its importance by the ADA House of Delegates in 2006, ADA's establishment of a National Oral Health Advisory Committee in 2007, and the release of a Health Literacy in Dentistry Action Plan for 2010-2015. In 2009, ADA conducted the first surveys among U.S. dentists, dental hygienists, and dental assistants to assess the state of oral health literacy among dental professionals. That survey concluded that

- The number of communication techniques used routinely varies greatly among dentists;
- There was low use of techniques most commonly recommended by health literacy experts—only 20 percent of dentists used teach-back, for example;
- Routine use of health literacy techniques was similar to that of physicians, nurses, and pharmacists; and
- Of those who responded to the survey, 73.3 percent had never had a course in health communication, and 68.5 percent indicated interest in taking such a course.

CDA was also an important leader in the effort to raise awareness about oral health literacy, particularly through the April 2012 issue of the *Journal of the California Dental Association* that featured oral health literacy. Going through the table of contents of the April 2012 issue of the *Journal of the California Dental Association*, Robinson noted that the issue included the ADA National Action Plan to Improve Health Literacy in Dentistry (Podschun, 2012), three papers from the Horowitz group at the University of Maryland (Braun et al., 2012; Horowitz and Kleinman, 2012; Maybury et al., 2012), a paper calling for a multicultural paradigm shift in oral health care focusing on oral health literacy to address the demographic changes occurring in California (Centore, 2012), and a practical example of incorporating oral health literacy messages in community health efforts among a migrant farm community in Illinois (Bauer, 2012). One of the articles from the Maryland group showed that if dentists and hygienists do not understand the importance of early cancer prevention and do not know how to conduct an appropriate oral cancer exam, "the public is going to be in really bad shape," said Robinson.

Another CDA initiative was the First Smiles program, which she explained was a $7 million program funded by the Tobacco Tax that was designed as an education and training program for dental and medical professionals on early detection and prevention of childhood caries. The materials developed for this program were translated into 10 languages for professionals to help them understand how to use preventive strategies, such as floride varnish, in a clinical setting.

Robinson noted that in 2007, CDA had released a consensus statement, Caries Management by Risk Assessment (CAMBRA), which explicitly included oral health literacy and tools for improving oral health (Young et al., 2007). The CAMBRA movement, in which CDA has been heavily involved Robinson said, is a paradigm shift in dentistry with the goal of moving the treatment of dental caries from a surgical, restorative model to a chronic disease management model. To further this paradigm shift, CDA has developed health-literate tools and resources that are available on its website.

In 2010, the CDA Foundation collaborated with the American College of Obstetricians and Gynecologists, District IX, to issue the report *Oral Health During Pregnancy and Early Childhood: Evidence-based Guidelines for Health Professionals*. The report was the product of an expert panel that concluded that prevention, diagnosis and treatment of oral diseases is beneficial and safe during pregnancy. It established clinical guidelines for dental health professionals on treating pregnant women. "The goal was to make dental professionals understand that it was safe and it was their responsibility to treat pregnant women," said Robinson. "It is amazing how many dentists still are very uncomfortable treating pregnant women." A further goal was to encourage prenatal care providers to integrate oral health into the care of pregnant patients to optimize the oral health of both mother and baby.

CDA's efforts now include funding a seat on the IOM's Roundtable on Health Literacy. Robinson was also a co-author of a Roundtable discussion paper on the use of the after visit summary in dentistry (Horowitz et al., 2014b). This paper makes the argument that the after visit summary is a powerful tool to assist in a patient's self-management that could be used in dentistry and especially in an integrated health care environment where dentistry and medicine are practiced under one roof or closely associated with each other. Federally qualified health centers would be a good environment in which to promote health literacy and oral health literacy using the after visit summary as a resource in primary care, she said.

Robinson noted the importance of the Maryland Health Literacy Model that is centered on the prevention and early detection of dental caries. This model is meant to address the challenge of the mismatch between the demands of the health care system and the skills of those using the system and working within the health care system with the specific focus on the prevention of cavities in children, she explained. The goals of this effort include

- Establish local or state needs;
- Determine what the public knows and does regarding caries prevention and early detection;
- Determine public's perceptions of provider communication skills;
- Determine what public agencies such as Head Start and Women, Infants, and Children know and do regarding caries prevention and early detection;
- Determine what health providers know and practice regarding caries prevention/early detection;
- Determine communication techniques of health care providers; and
- Conduct environmental scans of dental facilities.

Research shows that the general public, at least in Maryland, does not understand how to prevent tooth decay, does not know what fluoride is and what it does with regard to prevention, or what sealants are and their uses. Often, members of the public do not drink tap water, which Robinson said was unfortunate because it is an inexpensive and cost-effective method proven to reduce or even eliminate tooth decay (Horowitz et al., 2013b). Surveys of health providers were concerning given that many health providers, including dentists and dental hygienists, do not have a good understanding of decay prevention. Many do not provide dental sealants in their practice, and most did not use recommended communication techniques (Horowitz et al., 2013a; Maybury et al., 2013). Based on these findings, the Maryland group has published recommendations for steps that dental professionals can use to improve communication with patients (Horowitz et al., 2014a).

Robinson then turned to ADA's current efforts to improve oral health literacy. In 2014 the organization sent two staff members to the Institute for Healthcare Advancement (IHA) Annual Meeting to learn the basic principles of oral health literacy. As a result of this experience, ADA is in the process of revising all of its patient education materials to conform to health literacy principles, and ADA's Council on Access Prevention and Interprofessional Relations is providing content expertise for all IHA publications. In the week prior to this workshop, ADA convened a continuing education course called *Health Literacy: Foundation of Patient Understanding* and the organization has also reconvened the National Advisory Committee on Health Literacy and Dentistry. ADA will also take over funding of the Oral Health seat on the IOM Roundtable on Health Literacy and the organization is reviewing all of its policies to see if they can be updated to promote the use of health literacy principles.

Going forward, ADA is positioned to be the leader on health literacy in dentistry and is committed to continuing its support for the National Advisory Committee. The ADA Executive Director has also announced that the organization will work to adopt the 10 Attributes of a Health Literate Organization. In keeping with that announcement, ADA is implementing programs to educate its members about health literacy principles and is exploring opportunities to collaborate and support other organizations with the same goals of furthering health literacy in dentistry. As an example of how ADA is working to adopt the 10 Attributes, Robinson mentioned its effort with regard to Attribute Three: Prepares the workforce to be health literate and monitors progress. ADA is asking the Committee on Dental Accreditation to consider having health literacy included within the sections of the relevant standards for accrediting predoctoral dental education programs as a first step and will also explore including health literacy in actual standards.

CDA, meanwhile, will be working with the new California state dental director to incorporate health literacy principles within the work of state government and its programs aimed at improving the public's oral health. Robinson noted, too, that the Maryland and North Carolina research groups are still actively researching issues related to health literacy in dentistry. The bottom line, said Robinson in closing, is that health literacy is inextricably linked to improving oral health, especially among low-income groups. "Each of us has a role, opportunity and responsibility to improve oral health literacy of patients, providers, and the public," she said.

DISCUSSION

Cindy Brach, senior health policy researcher for AHRQ, began the discussion by asking Schuster if there was some role for continuing education programs to help professional school faculty become aware and supportive of the need for health literacy in medical professional education. She also asked if the development of curricula modules that schools could adopt would be helpful given the findings that health professional school deans strongly support the health literacy movement and are trying to incorporate the subject in their curricula. Schuster responded that one challenge is to first determine what the competencies are that health professionals need to develop, and then modules might help. However, she noted that asking a student to complete a module, particularly online, does not lead to long-term retention and behavior change. What is needed is for instructors who are watching students as they interact with patients to actively review the students' interactions and continually remind them about the importance of clear and effective communication. Brach agreed with Schuster's critique of modules and explained that she was thinking more about exercises or assessments that faculty could use with students. Schuster replied that it is always good to have tools that faculty can use to assess their students' actions. The most important step, though, is to include health literacy as a required competency. "If it doesn't become a competency for their program then it doesn't get counted and it doesn't get done," she said, noting that it is the responsibility of the faculty to write those competencies. She also added that her approach of integrating health literacy into other activities is to make them seem like they are not an add-on, but a natural part of what a student has to learn to be a competent health professional.

Following up on this idea, George Isham asked about the difficulty of including a health literacy standard into health professional education and if there might be some way for all health professions to work together to present a common front. Schuster replied that one approach might be for medical schools, pharmacy schools, nursing schools, dental schools, and others to work together as part of the intraprofessional education mandates that are common today.

Lori Hall, consultant on health education at the Lilly Corporate Center, asked Robinson if ADA had considered changing the term "oral health literacy" to "dental health literacy" to eliminate the confusion as to whether the reference is to health literacy as it applies to the mouth or to spoken communication. In fact, said Robinson, the ADA advisory committee just changed its name to the National Advisory Committee on Health Literacy in Dentistry, and she agreed that a change in terms might resonate better and make it more encompassing. "Dentists want to be thought of within the spectrum of health literacy and not standing by ourselves siloed as oral health literacy," said Robinson. Steven Rush, director of the Health Literacy Innovations Program at UnitedHealth Group, agreed with Hall's suggestion concerning renaming oral health literacy. He also expressed his thanks to Rudd for providing several frameworks for creating a business case that he could take to his organization.

Wilma Alvarado-Little, director of the Community Engagement/Outreach Center for the Elimination of Minority Health Disparities at the

University of Albany, asked how a patient would know if a resident had completed the ACGME Core Program requirements for health literacy. Schuster said that the patient's point of view is that the patient goes home knowing and having communicated with that care provider or that physician or resident in the room. "They feel good in that they have had their opportunity to ask the questions that they needed to ask," Schuster said, adding that the unfortunate part is that the patient often does not know or say what they did not understand. "They are confused and go home not knowing it." The challenge, she said, is to get health care professionals to a place where they not only communicate clearly, but can also pick up on the non-verbal cues to know when their patients are not understanding something, and that goes back to teaching basic communication skills and then learning other skills such as teach-back that allow the young health professional to find out that they have not been communicating clearly. Schuster noted that teaching students and residents how to use a translator is important because doing so stresses the importance of communicating clearly and using health literacy skills.

Sabrina Kurtz-Rossi, assistant professor of public health and community medicine and director of the Health Literacy Leadership Institute at Tufts University School of Medicine, said that she teaches an interprofessional course to dental, nutrition, and pre-med students and asked if all of the health professions have written health literacy standards and if these are getting incorporated into the various health professional schools. Schuster and Robinson both noted that getting standards written and incorporated into curricula takes champions with enough gravitas to get difficult and complex work done. Rima Rudd remarked that it might be possible to establish a dialog among the health professions to get one or two competencies as a starting point with which every professional organization would abide. One place to start, she offered, would be the use of plain language followed by teach-back.

Isham commented that the continued professionalization in health care and the resulting fragmentation of training and self-organization of professions in different silos has created a problem around consistency, particularly when those professionals then need to work together as part of a health care team. It also creates an opportunity, though, for those organizations to make demands of what they need in terms of prepared professionals.

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Looking to the Future

Instead of using formal presentations, the workshop's fourth panel session featured a moderated discussion about the future of health literacy. Terry Davis, professor of medicine and pediatrics at Louisiana State University Health Sciences Center in Shreveport, moderated the session. The four panelists were Betsy Humphreys, deputy director of NLM; Winston Wong, medical director for Community Benefit and director of Disparities Improvement and Quality Initiatives at Kaiser Permanente; Steven Teutsch, adjunct professor at the Fielding School of Public Health at the University of California, Los Angeles; and Michael Wolf, professor of medicine and learning sciences at the Feinberg School of Medicine at Northwestern University.

