

**Eradicating Low Health Literacy:
The First Public Health Movement of the 21st Century**

**Overview*
White Paper**

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- = This document represents a brief overview of important health literacy literature, prepared on behalf of Pfizer Inc.

White Paper on Eradicating Low Health Literacy: The First Public Health Movement of the 21st Century

INTRODUCTION

Over the last 10 years, the consequences of low health literacy have emerged as a major public health issue in the United States because of their devastating effect on the nation's overall health and health care systems. From the first published paper in 1990 to an Institute of Medicine report on Health Literacy expected in 2004, hundreds of articles have been published on the subject of health literacy. This issue now is taking center stage in the nation's health care dialogue and debate.

Low health literacy affects every person in the United States regardless of their age, race, education or income. It costs the country tens of billions of dollars each year, and yet it can't be detected by a physical examination, blood test or state-of-the-art diagnostic imaging system. Health literacy becomes even more important as patients are asked to take a more active and accountable role in their own health care.

This white paper explores how health literacy is defined, the scope of the problem, its methods of identification, the extent of its consequences, the range of solutions and possible responses that the nation could take as it attempts to address the first public health crisis of the 21st century.

DEFINING HEALTH LITERACY

Health literacy can be defined simply as the ability to read, understand and act on health information. Low, or inadequate, health literacy is far from being simple, as it affects people of all ages, races, educational levels and social classes, and is driven by a variety of social,

economic, cultural and other factors. Dr. David Baker notes that health literacy is “far more than a reading problem.”¹

Health literacy is a multidimensional issue. The understanding of written materials and the adequacy of patient-provider communications have been the subject of extensive health literacy work to date. Cultural relevance and sensitivity also have become part of the mix, as the diversity of the U.S. population, which requires that appropriate messages and images be tailored to meet the diverse values, beliefs and traditions of those receiving the information.

It is important to distinguish health literacy from health education and health communication. Health literacy is the goal; health education is one tool for reaching that goal. Similarly, the terms "health literacy" and "literacy" should not be freely interchanged. Health literacy encompasses more than just the ability to read written materials; it also means understanding the information so that a person can take an active role in managing his or her health.

THE SCOPE OF THE HEALTH LITERACY PROBLEM

The 1992 National Adult Literacy Survey, conducted by the U.S. Department of Education, reported that more than 90 million people in the United States have difficulty reading.² It is reasonable to assume, therefore, that the health of these individuals may be at risk when they are presented with written information related to their health.

Ethnic minority groups are disproportionately affected by low health literacy even though the majority of people with low literacy skills in the United States are white, native-born Americans. The latter group represents the largest segment of the population. Others who are

especially vulnerable to low health literacy include older patients, recent immigrants, people with chronic diseases and those with low socioeconomic status.

Some people at risk for low health literacy may have average or even strong literacy skills but, nonetheless, find medical terminology and medical concepts confusing.

Most adults are also confused by informed consent documents and insurance forms. In a study of patients with inadequate health literacy, 81 percent could not read the rights and responsibilities section of a Medicaid application, and 74 percent did not know whether they were eligible for free care.³

Information Gaps

Bridging the information gap between patients and their health care providers is the first major hurdle to improving health literacy. According to a Roper poll in 2002, 70 percent of physicians say they provide patients with additional resources that help them understand their medications, but just 41 percent of those patients say they have received this kind of assistance. This research provides tremendous evidence of a broad information gap that needs to be addressed.⁴

The information gap extends beyond medication management, however, to all communications between health care professionals and patients. Many patients simply are either unaware of or unwilling to admit to having difficulty with health care information. Interestingly, the studies show that even though individuals don't think they have a problem themselves, they believe others do.

- In one recent study, only 17 percent of patients reported that they sometimes or very often have trouble reading or understanding medical instructions, and just 14 percent stated that they felt awkward admitting that they found such information difficult to understand.