THE ROLE OF TECHNOLOGY IN HEALTH LITERACY[1]

Davis started the discussion by asking Betsy Humphreys about the role that technology might play in health literacy over the next decade, and her response was that technology, if done correctly with input from users, could make a significant impact on the integration of health literacy into all of health care by making the job of being a patient easier. In her opinion, despite the dozens of health literacy–related apps that are now available for mobile devices, none of them have yet reached the level of sophistication or utility that would make them must-have apps. Humphreys noted,

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[1] This section is based on the comments of Betsy Humphreys, deputy director of the National Library of Medicine, and the statements are not endorsed or verified by the IOM.

though, that technology could be a game changer as far as getting more health care professionals and patients onboard with health literacy simply by being something new and interesting that people want to play with and test themselves.

Humphreys also noted that NLM does fund a small number of health literacy projects, and that other NIH Institutes, such as the National Cancer Institute, have done a great deal with regard to creating health-literate information for patients and developing novel ways of getting such information into the hands of patients and families. One of the things that NLM and other NIH Institutes have done well is to engage end users in the development and testing of new technologies for interacting with patients. For example, NLM funded a study in which the researchers asked the elderly about health alert devices. Most seniors, it turns out, do not like these devices because it makes them feel and look like an old, sick person. What they want instead is a watch, something that does not send the signal "I'm old and feeble," yet can place emergency calls with the push of a button. Davis asked if the private sector will be the source and driver of such innovations. Humphreys replied that the private and public sectors both have a role to play in technology development. She added that NIH is focusing small-business research funds in this area.

Davis then asked Humphreys about the role that social media and blogs can play in health literacy, to which Humphreys replied that the public already uses social media to get information they think they understand on medical issues, and that agencies such as CDC, NIH, and NLM are already creating information for social media platforms, which Humphreys characterized as a good development. The problem with social media, for all of the good that it can do, is that "there's nothing to prevent anyone who uses social media from saying whatever they want about whatever health information or misinformation they have," she said. Given the reach of social media, incorrect information—the misinformation about the link between autism and vaccines, for example—can spread in a broader manner that is more difficult to control and correct once it has made it into the realm of social knowledge. The only way to counter this type of misinformation is to make sure that the public agencies and foundations that produce high-quality health information for the public do so from the start in a way that is interesting, engaging, understandable, and accessible, or as she put it, "to make it easier to find the good stuff than it is the bad stuff."

Going forward, NLM's main role in health literacy will be to organize all of the great information that is coming out at the appropriate literacy level and to help make it available in multimedia formats that communicate in ways that the written word cannot. Another role will be to make research available on what works and what does not in terms of technologies for disseminating health information and to do so not just for the public, but for the professional community as well. In general, NLM will not be translating materials—there are organizations that do this well already—but will focus on organizing it, collecting it, and making it easily accessible to all audiences, not just the technologically savvy.

Davis asked Humphreys if she thought print medical journals would still be available in 2024, to which Humphreys replied that she does not think those would still exist in 2024. What will develop, though, are more avenues for personal interactions with vulnerable populations to help them understand health information, and that this is a role in which libraries excel today. Libraries and librarians have very good reputations among the general public as trusted, unbiased sources of information. A library is seen as a clean, safe place to take children and a librarian is seen as someone who is going to be friendly, not someone who will be condescending or dismissive of questions. "I think that the library community is a great partner resource for literacy in general, but definitely for health literacy," said Humphreys. She added that she envisions that libraries in 2024 will not be much different than they are today—they will be pleasant, centrally located in every community, and staffed by friendly, knowledgeable persons who are ready to help the public find useful information. "Talking to a helpful person is not going to go out of style," she predicted.

HEALTH LITERACY AND POPULATION AND PUBLIC HEALTH[2]

Next, Davis asked Steven Teutsch to comment on the connection between health literacy and effective population health interventions and their need for public support to be most effective. Because social determinants account for about 40 percent of the health problems facing Americans, with health behaviors accounting for another 30 percent and the physical environment an additional 10 percent, we need to deal with those non-clinical factors to have a substantial impact on the nation's health. To do that the public first needs to understand the importance of these non-clinical factors, and this is particularly true among the most disadvantaged people, the ones who are suffering the greatest health disparities today. Getting people to change their lifestyles and getting governments and other organizations to develop policies that support those changes is going to take social and political will, Teutsch said, and that takes understanding of what the nature of those problems is and what the potential solutions are.

Population health has adopted the health in all policies mantra to make sure that the nation develops interventions in all areas that support health,

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[2] This section is based on the comments of Steven Teutsch, adjunct professor at the Fielding School of Public Health at the University of California, Los Angeles, and the statements are not endorsed or verified by the IOM.

whether it be for transportations systems, street design, or criminal justice. "Political leaders will benefit by engaging with the health sector so that the health implications are on the table and in their thoughts when they make decisions. We have tools such as health impact assessments that can further those discussions," said Teutsch. He added that while health impact assessments are not often seen as health literacy tools, they actually are because they can help people understand the problem and the health implications and understand how decisions about adopting a policy or modifying a program can maximize health benefits or minimize the harms.

When asked if he sees the process starting locally or if it will take a national agenda, Teutsch said it will take action at all levels. Problems are usually spotted at the community level, where information must be available to help catalyze action. At the same time, state and federal policies can have a huge effect in supporting or hindering local action and so again, information for policy makers must be available to help them make decisions that support public health goals. For example, Los Angeles has relatively few parks, so local communities are agitating for school playgrounds to remain open after school hours so that children have a safe place to play and where community members can get together and meet. How that gets done is a local issue. At the other end of the spectrum, federal agriculture policies and subsidies affect the availability of healthy food in communities and schools.

Teutsch noted that messages about the benefits of public health interventions do not need to reach everyone, but they do need to reach thought leaders who can drive change and mobilize communities to take action to benefit the health of their residents. Just as it is necessary to use health literacy to empower individuals to take responsibility for their own health, it is also important to use public health literacy to engage communities in the effort to improve public health.

Davis then asked Teutsch about the importance of trust when it comes to public health information, particularly with regard to vaccination. He explained that in California, parents can opt out of having their children vaccinated based on personal beliefs, and the problem is that too many personal beliefs about vaccination are formed based on misinformation being promulgated by blogs and celebrities that some members of the public consider more credible than health care and public health professionals. This problem is compounded by the fact that too many public officials have just as low a level of scientific and health literacy and do not have the kind of competence needed to address unreasonable fears, whether it is about vaccines or Ebola, or to promote preventive health measures such as vaccinations and cancer screenings.

In terms of addressing social determinants of health and the other nonclinical factors that influence health, improving the health literacy of individuals will help, but the focus should not be limited to individuals, Teutsch said. "We need to create the environments that make the healthy choice the easy choice, so that it is as easy to walk to work or use public transportation as it is to hop in the car and drive," he said as an example. Making the healthy choice has to become a natural part of daily life, and that becomes easier when the physical environment and the messages consumers receive support a healthy lifestyle. Toward that end, Teutsch is encouraged by the newfound focus of health systems on public health and their growing appreciation of the fact reimbursements are going to be determined in part by the health of their communities, not just the patients they happen to treat. Davis agreed that a tipping point in that regard may be at hand and that those attending and participating in this work are in a position to help get the nation on the other side of that tipping point.

RESEARCH ON HEALTH LITERACY[3]

Turning to the matter of health literacy research, Davis asked Michael Wolf if he believed, as she does, that the field may have lost its creative spark and is too focused on securing research funding rather than on thinking about problems and meaningful ways to address them. He said he appreciates the feeling that there's a bit of stagnation in health literacy research today, and he agreed there is a very challenging environment regarding research funding. There is also the challenge of deciding between what the field knows how to do and what is reasonable given the huge culture change that is needed to embrace all of the activities that health literacy research has shown are effective at improving communication between consumers and the health care system. What is needed, he said, is to figure out a better way to inform the health care community and funding agencies about the benefits of health literacy and to think about what the research community wants from existing funding programs.

As an example of the latter, the first program announcement from NIH about health literacy came out in 2004, and that program is still in place. When it was created, it had associated with it a special emphasis panel to protect funding and to create a consolidated agenda, and Wolf applauded those involved for making that happen and for bringing the field to where it is today. "The problem has been that we have lost steam," said Wolf, and he recounted being asked by a program officer attached to a specific NIH Institute to provide more information about what he was doing because many people in his Institute did not see the value of health literacy. Such

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[3] This section is based on the comments of Michael Wolf, professor of medicine and learning sciences at the Feinberg School of Medicine, and the statements are not endorsed or verified by the IOM.

an attitude in NIH has left him skeptical, confused, and concerned about the future of this program.

Wolf said he views the world of health literacy as a core piece that fits into many other areas of research, much like Russian nesting dolls. Health literacy research sits within health care equity and disparities, but it is also a component of safety, and issues around aging or special populations. The challenge, then, is to see how health literacy can fit into these other agendas. In reaction to that comment, Davis asked Wolf if he thought health literacy would still exist as a distinct field of research in 2024. Wolf said he believes that for the next 3 to 4 years, health literacy will continue to be myopically focused on how it is associated with one condition or another. One benefit from this is that an increasing number of studies and grants that he reviews, whether they come from a health literacy researcher or not, include health literacy as a covariant factor in models designed to study some other health determinant. That is an important development, said Wolf, because it means that people are measuring the impact of health literacy on a wide variety of outcomes.

The challenge to the field, though, is to find a way to develop and promulgate measures that will indicate whether increasing literacy is "pushing the field on outcomes" and that there is a "business case" for paying attention to health literacy. "How do you develop the business case for a health system to say it wants to do this, to adopt one of these toolkits, to start making these changes when there is no mandate in front of them?" asked Wolf. Getting to that point, he said, means that the field needs to start consolidating its work and looking at how other fields of study are doing what we would likely refer to as health literacy research.

Davis then asked if Wolf sees research shifting to trying to evaluate corporations and health systems rather than on whether the field is moving the needle on cancer, diabetes, or other specific health issues. Wolf responded that his perspective as a health services researcher in a school of medicine is to think about how to change or redesign clinical workflow or practice of a health system attribute in order to improve care and engagement of patients. He then wants to see research that not only looks at whether an intervention improved outcomes, but tries to understand how difficult it was to implement change in an organization. From that perspective, he said, "I think health literacy has given us a very pragmatic, a very touchable kind of research agenda that in some ways is the reason why so many people love this field. It is one of the best branded research agendas I've ever encountered, and it's so malleable, and it also allows people to really kind of grasp the complexity and the need to simplify." What will be important going forward is to find ways of disseminating this knowledge in the absence of mandates, such as those in the United Kingdom and Europe that mandate testing patients for understanding.

As a final question for Wolf, Davis asked where the money is going to come from to conduct this research and develop dissemination methods for health literacy tools in the absence of such a mandate. Wolf replied that the future of funding for this field rests on having a special emphasis panel and a program announcement that drives this research and that will allow for the consolidation he believes must happen. Unfortunately, he said, the current panel concerns him because its membership is shrinking and no longer has many members who understand the concepts and the importance of health literacy. "Keeping those protections in place, having more institutes involved, and quantifying the value of this research they have funded over the years is going to be important," said Wolf. He added that industry is starting to understand the value of health literacy when it comes to marketing new devices or drugs, and so it will be important to reconcile how the field works with industry going forward. Wolf noted in closing how important it is that foundations have become engaged in the health literacy movement.

HEALTH LITERACY AND DISPARITIES[4]

Addressing the final panelist, Winston Wong, Davis asked him to describe his dream of eliminating health and health care disparities, and he began by first saying that he is optimistic that this can in fact be done. "But part of the challenge is to change the vernacular as well and stop talking about health disparities and start talking about health equity," he said. "If we have health equity squarely in the picture of what we want to achieve as a nation, we're going to actually make much more progress in terms of identifying where disparities exist and in trying to plug the holes."

Thinking about health disparities and health equities work over the past 20 years, Wong said the focus of the first wave of work was on racial justice and concepts such as unconscious bias, access issues, a disproportionate lack of opportunity, and so on. Also, much of the discussion 20 years ago was on cultural competence from a perspective of race, nationality, immigration status, and other factors that compounded the difficulties people had in terms of gaining access to health care. Over the past decade, however, place has become as important a part of the discussion of health equity as race, and there is the awareness that a person's zip code is a more important determinant of health than his or her genetic code. To the point that Teutsch made about the physical environment, place matters as a proxy for understanding the social determinants of health in terms of whether

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[4] This section is based on the comments of Winston Wong, medical director for Community Benefit and director of Disparities Improvement and Quality Initiatives at Kaiser Permanente, and the statements are not endorsed or verified by the IOM.

communities have access to jobs, fresh food and recreation, educational opportunities, and health care, said Wong.

It is not that place trumps race or that race trumps place, he said, but that there is a confluence of factors that produce health disparities and the recent understanding that a person's environment can produce certain health-impacting stressors that others living in more hospitable environments do not experience. Wong referred to this last idea as "fate happens," and he said there is a new appreciation for how fate, as determined by where someone lives, can have a disproportionate impact on the burden of disease and the development of chronic disease. The question for health care providers, then, is how to interface with all of these elements and by extension to determine how health literacy fits into an honest discussion of how individuals understand their health and how they understand the value proposition for making changes that improve their health.

The bottom line, said Wong, is that the discussion is starting to mature and to reflect an understanding that there is more than one issue involved in health literacy. The discussion today is about how all of these factors interface with one another and about the complexity of how individuals, and thus communities, are able to interact with the health care system. He added that there are many implications about this maturing discussion for how health plans such as his interface and support community development and individual empowerment.

Davis then asked Wong for his views on some initial steps that the field could take to further this discussion. Wong reiterated statements by other speakers at the workshop that the quality of health has to be considered in all policies and that equity has to be at the center of how we develop a quality health care system. He said that he would push for all health care systems, all health care providers, and all entities that say they are concerned about public health and community health to measure how any policy will achieve equity in health care and access to health care. He said he would also push for the development of a set of core metrics that embody the issues of equity, one of which would measure health literacy. "How does health literacy become part of the calculus from which you understand how health equity is achieved in a given community or given target population?" asked Wong.

As far as the role that he sees health literacy playing in achieving equity and whether the field was promising more than it can deliver toward that end, Wong recounted a discussion he had recently with the leaders of Kaiser Permanente regarding the non-medical social needs of members and patients. The question came up during this discussion about what the core conversation should be with individuals when you see them for 15 minutes per year. "What is the core conversation that resonates with them in terms of what it means to go on this journey of being as healthy as possible," said

Wong. “One interesting proposition is that we should start the discussion with every person we come in contact with by asking ‘what does a good day mean to you,’ because that’s really a much more important question than ‘what hurts’ or ‘have you been taking your medicine today.’” That question, he said, reflects the fact that medicine can help with some problems, but what ultimately makes for a good day for someone is determined by a constellation of actors that foster good health. “As a health plan, we have to start thinking about what do we do to proactively address what makes for a good day,” said Wong.

As to whether it is possible to measure all of those social determinants, Wong said that one challenge is to move measurements of health literacy away from just the clinical interaction and to consider the value proposition to individuals about the decisions they make that enable them to function at a desired level of happiness. Capturing that in a way that can be used by the entire health care arena will enable health care systems to better craft messages that will help people make smarter decisions that benefit their health. Doing so will require asking individuals if their health plan or health provider meets their needs to live the best day possible, and those kind of measures, said Wong, have yet to be developed. Ultimately, he said in closing, it will be necessary to have measures that health care organizations can use to determine if the money they are investing in crisis-oriented, intensive chronic care centers is providing real value for the individuals and purchasers of health care in terms of preventing high-cost intensive medical therapies.

DISCUSSION

George Isham started the open discussion period by asking Wolf to describe a research agenda around measuring and describing complexity, and specifically, how it might be possible to engage in all of the many aspects of complexity in terms of the universal precautions approach or a tailored approach to help people help themselves. Wolf replied that the evidence of complexity can come from the studies that focused on individual skills if the observed markers are framed differently. For example, if the majority of individuals in some patient population or consumer group are struggling to understand something, that is actually an indicator of the evaluation of complexity of that particular task. Ideally, said Wolf, the assessments would be refined enough to understand what parts of the task are so complicated and to then redesign the learning task or to support the task differently. He remarked that what researchers need to continue measuring is how people are performing with what they are being given. “Otherwise, we won’t really understand from our end how we’re doing,” adding that much of the information that is given to patients has had little forethought in terms of what is being asked of the patient, whether it is in a discharge instruction, after visit summary, or medication label. “I think that we still have to think about the individual skills measures or the individual task performance measures as attributes not of the individual, but of actually what we’ve designed for this system, and those could be ways for us to continue to assess how we’re doing,” said Wolf.

In terms of translating that kind of research into an agenda for health care systems that could be used to describe how complex health care is at one health system compared to another, Wolf said it would be useful to have something resembling a Joint Commission quality ranking related to the complexity of a system and its performance. Many of the toolkits available today are trying to set standards against which complexity could be measured and that health systems can use as benchmarks in their efforts to simplify their systems and be more accommodating to the needs of the specific populations they serve, given where they are located and the demographics of those communities. He said that satisfaction measures and feedback from patients can serve as an indicator of how well a system is doing in terms of reducing complexity, engaging its community, and enabling patients to do what they are being asked to do to improve their health. The key, though, will be for health systems to actually use the tools that Rothman identified to start measuring health literacy and organizational performance.

Going back to the question of whether the field has lost its spark, Humphreys wondered if someone were to come up with a truly brilliant new idea if they would be able to get funding to develop and test that new idea. Davis responded that some of the most fun and creative research that she did was in collaboration with a group of researchers based on findings in the literature and with no funding. Instead, she and her collaborators used medical students and sent them forth into the clinic to test this idea. Wong remarked that he believes that funding is available for applied research in the context of care transformation given the pressures that health care systems are under to demonstrate the value of the services they are delivering in terms of outcomes. Put into that context, health literacy studies will find funding. Wolf agreed and added that health systems are starting to appreciate the need to measure the degree of engagement with their patients and community and that health literacy fits into that need.

Yvette Morello with the March of Dimes noted that organizations such as hers are also sharing information with people that they call consumers because they are not providing direct care or giving medical advice. She encouraged the research community to work with other organizations that are communicating with consumers outside of the actual clinical setting. Humphreys agreed that this was an important point, which triggered a question from Isham, who asked Humphreys how a librarian, or NLM, goes about vetting the many branded information sources on the Web in terms of its reputation and the accuracy and utility of the information these sources provide. Humphreys replied that all libraries are selective in the materials they use. NLM has published guidelines for how it selects the information that it organizes, and points to within MedlinePlus, for example, and other organizations use these guidelines in their own selection process.

Humphreys noted that she and her colleagues partner with many organizations, not just libraries, but public health departments and community-based organizations, in terms of reaching out to underserved populations to help them find information and understand the quality of the information available from various sources. Through these efforts, consumers learn to look at the context of the information; for example, is drug information right next to an ad about how to buy that drug or is information about a surgical procedure coming from a surgeon's website with a link at the end of the information to make an appointment?

She also commented that reputable sources can have information that turns out to be incorrect, such as in the case of the study that professed to demonstrate a link between vaccination and autism that was published in a reputable medical journal. By the time it was retracted, there was a vocal group of people who nonetheless felt the article was accurate and that there was some conspiracy behind its retraction. Nonetheless, she has heard stories from her colleagues who do health information outreach at health fairs, senior centers, churches, and community centers that most people do have a healthy skepticism about information and that they do exercise good judgment about the veracity of information sources.

Ruth Parker asked the panel to talk about what cost, transparency, and value-based care might look like in 2024 and how it might affect vulnerable populations and what role health literacy might play in providing value-based care. Teutsch replied that from a population health perspective, there is a major move afoot to look at the economic and health returns of interventions outside of health care, such as early childhood development and education programs, in terms of their health impacts and overall value. He also noted that he dislikes the term "return on investment" when applied to health care. "When you talk about return on investment, what you're really are talking about is the return to society or to the individuals directly impacted."

Price transparency in the health care system is also needed, added Teutsch. As an example of what is currently wrong with the system, he cited the benefits statement he gets that claims the drugs he received are worth $2,000, when in fact they cost $8 at his local pharmacy. Humphreys said she had being trying to think of places where technology has decreased the cost of health care and was not familiar with many, probably because cost is not transparent and so it is hard to judge whether technology has had an impact on cost. Wolf said that health care is still trying to figure out how to integrate technology into the system to provide cost transparency and to improve patient satisfaction and patient engagement. In particular, he remarked that all of the work being done to create patient portals and mobile apps for accessing electronic health records all assume patients want 24-hour access to their medical record. "We've never really worked with patients in designing these kinds of engagements or in thinking about how they would use them," said Wolf.

With regard to a research agenda, Wolf said it is important to better understand what can be done from a health literacy perspective to better engage patients so that they can more effectively use various interventions and technologies. In particular, research is needed to better understand how to deal with an aging population that will need to have its sights recalibrated regarding how much interventional health care they really need compared to what they have come to expect. Many people, for example, still believe that generic drugs are inferior to the brand name equivalent. "How do we move forward with a health care system that is trying to provide evidence-based care, but is being perceived as pulling resources out to try to save money? I think that's a very big health literacy challenge for us," said Wolf.

Wong views this as an issue of cost relative to affordability given the constraints of the marketplace. "This is going to be a value proposition in terms of I put out X number of dollars for my family, and how much do I get back?" asked Wong. Health-literate organizations are likely to do better in that case because consumers are more likely to understand the services they receive for their health care dollars and better appreciate the value of those services relative to those provided by organizations that are not transparent and not health literate. Teutsch added that the ability to understand value comes from being an educated consumer, for which health literacy plays an obvious role.

Wilma Alvarado-Little, asked if it is really known how consumers want to get their health information. She recounted how reluctant she was to go from a physical book to an e-reader, and how her organization had created what it thought was a fantastic website only to have community members say they still wanted print information. Humphreys replied that there are two aspects to this question. First, there are people who are intrigued with what technology can do and are developing products and hoping that consumers will use them. Some of these products may encourage people to live a healthier lifestyle by feeding data into an EHR, which would be a good thing. Another way in which technology could be useful for providing information would be if it made it possible for an individual or his/her physician to compare a health profile to de-identified consolidated data from patients with the same profile. Those would be dream applications that may not be available for another 30 years, said Humphreys. What needs to happen in the meantime, she said, is for technology developers to rely less on their desires and to focus more on what consumers actually want.