- Although most patients reject the notion that they personally have experienced difficulty with health information, 79 percent of those surveyed stated that they believe that many *other people* have difficulty.
- Nine out of 10 of the patients surveyed reported that they always read the instructions given to them by health care providers, but revealingly, they estimated that just 34 percent of *other people* do so.⁴

Among the implications of these findings is the fact that providers cannot rely on patients to share their difficulties in understanding. Furthermore, there are social consequences to be faced. People with low health literacy skills also have more problems connecting with and feeling a part of the social structure and communities around them.¹¹ As discussed earlier, many individuals have learned to compensate for their literacy limitations. The anxiety that accompanies some of the compensating behaviors mentioned can serve to alienate these people from others if they keep this information to themselves. That is why it is so important to strive toward a solution.

METHODS OF IDENTIFICATION

The Warning Signs of Low Health Literacy

Just as people with low levels of general literacy have developed a number of clever and successful coping strategies that allow them to conceal their problems, people with low health literacy are experts at concealing their limitations as well.

There are a number of warning signs that identify patients who may be having difficulty understanding the medical information they are receiving. When people are embarrassed, intimidated or confused during medical encounters, they are likely neither to ask questions nor seek further clarification from their health care providers. As a result, it is important that the health care provider be alert to nonverbal cues.

Some patients bring with them a friend or family member who can assist with reading or who can serve as a “second set of ears.” Patients may also watch the behavior of others in the same situation and copy their actions. Some ask for help from the medical staff, while others may ask for assistance from other patients.

Other clues that signal that a patient may have poor health literacy skills include:

- Registration and other forms filled out incompletely or incorrectly.
- Written materials handed to a relative or other person accompanying the patient.
- Statements such as “I will read this at home,” or “I can’t read this now; I forgot my glasses.”
- Aloofness or withdrawal during physician/provider explanations.
- Missed appointments, including appointments for specialty consultations or diagnostic tests.
- Frequent errors in medications or self-care instructions, which may lead the health care provider to consider the patient noncompliant.⁵

All these behaviors could signal a potential health literacy problem. If physicians and other health care professionals can recognize some of these silent signs of low health literacy, then they can reduce the negative effects of their patient’s actions. Just as important, physicians can reduce the shame and anxiety their patients may feel as a result of their lack of understanding.

Health Literacy Tests

Of the many tests that actually measure reading skills in adults, the one most often used in the setting of clinical medicine is the Rapid Estimate of Adult Learning in Medicine (REALM). The REALM test was designed for use in public health, primary care and medical research settings to identify patients with low (below the ninth grade) reading levels.⁶ This test may be administered in one to two minutes and is based on word recognition. When scored, the

test yields an approximate reading level that providers may use to tailor patient educational efforts to the needs and ability of a specific patient. The REALM is available in English.

The Test of Functional Health Literacy in Adults (TOFHLA) requires 15 to 20 minutes to administer and is available in a Spanish-language version.⁵ Recently, a Short Test of Functional Health Literacy in Adults (S-TOFHLA) has come into use in the clinical setting. The shorter version takes no more than 12 minutes to administer. The S-TOFHLA uses actual materials that patients may encounter in a health care setting.

Use of these tools, especially in high-risk environments, may appropriately target high-risk patients. Interventions can be taken immediately, thereby potentially reducing the negative consequences that may result from not being able to understand or act on health care information. The initial benefits of these tools would be to identify those at risk for low health literacy, as well as related medical and financial consequences to patients and society.

IMPACT AND CONSEQUENCES OF LOW HEALTH LITERACY

Using TOFHLA in a 1994 study, researchers found that among adults who stayed overnight in a hospital, those with low literacy skills averaged 6 percent more hospital visits and stayed in the hospital nearly two days longer than adults with higher literacy skills.⁷

That same study showed that among adults with at least one doctor visit in 1994, those with low literacy skills had, on average, one more doctor visit than adults with higher literacy skills. More important, when self-reported health status is taken into account, patients with low literacy skills had fewer doctor visits but used significantly more hospital resources.^{ibid}

Health Consequences

Only about 50 percent of *all* patients take medications as directed.³ According to Roper Research, one-third of all patients and two-thirds of physicians know someone who has had health problems because they did not understand how to take a prescription medication correctly.⁴

Other recent studies have shown that people with low health literacy are less able to comply with other prescribed treatments and self-care routines.⁵ They fail to seek preventive care, and they are at higher – more than double – risk for hospitalization.^{5, 8} And when they do seek treatment, they lack the skills needed to successfully navigate our complex healthcare system.^{ibid}

A recent study published in the *Journal of the American Medical Association (JAMA)* illustrates the correlation between low health literacy and health outcomes in patients with diabetes.⁹ Patients with inadequate health literacy were found to be less likely than patients with adequate health literacy to have effective glycemic control. Patients with low health literacy were also more likely than others to report vision problems caused by their diabetes.