Wolf said, "We know quite a bit about how to make information better, we just don't do it. We're variable and have not done well at being consistent, and we either don't have the stomach to follow through or we don't have the accountability there to say that we're putting out these standards and then have some sort of follow-up to ensure that people are following them." He added that health systems could make better use of technology to push information out to consumers, and he cited a project that his staff suggested to study the utility of an application that makes his phone vibrate when he is supposed to take a medication. What's needed to make such tools useful is to aggregate content and to actually ask consumers how they want that content delivered. "We just haven't figured out how to disseminate information," said Wolf.

Catina O'Leary commented that too often the people who control information that could be useful to patients do not want to share that information or consolidate it in a way that would benefit patients. She then asked if anyone on the panel had any thoughts about how to change the way people who have the power to make decisions about data access think about this problem. Wolf said that companies such as Microsoft and Google are trying to change the equation by developing applications that give patients ownership over their health information. Today, he added, pharmacists and physicians alike do not have a good idea on how to provide information using technology in ways that would be useful to them and their patients, and that this is in part a failure of the health literacy community to help providers know how to get information into the hands of those who need it.

Humphreys said that the issue of being able to exchange and integrate health data is one that has engaged her for some time. From that perspective the situation is a great deal better now than it was, and there are policies and laws in place that will improve the situation further over time. Consumers now understand that EHRs exist, and they want to know why their data have not become easier for them to access. This problem is now visible and people are working to address it. She believes, in fact, that this challenge will be solved in the next 5 to 10 years and individuals will have access to and will own their health data. As an example of the progress being made, she said the latest revision to the *Clinical Laboratory Improvement Amendments* and HIPAA make it clear that patients are entitled to get laboratory data, including entire genome data that may have been generated in the context of some specific diagnostic test.

Robert Logan, communications research scientist at NLM, remarked that there are some people in clinical informatics who argue that what is needed is not just information, but health information that patients and caregivers can use to help them make decisions. He asked the panel if they agreed that this was really the vital missing element and if so, would having that kind of information available create a new health equity problem because the information-rich will get richer and the information-poor will get poorer. Teutsch said the type of system Logan asked about is not on the horizon. Something as simple as being able to provide information about what standard evidence-based guidelines do exist and incorporate them into a clinical care system linked to the electronic medical record is a real challenge, not from a technical viewpoint but from an adoption viewpoint. He did think that at a minimum it should be possible to codify standard guidelines and make them available to both physicians at the point of care and to their patients. It would make sense, he said, for patients to be able to go online before their appointment and see what services are standard for their condition and then be able to talk to their physician about those services.

Humphreys said there are ways of doing that now, such as the system that enables a patient to click on a drug in their patient portal and access health-literate information, often from NLM, on that drug. The next step would be to have a system that could access a patient's medical record and would push relevant information to the patient. This would require health literacy research to understand how to best deliver that information so that it would enable patients to make better decisions about their health and the treatments they receive. Even better, she said, would be a customized model for each patient that would provide evidence-based information that would help each patient live a healthier life. For example, a single mother's model might provide information about what they could best do in a limited amount of time to improve their health, such as walk her child to the bus stop instead of driving the child.

For the final remarks of this session, Isham referred to Wong's comment that the most important thing is to ask a patient what a good day means to him or her, which he said suggests that outcome is not health itself, but social function however it is defined by the patient. Given that, Isham wondered if the field is being too narcissistic in its conversations about health and health literacy and if the skills needed to be health literate might overlap with the skills needed to be financially literate or to be effective at a job or as a family member. "So what can we learn, what questions should we be asking as a field about what the overlaps are, what the common agendas might be that might either enable our agenda to be more effective, or that might cause us to learn from those other fields how we might be more effective in health literacy?" asked Isham. Wong replied that there is an aspect of being a health provider that should lead to considering how to best make a difference in people's lives. "If the person says a good day to me is if I don't have to go to bed hungry or to have a job interview, we need to be able to deal with that," he explained. "Perhaps that is going to be as important to that individual as taking his/her statin to lower cholesterol."

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Where Do We Go from Here?[1]

The final session of the workshop featured a presentation by Scott Ratzan, vice president of global corporate affairs at Anheuser-Busch InBev. George Isham introduced him as a long-time advocate for health literacy and a former member of the roundtable. Ratzan was asked to speak about where the health literacy field needs to go from this point forward. He started by comparing where the field or discipline of health literacy is today and where the field of health communication was when he started a master's degree program for that discipline at Tufts University 20 years ago. Some 450 people have since graduated from what was then the first health communication program in the nation, and today there are 46 such programs in the United States. "That field has found its place and I think health literacy is on its way," said Ratzan.

Ratzan noted that there is a public–private partnership forum within the IOM that is looking at global health and safety, as well as other areas that tie into this Roundtable's activities. He expressed hope that the two groups could engage each other. In his current position at Anheuser-Busch InBev, he is learning what beer companies do well that can be translated into public health. He also stated that everyone at this workshop, regardless of what sector they come from, contributes to health literacy and has a role to play in moving the field forward.

The *Journal of Health Communication*, he explained, has published several supplements specifically on health literacy and also recently pub-

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[1] This section is based on the presentation by Scott Ratzan, vice president of global corporate affairs at Anheuser-Busch InBev, and the statements are not endorsed or verified by the IOM.

lished an evidence summit supplement for the U.S. Agency for International Development and UNICEF that had a subset on health literacy. There were not enough data in the global health world, he noted, for the inclusions criteria of populations younger than 5 years. “There is health literacy there, but the evidence base could be much stronger in certain areas,” said Ratzan. He also said that health literacy has now become a strategic tool that is used in global organizations to maintain and generate coherence and coordination among multispectral programs, particularly because the United Nations held a regional meeting of the Economic and Social Committee in Beijing. Since then, health literacy has been included in three United Nations resolutions and has been integrated into national action plans of China and other countries. More people, he said, are realizing that literacy, communication, and education have a role to play in global health.

What drives the global community, said Ratzan, are the data showing a link between literacy and health. For example, a systematic analysis of 175 countries between 1970 and 2009 found that more than half of the recent reductions in child deaths are linked to gains in women’s educational attainment (Gakidou et al., 2010), while another study showed that education has a positive impact on an entire community’s well-being, not just on a child’s health (Basu and Stephenson, 2005).

To move forward and be most impactful, the next frontier in public health needs to be “smarter” and to consider theories and ideas from diverse fields, including behavioral economics, social psychology, sociology, demography, and communication. He referred to the model that Ruth Parker presented in the workshop’s first panel session that puts health literacy at the intersection between an individual’s skills and abilities and the demands and complexity of the information and what is being asked of the individual. The importance of this model, Ratzan said, is that it points not just to the role of the individual, but to the system as a place where work is needed to improve health literacy. He then discussed Ilona Kickbusch’s model that says that efforts to impact health literacy and create a health-competent society require a system that is functioning; an educational system active in the home, community, and workplace; and media and new technology that can reach into society. In addition, a foundation of support must exist in the policy and political arena for such efforts to maintain a sustainable focus on the health of the individual (Adams et al., 2009; Kickbusch, 2010).

What Ratzan has done, he said, is take Parker’s model and add a third arrow, one that denotes the integration of more social influence and technology into the health literacy framework as a means of inspiring individuals to make the right choices to benefit their health. He also took as a challenge the idea that health could be represented by a small number of variables in the same way that astrophysicist Martin Rees described the universe using just six numbers (Rees, 1999) and created the Digital Health Score, which functioned something like a credit score and serves as a health literacy metric for chronic disease (Miron-Shatz and Ratzan, 2011; Ratzan et al., 2013). The score includes measures of body mass index, blood pressure, cholesterol, fasting blood sugar, smoking or tobacco use, physical activity, and alcohol usage, with no adjustment for age and one adjustment for gender and alcohol use. The Digital Health Scorecard is a HIPAA-compliant app for an Android or Apple smartphone that can give consumers an overall health score and ideas on what could happen if they improved their health risk factors. One thing he learned from this exercise was that no matter how good an idea is, without marketing muscle behind it or the ability to disseminate it using older technologies, it will just sit in the app stores.

Ratzan then brought up the question of how to link this type of work with communication strategies for Ebola, something he said should be simple but is not. He noted that in 2013 he predicted that the health community was not prepared for communicating health-literate information about the next global pandemic (Ratzan, 2013), and as it turned out, he was correct (Ratzan, 2014). This was a failure not of health literacy, but of how the system implements health literacy. “If we can use this as an example of that teachable moment and be prepared for the next one, it would make a huge difference,” said Ratzan. The health literacy community, he added, has a great opportunity to do something in this regard.

Another opportunity for the community is to take advantage of mobile technologies to enhance health literacy. Mobile telecommunications, he said, can bridge the global health gap and bring health and health information to millions of people. Some 85 percent of the world’s population is now covered by one or more commercial wireless signals, and mobile phones have a much broader reach than other forms of digital communication and therefore can be an important avenue for reducing the digital divide. As an example, he described an application, Text4Baby, that can deliver free tips on a cell phone to help mothers through their pregnancy and their baby’s first year of life. This was developed through a public–private partnership with the White House Office of Technology Policy and involved some 800 nongovernmental organizations. The app is now being evaluated by HRSA and the methodology used to develop it has been published (Whittaker et al., 2012). He noted that Text4Baby is a simple, generation 1.0 example of how health can be within arm’s reach, though he also cautioned that in addition to putting health within arm’s reach, cell phones are creating a health hazard—distracted driving—within arm’s reach, too.

Ratzan then challenged the health literacy community to start thinking big in terms of what it can accomplish with respect to big issues. The World Economic Forum, he said, comes out with a Global Agenda Report each year that lists the biggest risks to the world's financial system, and it turns out there are many health issues on this list, including chronic diseases in developed countries, developing world diseases, climate change, and pandemics. This list prompts a rhetorical question of whether the health literacy community is doing enough in these areas, but it also led Ratzan to discuss another area in which he is interested: traffic accidents, the number one cause of death worldwide for persons ages 15 to 29 and the eighth leading cause of death for all age groups globally. This is a public health issue that is only projected to get worse and soon become the fifth leading cause of death, surpassing diabetes and lung and throat cancer, he said.

In his new role at Anheuser-Busch InBev, Ratzan said he is trying to think big and create a new coalition called Together for Safer Roads with the big vision that roads are safe for all people: pedestrians, bicyclists, motorcyclists, and drivers alike. So far, this effort has drawn in companies such as AIG, AT&T, Chevron, Facebook, IHeartRadio, PepsiCo, and Walmart. This initiative was launched at the United Nations Headquarters on November 13, 2014, with the goal of bending the curve on road traffic accidents so that they are no longer one of the leading causes of death and injuries worldwide. Health literacy, said Ratzan, needs to play a role in setting the new social norms that are needed to meet this challenge.

The path forward on health literacy, said Ratzan, will involve the Internet, and the field must figure out a way to leverage this web of technology to benefit and not harm individuals. If computers replace primary care physicians in some places, for example, will that lead to having empowered, engaged, emancipated, and competent consumers? It can if health literacy principles play a role in the development of such technology. The biggest challenge for the field is to empower consumers, said Ratzan, not just in the United States, but worldwide.

Ratzan concluded his presentation with a list of key areas that the roundtable and the field should consider. He believes, for example, that it would be great to have a new IOM consensus report on health literacy that included recommendations for integrating in the new health system the use of new technologies and for including health literacy in the ACA. He also proposed elevating health literacy models for social and behavior change with effective communication training to change social norms and to link with key organizations and institutions.

Ratzan noted that Columbia University, where he teaches a course as an adjunct professor, is going to offer a state-accredited health communication certificate program that will have a health literacy component, a step he believes will raise the level of the health literacy field in the same way that the creation of the health communication program at Tufts benefited the health communication field. He applauded the IOM's continued efforts to drive the field of health literacy forward, but said it is time for other organizations to get involved and start their own activities. Along those lines, it is important to continue to build and disseminate the interventions that will enable people to make smarter choices as the nation moves from an eminence-based to a patient-centered health system.

Finally, he asked, "How do we invest in communication technology and innovations and advancing these partnerships to improve health literacy and thereby produce better outcomes?" There is no longer a need to prove that health literacy and health communication make a difference in health outcomes, but what is necessary is that health literacy and health communication have to develop scale. Ratzan recounted how he used to chair an innovation working group and that he would remind people that there is no such thing as a fool-proof innovation. "You've got to try ideas and if they fail, learn from that and try another idea and another idea," said Ratzan, who encouraged the health literacy community to learn from that and start pushing innovations into the marketplace.

DISCUSSION

Stacey Rosen, associate professor of cardiology at Hofstra North Shore–LIJ School of Medicine, started the discussion with two ideas that she was taking away from the workshop. The first was that not only is the field witnessing a paradigm shift in terms of moving from the myopic focus on individuals to professionals and institutions, but also in moving to a greater focus on physical determinants of health and issues of equity, where health literacy can play an important role. The second take-away, one that was not as positive, was the recognition that those who work in the field of health literacy remain disengaged from the consumers of health information. She remarked that "one of the oldest tenets in the field of health education in public health is that you do rigorous work, you do rigorous formative research, you do rigorous piloting, and you engage with members of the intended audience to help identify the problems and help generate the solutions," said Rosen. "We don't seem to be doing that." What happens, she said, is that an occasional innovative program does do that, but that then does not become the baseline for rigor or engagement with the intended audience.

Along the same lines, Kim Parson, from the Consumer Experience group at the Humana Center of Excellence, echoed comments from Rima Rudd and Ruth Parker, who pointed out that patients are the experts and the field must figure out how to partner with them. "What I've heard throughout the day is that's where opportunities still lie, and yet I don't know that we really have figured out how to partner with them or if we've really made the amount of effort that we need to figure out how to partner with them," said Parson. She proposed that this is an opportunity going forward that the field should seize upon to create both a health-literate population and health-literate organizations.

Wilma Alvarado-Little, noted her appreciation of Howard Koh's opening comments on health literacy and Culturally and Linguistically Appropriate Services (CLAS) standards, particularly as the United States becomes a majority/minority country and needs to be aware of those standards and implement them into health, health care, and social services. She also commented on Gerald McEvoy's remarks that drugs can have different names depending on an individual's country of origin. As a translator and language advocate, she sees the confusion that this can cause with increasing frequency. She noted, too, the importance of Wong's remarks about health equity and race, place, and fate.

Catina O'Leary voiced her agreement with Rosen's remarks about a lack of connection and rigor, and added that the field is also neglecting to address important methodological questions. She noted that the field hasn't dug deeply enough to understand some of the methodologies and approaches to data analysis that it uses. "We need to think about not just what we ask but who we ask when we ask these questions, where we ask them, and who is doing the actual asking," said O'Leary. She added that the research community needs to consider clearly the methods used to assess organizational health literacy, not just in terms of reliability and validity, but also with regard to utility, appropriateness, and bias. She appreciates the need to acquire multiple data sources, but added that "we can't triangulate if we don't actually have a real clear conceptualization of how these things work together and how we frame the meeting."

Bernard Rosof reflected on Koh's statement that there is an organizational responsibility for health literacy and a need to change culture within an organization to promote systems change. "You've heard me say before that culture eats strategy for lunch, and I think we need to focus on the culture change within an organization and integrate that into what other people are doing within the organization," said Rosof. "It's a bottom-up philosophy rather than a top-down philosophy." He also reiterated Wong's message that social determinants must be addressed to improve health and achieve health equity and that the conversation about that must be moved to the community so that both the health system and the community understand what is at stake.

Robert Logan from NLM recounted the repeated experience he has had when he asks audience members how not having access to health insurance affects their lives. At first, he said, nobody answers, so he reframes the question to ask how many people in the audience have had to work extra because someone in their family was ill, and that provokes a lively discussion. He then asks if anyone in the audience had ever had this discussion in college or in high school, and in all the years he has been conducting this exercise, only one person responded yes. He told this story to drive home the point that the field needs to work with people who want to spark discussions about prevention, wellness, and health information seeking in the K-12 setting and in universities across the country. "I realize today we've heard a lot about professional education and I agree with that, but I think the job is actually much more significant than that," said Logan. He also noted as important the comments that were made throughout the day on community outreach initiatives and the opportunity to partner with community groups going forward.

Winston Wong remarked on the restlessness in the field because, as he put it, "the train always seems to be a couple of stops in front of us," a situation he blamed on the nature of how health literacy is defined, on how society is now defining health, and on how individuals, consumers, and patients are framing questions about health for themselves in the 21st century. As a result, the health literacy conversation, he said, is only relevant to how people are starting to relate to the question of wellness and health. This is no longer just a matter of health delivery reform, but is now a broader question with regard to individuals and their interface with communities and society. "We have to be relevant to that," said Wong. Isham called that a wise comment and one with which he wanted to be associated, and also commented on the wisdom of the practical ideas that Ratzan listed at the end of his presentation and of thinking about considering a new IOM report on health literacy. Isham also reiterated the points that health literacy should consider the context of what a good day means to the intended audience for health information, that the field is moving to broaden its horizons beyond health care to community health, and that health literacy is just one piece of a complex systems issue.

Laurie Myers, leader of health care disparities and health literacy strategy at Merck & Co., Inc., reinforced the message that health literacy will advance when it is integrated with other things that are important to health organizations. She also noted the importance of health literacy with regard to increasing the representation of minorities in clinical trials and in running clinical trials. "We need to ask patients about clinical trials, their perspectives, and what the things that are critical to them are, and we need to train minority-serving investigators, not just minority investigators," said Myers. She said that she and her colleagues have been piloting a program around cultural competence and teach-back that has been incredibly well received. She also noted the need to educate pharmaceutical companies about the importance of health literacy in clinical trials and to apply the principles of health literacy throughout the clinical trials process, including informed consent, patient diaries in clinical trials, lay summaries of the trial procedures for participants, and ultimately in the patient labeling that is submitted for regulatory approval.

Laurie Hall, remarked that pharmaceutical companies are in fact trying to do a better job of listening to what patients and clinical trial participants want in terms of information and how they want to receive it. Pharmaceutical companies, she said, are not merely the sales and marketing machines that they are often portrayed as being, but are really motivated by the concept of shared value. She recounted something she heard from a colleague of hers who works in the clinical development innovation space, who said that in the past, those running clinical trials treated volunteers as raw materials in a supply chain process, but now volunteers are being brought into the process, being asked for input into trial design, and being honored for their contributions to the trial process. Part of that honoring, said Hall, comes from keeping volunteers engaged all along the trial process, which in turn comes back to communication. Betsy Humphreys commented that it should be possible to build into late-stage clinical trials the information on how a therapeutic candidate will be used to test the utility of that information along with the therapy itself in the clinical trial.

Continuing with her comments, Myers said she agreed with Michael Wolf's remarks that the field has lost some energy and that it needs to expand the conversation beyond the same people who participate in virtually every meeting on health literacy. She wondered if one way to do that would be to create what she called cheat sheets on health literacy and numeracy methods for people who want to engage, but do not have the time to invest in learning everything.

Michael Villaire commented that he is heartened by the way the medical model has been flipped from one in which patients had to come to the health care system for information to one in which the health care system reaches out to the patient and listens to what the patient needs and wants. He noted that with the passage of the ACA and the resulting influx of more people into the health care system, there are more opportunities for the health literacy community to do more listening and, in particular, to use new technologies to do so. He also remarked that health literacy is required and less optional today, which also creates opportunities for the field. What needs to happen, though, is for the health literacy community to do a better job disseminating its knowledge throughout the health care enterprise.

Ruth Parker, commenting on Ratzan's call for a new IOM report on integrating health literacy into a new health system, asked if he thought whether emphasizing the role of technology as a means of simplifying health messages and messaging would help secure funding for such a report. Ratzan replied that while he could not answer that question, he did think that Parker's suggestion was a good one and he did suggest that funding sources beyond the traditional government agencies that have been involved from the start should be brought into the process. He, in turn, wondered how things such as checklists, scorecards, and algorithms that have helped make health care safer and reduce costs could be adapted using technology for the consumer. He noted that all of the big technology companies are looking for ways to get a piece of the health care pie, but the key will be to get the health and health care communities leading where technology should go rather than the other way around.

Isham's take from the discussions about complexity is that in order to get simplicity, it is necessary to understand the causes of complexity at a more robust level, which is a place for academic research. But there is a combination of opportunities for health literacy that involves policy, initiatives in the private sector, and the development of rules and a common understanding of how complex systems work. Following up on the conversation about simplicity, Lindsey Robinson said that preventing oral disease and dental disease is simple, but implementing that and getting the word out is difficult, and that is where the field needs to pay attention to social determinants. She noted, too, that there needs to be a business case made for oral health literacy that could start with the observation that in the last recession, when many states eliminated Medicaid funding for adult dental care, emergency department visits for oral health problems soared by more than 4 million at a cost of $2.7 billion. Sixty percent of these patients had insurance, yet they could not access care because they did not understand how to get care under the provisions of their insurance.

Marin Allen, deputy associate director for communications and public liaison and director of public information at NIH, said she would like the field to develop a 360-degree operationalization of what equity is so that it does not have to be built piece by piece. She also voiced the need to integrate health literacy into core services so that it is not seen as just a nice add-on to current processes and to study the complexity of risk, particularly with regard to the emotion of risk and its relationship to trust and fate.

Andrew Pleasant, senior director for health literacy and research at Canyon Ranch Institute, also supported the need to embrace and address complexity in actionable ways that do not just accept complexity as a barrier to improving health and advancing health equity. He remarked that the health literacy field needs to get away from blaming various segments of the population because they are not fully health literate and to add a focus on prevention to future research. He then noted that the Roundtable's next workshop, on March 24, 2015, will look at health literacy and new technology.

Cindy Brach, a member of the Roundtable, noted her surprise at hearing so much during the workshop on social determinants of health given that much of her work over the past 18 years at AHRQ has been about fixing a broken system. She also commented that back in 2010, the field seemed to be at a tipping point given that health literacy was included in the ACA, there was the Plain Writing, and there was the National Action Plan to improve health literacy, but today, 4 years later, she said she believes the field has lost momentum. She wondered why the field is still "fighting and slogging to drag organizations to address health literacy," when nobody would argue that it is important to patients to be able to understand communications from their health systems and for individuals to understand what to do to stay healthy. While she agreed with Rosof that culture eats strategy for lunch, she noted that "you can't start with culture change." What then, she asked, are the policy levers that have to be pulled to really get to a tipping point and get past it? In her mind, said Brach, "we need to link health literacy and cultural competence to patient safety, because that is what everyone is paying attention to," particularly with the emphasis on patient-centered care, self-management, and shared decision making. In thinking about future opportunities, she said that palliative care and end-of-life care would be good areas for the Roundtable to explore. Isham concluded the discussion, and the workshop, by restating the need to move health literacy more broadly into health and to think about health literacy from a systems perspective and not just as an issue for individuals.

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Appendix A

Workshop Agenda

Institute of Medicine
Roundtable on Health Literacy

Health Literacy: Past, Present, and Future: A Workshop
November 6, 2014

National Academy of Sciences Building
Lecture Room
2101 Constitution Avenue, NW
Washington, DC

8:30-8:45	Introduction *George Isham, M.D., M.S.* *Roundtable Chair*
8:45-9:00	Welcome *Victor Dzau, M.D.* *President, Institute of Medicine*
9:00-9:20	Health Literacy at the U.S. Department of Health and Human Services: Progress and Possibilities *Howard Koh* *Professor of the Practice of Public Health Leadership* *Harvard School of Public Health*
9:20-10:30	Panel 1: Health Literacy and Medications
9:20-9:25	Introduction of Speakers
9:25-9:40	Overview: Where we started 10 years ago and where we are now—a general overview of what has been happening in the area of medications and health literacy *Ruth Parker, M.D.* *Professor, Emory University School of Medicine*

9:40-9:55 Creating a Standard and Best Practices for Medication Prescription Labels
Gerald McEvoy, Pharm.D.
Assistant Vice President of Drug Information
American Society of Health-System Pharmacists

9:55-10:10 Health Literacy at the U.S. Food and Drug Administration
Theresa Michele, M.D.
Director, Division of Nonprescription Clinical Evaluations
Food and Drug Administration

10:10-10:30 Discussion

10:30-10:45 BREAK

10:45-12:15 Panel 2: Use and Delivery of Health Care

10:45-10:50 Introduction of Speakers

10:50-11:05 Overview: Where we started 10 years ago and where we are now—a general overview of what has been happening in the area of health care and health literacy
Michael Paasche-Orlow, M.D., M.A., M.P.H.
Associate Professor of Medicine
Boston University School of Medicine

11:05-11:20 Health Literacy and Quality
George Isham, M.D., M.S.
Senior Advisor, HealthPartners

11:20-11:35 Creating Health-Literate Health Care Delivery
Russell Rothman, M.D., M.P.P.
Director, Center for Health Services Research
Vanderbilt University

11:35-11:50 Health Literacy and the Affordable Care Act
Victor Wu, M.D., M.P.H.
Managing Director for Clinical Transformation
Evolent Health

11:50-12:15 Discussion

12:15-1:00	LUNCH
1:00-2:15	Panel 3: Education
1:00-1:05	Introduction of Speakers
1:05-1:20	Overview: Where we started 10 years ago and where we are now—a general overview of what has been happening in the area of education and health literacy. It will be followed by two specific examples. *Rima Rudd, Sc.D., M.S.P.H.* *Senior Lecturer, Harvard School of Public Health*
1:20-1:35	Professional Education *Barbara Schuster, M.D.* *Campus Dean, Georgia Regents University/ University of Georgia Medical Partnership*
1:35-1:50	Education in Oral Health Literacy *Lindsey A. Robinson, D.D.S.* *Past President, California Dental Association*
1:50-2:15	Discussion
2:15-3:30	Panel 4: Looking to the future. This will be a different format. There will be a moderator who prompts the panel with questions about the future of health literacy efforts in the following areas.
2:15-2:35	Introductions
2:35-3:30	Moderator: Terry Davis: Description of Panel Process Technology *Betsy Humphreys, M.L.S.* *Deputy Director, National Library of Medicine* Disparities *Winston Wong, M.D., M.S.* *Medical Director, Community Benefit* *Kaiser Permanente*

	Population and Public Health *Steven Teutsch, M.D., M.P.H.* *Adjunct Professor, Fielding School of Public Health* *University of California, Los Angeles*
	Research *Michael Wolf, Ph.D., M.P.H.* *Professor, Medicine and Learning Sciences* *Feinberg School of Medicine*
3:30-3:45	BREAK
3:45-4:15	Discussion
4:15-4:35	Where Do We Go from Here? *Scott Ratzan, M.D., M.P.A., M.A.* *Vice President, Global Corporate Affairs* *Anheuser-Busch InBev*
4:35-5:15	Reflections of the Roundtable Members on Key Lessons Learned
5:15	Adjourn

Appendix B

Biographical Sketches of Workshop Speakers

Terry C. Davis, Ph.D., a pioneer in the field of health literacy, is a professor of medicine and pediatrics at Louisiana State University Health Sciences Center in Shreveport. For the past 25 years, she has led an interdisciplinary team investigating the impact of patient literacy on health and health care. Seminal achievements include development of the Rapid Estimate of Adult Literacy in Medicine (REALM) and creation of user-friendly patient education and provider training materials that are being used nationally.

Dr. Davis has more than 120 publications related to health literacy and health communication. She has served on Health Literacy Advisory Boards for both the American Medical Association (AMA) and the American College of Physicians (ACP). She was an independent agent on the Institute of Medicine (IOM) Committee on Health Literacy and a developer of the AMA's Train-the-Trainer Health Literacy Curriculum. Currently she is a member of the *Healthy People 2020* Health Literacy/Health Communication Section and serves as a health literacy advisor to the U.S. Food and Drug Administration (FDA). She chaired Louisiana's statewide Health Literacy Task Force, the first legislatively mandated health literacy group in the nation. She received the Louisiana Public Health Association's Founders Award for Significant Achievement in Public Health Research. As a frequent speaker at national conferences, she has integrated her research findings into practical lessons for providers and policy makers.

Dr. Davis is the Health Literacy Principal Investigator (PI) on a National Institutes of Health (NIH) grant for the Louisiana Clinical and Translational Science Center, an unprecedented collaborative effort among eight academic institutions in Los Angeles. She is PI on a 5-year National

Cancer Institute health literacy intervention to increase regular breast and colorectal cancer (CRC) screening among patients in federally qualified health centers. Building on this work, she was recently awarded an American Cancer Society (ACS) grant to evaluate follow-up strategies to improve regular CRC screening in rural clinics in the state. Dr. Davis is also working with Drs. Mike Wolf and Ruth Parker on studies funded by the Agency for Healthcare Research and Quality to improve patient understanding and actual use of prescription medication labels in English and Spanish. Along with a team from the University of North Carolina and University of California, San Francisco, she has been funded by the ACP to develop and test practical self-management guides and videos for patients with diabetes, chronic obstructive pulmonary disease, coronary artery disease, obesity, and rheumatoid arthritis. ACP has distributed more than 5 million copies of these guides.

Victor J. Dzau, M.D., is the eighth President of the IOM. He is Chancellor Emeritus and James B. Duke Professor of Medicine at Duke University and the past President and CEO of the Duke University Health System. Previously, Dr. Dzau was the Hersey Professor of Theory and Practice of Medicine and Chairman of Medicine at Harvard Medical School's Brigham and Women's Hospital, as well as Chairman of the Department of Medicine at Stanford University.

Dr. Dzau has made a significant impact on medicine through his seminal research in cardiovascular medicine and genetics, his pioneering of the discipline of vascular medicine, and his leadership in health care innovation. His important work on the renin angiotensin system (RAS) paved the way for the contemporary understanding of RAS in cardiovascular disease and the development of RAS inhibitors as widely used, lifesaving drugs. Dr. Dzau also pioneered gene therapy for vascular disease, and his recent work on stem cell paracrine mechanisms and the use of microRNA in direct reprogramming provides novel insight into stem cell biology and regenerative medicine.

In his role as a leader in health care, Dr. Dzau has led efforts in health care innovation. His vision is for academic health sciences centers to lead the transformation of medicine through innovation, translation, and globalization. Leading this vision at Duke, he and his colleagues developed the Duke Translational Medicine Institute, the Duke Global Health Institute, the Duke-National University of Singapore Graduate Medical School, and the Duke Institute for Health Innovation. These initiatives create a seamless continuum from discovery and translational sciences to clinical care, and they promote transformative innovation in health.

As one of the world's preeminent academic health leaders, Dr. Dzau advises governments, corporations, and universities worldwide. He has been a member of the Council of the IOM and the Advisory Committee to the Director of NIH, as well as Chair of NIH Cardiovascular Disease Advisory Committee and the Association of Academic Health Centers. He served on the Governing Board of the Duke-National University of Singapore Graduate Medical School and the Board of Health Governors of the World Economic Forum and chaired its Global Agenda Council on Personalized and Precision Medicine. He also served as the Senior Health Policy Advisor to Her Highness Sheikha Moza (Chair of the Qatar Foundation). Currently, he is a member of the Board of Directors of the Singapore Health System, the Expert Board of the Imperial College Health Partners, United Kingdom, and the International Advisory Board of the Biomedical Science Council of Singapore. In 2011, he led a partnership between Duke University, the World Economic Forum, and McKinsey, and he founded the International Partnership for Innovative Healthcare Delivery and currently chairs its Board of Directors.

Among his honors and recognitions are the Gustav Nylin Medal from the Swedish Royal College of Medicine; the Max Delbruck Medal from Humboldt University, Charité, and the Max Planck Institute; the Commemorative Gold Medal from the Ludwig Maximilian University of Munich; the Inaugural Hatter Award from the Medical Research Council of South Africa; the Polzer Prize from the European Academy of Sciences and Arts; the Novartis Award for Hypertension Research; the Distinguished Scientist Award from the American Heart Association (AHA); and the AHA Research Achievement Award for his contributions to cardiovascular biology and medicine. Recently, he was awarded the Public Service Medal by the President of Singapore. He has received eight honorary doctorates.

Betsy L. Humphreys, M.L.S., is deputy director of the U.S. National Library of Medicine (NLM). As deputy director, she shares responsibility with the director for overall program development, program evaluation, policy formulation, direction, and coordination of all NLM activities. In addition, the deputy director is responsible for the day-to-day operations of NLM, and in the absence of the director, assumes full responsibility for all functions performed by NLM. Ms. Humphreys also coordinates the Unified Medical Language System (UMLS) project, which produces knowledge sources to support advanced retrieval and integration of information from disparate electronic information sources, and NLM's activities related to health data standards. She contributes to the development of NIH and HHS policy on a range of matters, including health information technology, public access to research results, clinical trial registration and results reporting.

Ms. Humphreys received a B.A. from Smith College, where she was elected to Phi Beta Kappa, and an M.L.S. from the University of Maryland, College Park. She is a member of the IOM, a fellow of the American College of Medical Informatics, and a fellow of the Medical Library Association. She has received a number of awards, including the Marcia C. Noyes Award, the Medical Library Association's highest honor, the Morris F. Collen Award of Excellence from the American College of Medical Informatics, considered the highest honor in the field of medical informatics, and the rank of Meritorious Executive in the Senior Executive Service, conferred by the President of the United States.

George J. Isham, M.D., M.S., is Senior Advisor to HealthPartners, responsible for working with the board of directors and the senior management team on health and quality of care improvement for patients, members, and the community. Dr. Isham is also Senior Fellow, HealthPartners Institute for Education and Research, and facilitates progress at the intersection of population health, research, and public policy. Dr. Isham is active nationally and currently co-chairs the National Quality Forum convened Measurement Application Partnership, chairs the clinical program committee of the National Committee for Quality Assurances (NCQA), and is a member of NCQA's committee on performance measurement. Dr. Isham is chair of the IOM's Roundtable on Health Literacy and has chaired three studies in addition to serving on a number of IOM studies related to health and quality of care. In 2003 Isham was appointed as a lifetime National Associate of the National Academy of Sciences in recognition of his contributions to the work of the IOM. He is a former member of the Centers for Disease Control and Prevention's (CDC's) Task Force on Community Preventive Services and the Agency for Healthcare Research and Quality's U.S. Preventive Services Task Force and currently serves on the advisory committee to the director of CDC. His practice experience as a general internist was with the U.S. Navy; at the Freeport Clinic in Freeport, Illinois; and as a clinical assistant professor of medicine at the University of Wisconsin Hospitals and Clinics in Madison, Wisconsin.

Howard K. Koh, M.D., M.P.H., is professor of the Practice of Public Health Leadership and director of the Leading Change Studio at the Harvard School of Public Health. From 2009 to 2014, Dr. Koh served as the 14th Assistant Secretary for Health for the U.S. Department of Health and Human Services (HHS). He oversaw 12 core public health offices, including the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps, 10 Regional Health Offices across the nation, and 10 Presidential and Secretarial advisory committees. He also served as senior public health advisor to the Secretary. During his tenure, he championed the critical public health dimensions of the Affordable Care Act (ACA), promoted the enrollment of underserved populations into health insurance coverage, and was the primary architect of landmark HHS strategic plans for tobacco control, health disparities, and chronic hepatitis. He also led interdisciplinary implementation of *Healthy People 2020* and the National HIV/AIDS Strategy as well as initiatives in many other areas. Dr. Koh previously served at Harvard School of Public Health (2003-2009) as the Harvey V. Fineberg Professor of the Practice of Public Health, associate dean for Public Health Practice, and director of the Harvard School of Public Health Center for Public Health Preparedness. He has published more than 250 articles in the medical and public health literature.

Dr. Koh was Commissioner of Public Health for the Commonwealth of Massachusetts (1997-2003). As Commissioner, Dr. Koh led the Massachusetts Department of Public Health, which included a wide range of health services, four hospitals, and a staff of more than 3,000 professionals. He emphasized the power of prevention and strengthened the state's commitment to eliminating health disparities. During his service, the state saw advances in areas such as tobacco control, cancer screening, bioterrorism response after 9/11 and anthrax, health issues of the homeless, newborn screening, organ donation, suicide prevention, and international public health partnerships.

Dr. Koh graduated from Yale College and Yale University School of Medicine. He completed postgraduate training at Boston City Hospital and Massachusetts General Hospital, serving as chief resident in both hospitals. He has earned board certification in four medical fields: internal medicine, hematology, medical oncology, and dermatology, as well as an M.P.H. from Boston University. At Boston University Schools of Medicine and Public Health, he was professor of dermatology, medicine, and public health as well as director of cancer prevention and control.

He has earned more than 70 awards and honors for interdisciplinary accomplishments in medicine and public health, including the Dr. Martin Luther King, Jr. Legacy Award for National Service, the Distinguished Service Award from ACS, and four honorary degrees. President Bill Clinton appointed Dr. Koh as a member of the National Cancer Advisory Board (2000-2002). He is an elected member of the IOM. A past chair of the Massachusetts Coalition for a Healthy Future (the group that pushed for the Commonwealth's groundbreaking tobacco control initiative), Dr. Koh was named by the New England Division of ACS as "one of the most influential persons in the fight against tobacco during the past 25 years." He has also received the 2012 Champion Award from the Campaign for Tobacco Free Kids, the "Hero of Epilepsy" Award from the Epilepsy Foundation and the Baruch S. Blumberg Prize from the Hepatitis B Foundation. He was named to the K100 (the 100 leading Korean Americans in the first century of Korean immigration to the United States) and has received the Boston University Distinguished Alumnus Award.

Gerald K. McEvoy, Pharm.D., is assistant vice president (AVP) of Drug Information at the American Society of Health-System Pharmacists (ASHP). In addition, Dr. McEvoy has served as editor-in-chief of *AHFS Drug Information* (AHFS DI) for more than 30 years. In his capacities as AVP of Drug Information and editor-in-chief of AHFS DI, *AHFS Consumer Medication Information* (AHFS CMI), and *ASHP's Handbook on Injectable Drugs*, Dr. McEvoy is responsible for a variety of publishing and database management projects within ASHP focusing on dissemination of drug information in both electronic and print formats to various audiences, including health professionals and patients.

AHFS DI is designated an official compendium by the Centers for Medicare & Medicaid Services for establishing prescribing standards for medications based on accepted medical practice. AHFS CMI is the core medication information in the NLM's publicly accessible MedlinePlus website and in its MedlinePlus Connect service for linking patient portals with electronic health records.

Dr. McEvoy has spoken widely on evidence-based development of drug prescribing information as well as on medication safety, best practices in prescription container labeling, and electronic data interchange through SGML and XML (e.g., structured product labeling, or SPL) data structuring and coding.

Dr. McEvoy currently serves on the National Council on Patient Information and Education Board. He also served on the IOM Panel on Changing Prescription Medication Use Container Instructions to Improve Health Literacy and Medication Safety and subsequently was appointed co-chair of U.S. Pharmacopeia's (USP's) Health Literacy and Prescription Container Labeling Advisory Panel, which he continues to co-chair under its new name, Prescription Container Labeling Expert Panel. In addition, Dr. McEvoy is a recognized authority on consumer medication information, testifying before and advising FDA on medication safety communication issues involving consumers, advising *Consumer Reports* on medication use issues, being engaged for his expertise in this area by the Engelberg Center for Health Care Reform at The Brookings Institution, testifying before the Senate Special Committee on Aging, and speaking internationally on the provision of safe medication use information to consumers. His recognition also has resulted in appointment to additional IOM expert panels as part of workshops conducted by their Roundtable on Health Literacy and engagement in CDC to aid in development of the National Action Plan to Improve Health Literacy. Dr. McEvoy also is engaged in CDC's PROTECT Initiative on medication safety.

Dr. McEvoy also participates in the development of medication data transfer standards through work with the National Council for Prescription Drug Programs (NCPDP). He currently serves as co-lead of NCPDP's

SPL Activities Task Group, its SPL REMS Requirements Task Group, and its Naming Standards for Drugs, Biologics, and Biosimilars Task Group. Dr. McEvoy also is engaged in activities of the SPL Working Group (formed by the Pharmaceutical Research and Manufacturers of America's HL7 Task Group), FDA's Health and Regulatory Data Standards initiative, and NLM's SPL/DailyMed initiatives. Through work with NCPDP, CDC, FDA's Safe Use Initiative, and the American Pharmacists Association, he also has been instrumental in advancing national best practices aimed at avoiding inadvertent acetaminophen overdosage by patients and in advocating U.S. adoption of the mL as the standard unit for consumers to measure liquid oral medications. He recently completed his tenures on the BMJ Group North American Advisory Board and USP Safe Medication Use Expert Committee. Dr. McEvoy obtained both his baccalaureate and coctorate degrees in Pharmacy from Duquesne University and completed a hospital residency at Mercy Hospital in Pittsburgh. He recently was awarded the Duquesne University Pharmacy Alumni Achievement Award and inducted into the Cosmos Club for meritorious original work in science.

Theresa Michele, M.D., is the director of the Division of Nonprescription Drug Products (DNDP) in the Office of New Drugs, Center of Drug Evaluation and Research, at FDA. Previously the director of the Division of Nonprescription Clinical Evaluation (over-the-counter, or OTC, products regulated via the New Drug Application process), Dr. Michele oversaw the recent merger of that division with the Division of Nonprescription Regulation Development (OTC drugs regulated via the monograph process) to form DNDP. Prior to joining FDA, she spent 10 years in industry, with clinical research experience across a variety of therapeutic areas in both commercial and development-stage companies. Dr. Michele left industry in 2007 to join FDA in the Division of Pulmonary and Allergy Drug Products, where she served as a clinical reviewer and a team leader. She is board certified in internal medicine, pulmonary medicine, and critical care medicine, and completed her training at Johns Hopkins University. She obtained her B.S. in Integrated Life Sciences from Kent State University and her M.D. from Northeastern Ohio Universities College of Medicine as part of a 6-year combined program.

Michael Paasche-Orlow, M.D., M.A., M.P.H., is associate professor of medicine, Boston University School of Medicine. He is a general internist and a nationally recognized expert in the field of health literacy. Dr. Paasche-Orlow is currently a co-investigator with five funded grants that examine health literacy, including two intervention studies evaluating simplified information technologies for behavior change among minority patients with a range of health literacy levels. Dr. Paasche-Orlow's work has brought attention to the role health literacy plays in racial and ethnic disparities, self-care for patients with chronic diseases, end-of-life decision making, and the ethics of research with human subjects. Dr. Paasche-Orlow is the associate program director for the Boston University School of Medicine's General Internal Medicine Academic Post-Doctoral Fellowship Program and the associate section chief for research for the Section of General Internal Medicine in the Boston University School of Medicine's Department of Medicine.

Ruth Parker, M.D., is a Professor of Medicine and Public Health at Emory University School of Medicine. She developed one of the first measurement tools to quantify patients' abilities to read and understand health information, the Test of Functional Health Literacy in Adults; co-wrote the definition of health literacy that is used by Healthy People, NIH, and the IOM report *Health Literacy: A Prescription to End Confusion*; and is the developer of a model of health literacy that is achieving growing recognition in the United States and internationally. Dr. Parker worked to define medication labels as an issue at the intersection of health literacy and patient safety, and she co-wrote the seminal white paper on the topic, which was presented to the IOM at a workshop on standardizing medication labels. This led to pivotal work by USP, where Dr. Parker worked on an expert panel to create standards for improved medication labels. This standard has now been published by USP.

Dr. Parker also works with FDA as a scientific expert Special Government Employee regarding medication labels and with the Nonprescription Drug Advisory Committee as an expert in consumer understanding of medication labels.

Dr. Parker is also a strong advocate for health literacy and its importance to health. She has worked tirelessly with professional societies, federal and state agencies, and congressional staff to inform them about health literacy issues and to encourage them to recognize health literacy as a priority issue.

Scott Ratzan, M.D., M.P.A., M.A., is vice president, global corporate affairs at Anheuser-Busch InBev. He has made major contributions to improve public health domestically and internationally. Dr. Ratzan is a pioneer in the areas of health literacy and mobile health (mHealth) communication. Additionally, he is the editor-in-chief of the peer-reviewed *Journal of Health Communication: International Perspectives*, serves as co-chair of the United Nations Secretary General's Every Woman Every Child Innovation Working Group, serves on the World Economic Forum Global Agenda Council on Well-Being and Mental Health, and is a former Ambassador for global health research selected by Research!America. Dr. Ratzan maintains faculty appointments at the Columbia University Mailman School of Public Health, the Tufts University School of Medicine, and the George Washington University School of Public Health and Health Services. Prior to joining Anheuser-Busch InBev, Dr. Ratzan was vice president of global health at Johnson & Johnson, where he most recently was based in New Jersey, and previously was vice president of government affairs and policy based in Brussels, Belgium. Prior to joining Johnson & Johnson, he held positions in public health at the U.S. Agency for International Development and the Academy for Educational Development in Washington, DC, where he directed and developed a number of research and campaign activities for international institutions (including the World Health Organization) and the public and private sectors. He also spent a decade in Boston in academia as founder and director of the Emerson-Tufts Master's Program in Health Communication. During that time he became editor-in-chief of the *Journal of Health Communication*, a monthly peer-reviewed publication.

Dr. Ratzan graduated from the University of Southern California with an M.D. in Medical Science, as well as an M.P.A. from the Kennedy School of Government at Harvard University and a master's in Communication Studies from Emerson College. He has published several books and articles in the field of public health and he is a member of the Board of Scientific Counselors, Office of Infectious Diseases, CDC.

Lindsey Robinson, D.D.S., has maintained a full-time pediatric dental practice in Grass Valley for the past 16 years since receiving her certificate in pediatric dentistry from the University of Florida in 1995 and her D.D.S. degree from the University of Southern California in 1990. Dr. Robinson was a member of the ADA Council on Access, Prevention, and Interprofessional Relations for 6 years, and during her tenure served as Chair for 2 years. As CAPIR Chair she hosted two national access summits convened by the ADA, the American Indian/Alaska Native Oral Health Access Summit in 2007 and the Access to Care Summit in March 2009. She is a founding board member of the U.S. National Oral Health Alliance. Dr. Robinson currently serves as President-elect of the California Dental Association and is past Chair of the California Dental Association Foundation.

Russell Rothman, M.D., M.P.P., is an associate professor of internal medicine and pediatrics at Vanderbilt, and serves as director of the Vanderbilt Center for Health Services Research and chief of the Internal Medicine/Pediatrics Section. Dr. Rothman received his bachelor's and medical degrees from Duke University. During this time he also completed an M.P.P. at the Sanford Institute of Public Policy at Duke. After this, Dr. Rothman remained at Duke, where he completed a combined Internal Medicine and Pediatrics residency in 2000. From 2000 to 2002, he served as a Robert

Wood Johnson Foundation Clinical Scholar at the University of North Carolina at Chapel Hill. In 2002, he joined the faculty at Vanderbilt.

Dr. Rothman's current research focuses on improving care for adult and pediatric patients with diabetes, obesity, and other chronic diseases. He has been funded by NIH, American Diabetes Association, and other sources to examine the role of literacy and numeracy in patients with diabetes and obesity. He has been PI on more than $20 million in extramural funding and has authored more than 90 manuscripts. He is currently PI on several NIH-funded studies addressing literacy and health communication in obesity prevention and diabetes. He is also PI of the Patient-Centered Outcomes Research Institute (PCORI) funded Mid-South Clinical Data Research Network, which engages more than 50 hospitals and thousands of ambulatory practices reaching patients across the nation. Dr. Rothman currently serves on the PCORI Health Disparities Advisory Board and the PCORnet Executive Steering Committee. He is also on the Board of Directors for the American Academy on Communication in Healthcare. Dr. Rothman has served as a reviewer on multiple NIH study sections, including the NIH Special Emphasis Panel on Health Literacy, and has been a Pfizer Visiting Professor in Health Literacy at several academic institutions. As director of the Vanderbilt Center for Health Services Research, Dr. Rothman oversees a center that engages more than 120 faculty across the university engaged in health services research, implementation science, behavioral research, health disparities research, quality improvement research, and other areas aimed at improving health outcomes.

Rima Rudd, Sc.D., M.S.P.H., is the Senior Lecturer on Health Literacy, Education, and Policy at the Harvard School of Public Health. Her work centers on health communication and on the design and evaluation of public health community-based programs. She has been teaching courses on innovative strategies in health education, program planning and evaluation, psychosocial and behavioral theory, and health literacy since 1988. Dr. Rudd is focusing her research inquiries and policy work on literacy-related disparities and literacy-related barriers to health programs, services, and care, working closely with the adult education, public health, oral health, and medical sectors.

Dr. Rudd wrote several reports that help shape the agenda in health literacy research and practice. They include the health literacy chapter of the Health and Human Services report *Communicating Health: Priorities and Strategies for Progress* (2003) and helped shape the 2010 *National Call for Action*. She coded all health related items in the international surveys for assessments of adult literacy skills enabling the United States, Canada, Australia, New Zealand, and other countries to assess national health literacy skills. She authored the Educational Testing Services report *Literacy* *and Health in America* (2004) and contributed to other national assessments. Dr. Rudd provided two in-depth literature reviews (Review of Adult Learning and Literacy volume 1 in 2000 and volume 7 in 2007). She served on the IOM Committee on Health Literacy, the National Research Council Committee on Measuring Adult Literacy, the National Institute of Dental and Craniofacial Research Workgroup on Oral Health Literacy, on the Joint Commission Advisory Committee on Health Literacy and Patient Safety and contributed to the ensuing reports and white papers as well as to several IOM Health Literacy Round Table publications. She has received national and international awards for her work in health literacy. Most recently, the University of Maryland named a doctoral scholar's award in her honor.

Barbara L. Schuster, M.D., MACP, is Campus Dean, Georgia Regents University/University of Georgia Medical Partnership. Previously, she was a professor of internal medicine at Wright State University and the former chair of the Department of Internal Medicine for nearly 12 years. During the 2007-2008 academic year, she was a Robert G. Petersdorf Scholar-in-Residence at the Association of American Medical Colleges (AAMC). Before accepting the chair position at Wright State University, Dr. Schuster was program director of the Primary Care Program in Internal Medicine and the combined Internal Medicine/Pediatrics Program in Rochester, New York. She completed an undergraduate degree in Biology and a master's of Science in Education at the University of Pennsylvania. She received her M.D. from the University of Rochester and completed her residency in the Associated Hospitals Program in Rochester.

Dr. Schuster is a past president of the Association of Professors of Medicine and served on the Board of the Alliance for Academic Internal Medicine. She is also a former president of the Association of Program Directors in Internal Medicine. She served as the chair of the Council of Academic Societies of AAMC in 2003-2004 and served 6 years on the Executive Council of AAMC. Dr. Schuster also has been actively involved in ACP. As a Regent, she served on the Recertification Committee and the Nominations Committee. She chaired the Awards Committee, ACP Education Committee, and ACP Foundation Board of Trustees. She was honored with Mastership in ACP in 1996.

Steven M. Teutsch, M.D., M.P.H., was formerly the chief science officer of Los Angeles County Public Health, where he worked on evidence-based public health and policy. He had been in the Outcomes Research and Management program at Merck, where he was responsible for scientific leadership in developing evidence-based clinical management programs, conducting outcomes research studies, and improving outcomes measurement to enhance quality of care. Prior to joining Merck, he was director of the Division of Prevention Research and Analytic Methods (DPRAM) at CDC, where he was responsible for assessing the effectiveness, safety, and cost-effectiveness of disease and injury prevention strategies. DPRAM developed comparable methodology for studies of the effectiveness and economic impact of prevention programs, provided training in these methods, developed CDC's capacity for conducting necessary studies, and provided technical assistance for conducting economic and decision analysis. The Division also evaluated the impact of interventions in urban areas, developed the *Guide to Community Preventive Services*, and provided support for CDC's analytic methods. He has served as a member of that Task Force and the U.S. Preventive Services Task Force, which develops the *Guide to Clinical Preventive Services*. He was also in America's Health Information Community Personalized Health Care Workgroup and the Evaluation of Genomic Applications in Prevention and Practice (EGAPP) Workgroup. He chaired the Secretary's Advisory Committee on Genetics Health and Society; served on and has chaired IOM panels, Medicare's Evidence Development and Coverage Advisory Committee, and several subcommittees of the Secretary's Advisory Committee on *Healthy People 2020*. He has been on multiple IOM panels.

Dr. Teutsch came to CDC in 1977, where he was assigned to the Parasitic Diseases Division and worked extensively on toxoplasmosis. He was then assigned to the Kidney Donor and subsequently the Kidney Disease Program. He developed the framework for CDC's diabetes control program. He joined the Epidemiology Program Office and became director of the Division of Surveillance and Epidemiology, where he was responsible for coordinating CDC's disease monitoring activities. He became chief of Prevention Effectiveness Activity in 1992.

Dr. Teutsch received his undergraduate degree in biochemical sciences at Harvard University, an M.P.H. in Epidemiology from the University of North Carolina School of Public Health, and his M.D. from Duke University School of Medicine. He completed his residency training in Internal Medicine at Pennsylvania State University, Hershey. He has been certified by the American Board of Internal Medicine and the American Board of Preventive Medicine, and is a Fellow of the American College of Physicians and American College of Preventive Medicine. Dr. Teutsch is an adjunct professor at the Emory University School of Public Health, Department of Health Policy and Management; University of North Carolina School of Public Health; adjunct professor at the University of California, Los Angeles, School of Public Health; and Senior Scholar at the Schaeffer Center at the University of Southern California.

Dr. Teutsch has published more than 200 articles and 8 books in a broad range of fields in epidemiology, including parasitic diseases, diabetes, technology assessment, health services research, and surveillance.

Michael S. Wolf, M.A., M.P.H., Ph.D., is professor of medicine, associate division chief (Internal Medicine & Geriatrics), and director of the Health Literacy & Learning Program within the Feinberg School of Medicine, Northwestern University. He also holds appointments in Cognitive Sciences, Communication Studies, Medical Social Sciences, Psychiatry & Behavioral Sciences, and Surgery. As a health services researcher and cognitive-behavioral scientist, Dr. Wolf has extensively studied cognitive, psychosocial, and health-system determinants of health, specifically in the area of health literacy and health communications research. His work has primarily focused on understanding health care complexity; Dr. Wolf has led several large-scale, pragmatic trials to evaluate multifaceted interventions to promote patient engagement in health, targeting chronic disease self-management, medication safety, and adherence.

Winston F. Wong, M.D., M.S., serves as Medical Director, Community Benefit, Kaiser Permanente, and is responsible for the organization's partnerships with communities and institutions in advancing population management and evidence based medicine, with a particular emphasis on safety net providers and the elimination of health disparities. As a Captain of the Commissioned Corp of the U.S. Public Health Service from 1993 to 2003, Dr. Wong was awarded the Outstanding Service Medal. Wong currently has served on a number of national advisory committees, including those sponsored by the National Quality Forum, Centers for Medicare & Medicaid Services, and the IOM, addressing issues of access and quality for diverse populations, most recently as a member of the IOM Committee on the Integration of Primary Care and Public Health. In 2013, Dr. Wong was appointed to the IOM's Board on Population Health and Public Health Practice. He is also a Board member of The California Endowment, the Essential Hospitals Institute, and the School Based Health Alliance. Bilingual in Cantonese and Toisan dialects, and a graduate of the University of California, Berkeley, and the University of California, San Francisco, School of Medicine, Dr. Wong continues a small practice in Family Medicine at Asian Health Services, a federally qualified health center based in Oakland, where he previously served as Medical Director. Dr. Wong was featured as a "Face of Public Health" in the May 2010 issue of the *American Journal of Public Health*.

Victor Yung-Tao Wu, M.D., M.P.H., is the managing director for clinical transformation at Evolent Health, a Population Health Services organization. Before joining Evolent, he served as a 2013-2014 White House Fellow in the HHS Office of the Secretary. He was involved in the ACA outreach and enrollment and worked on the President's My Brother's Keeper initiative, among other projects, during his time as a Fellow. Dr. Wu completed his medical school, public health, and residency training in Primary Care Internal Medicine at Emory University. He also served as chief medical resident at Grady Memorial Hospital, during which time he collaborated with the IOM Roundtable on Health Literacy to develop a Health Insurance Literacy toolkit and consumer education series around the basics of health insurance. His completed his undergraduate studies at Vanderbilt University in Biomedical Engineering.