Economic Consequences

The economic impact of the adverse actions related to poor health literacy skills is tremendous. Annual health care costs for individuals with low health literacy skills are *four times higher* than for those with higher health literacy skills.⁵

The National Academy on Aging Society examined the impact of literacy on the use of health care services and confirmed that people with low health literacy skills do use more of these services.¹⁰ The study showed that the estimated additional health care expenditures as a result of low health literacy skills are about \$73 billion in 1998 health care dollars. This includes

an estimated \$30 billion for the population that is functionally illiterate, plus \$43 billion for the population that is marginally literate.⁹

In a larger context, people with low health literacy skills also have more problems connecting with and feeling a part of the social structure and communities around them.¹¹ As discussed earlier, many individuals have learned to compensate for their literacy limitations. The anxiety that accompanies some of the compensating behaviors mentioned can serve to alienate these people from others if they keep this information to themselves. That is why it is so important to strive toward a solution.

THE SOLUTION

The responsibility of finding a solution to this complex issue does not belong to one individual, group or organization. It begins with communications that are culturally sensitive and that acknowledge that American society is composed of many different ethnic, cultural and linguistic groups. The solution must also recognize the importance of reducing health disparities – the differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States.

Taking Culture and Context Into Consideration

In creating educational and self-care materials, it is important to be aware of and sensitive to the intended audience's age, gender and ethnicity. In the United States, a language other than English is the primary language spoken by more than 14 percent of American residents. Beyond English, the main languages spoken in the United States today are Spanish, French or Creole, German, Chinese and Italian.

The distribution of foreign language speakers varies significantly by state. For example, 36 percent of New Mexico's population speaks a language other than English. That percentage is 31 percent in California and between 20 percent and 31 percent in Arizona, Hawaii, New Jersey, New York and Texas.

Much can and is being done to incorporate cultural issues into the definition and study of health literacy. A forthcoming study from Zarcadoolas, Lane, Blanco et al and colleagues, for example, observes that a key gap in health materials is that while these materials may often be translated, the quality of translation is culturally inappropriate for many people.¹⁷

Guidelines to Ensure Cultural Sensitivity: Involve the Audience

Health information is very personal, and the reader should feel that the materials are meant for (and relevant to) him or her. Culturally sensitive materials acknowledge cultural differences and addresses these differences in the choice of content, language and visual elements, so that the intended message is communicated accurately and appropriately to its specific audience. The most effective way to ensure that health information is culturally and personally relevant is to involve members of the intended audience in the initial design and subsequent development of the materials.

For example, Southeast Asian cultures, Vietnamese in particular, have strong traditions against talking about reproductive systems, particularly those of women. According to Orthodox Jewish law, men are prohibited from touching women (for example, shaking hands) who aren't their wives. Cultural realities must be respected because they affect the way health care information is received and acted upon.

The way in which a particular ethnic or age group expresses symptoms (pain, for example) or interprets the concept of “health” should also be kept in mind when developing culturally appropriate health information resources. Other useful guidelines include:

- Choose words and phrases that are familiar to or easily identified by the audience.
- Use language that is appropriate to the recipient.
- Suggest a clear course of action that is both within the readers’ abilities and culturally appropriate.
- Avoid overuse of negative wording (“Don’t eat...” or “You shouldn’t...”).
- Use graphics that are relevant to the intended audience.

Even the choice of the communications media should be evaluated for relevance and effectiveness. Written documents, for example, may be less effective than television and radio messages for some cultural or age groups.

Effective Health Communication: The Foundation for Solutions in Health Care Delivery

Effective health communication is the very foundation of the healthcare delivery system. Inadequate communication affects the spectrum of care, from prevention and screening to history taking and explaining diagnosis and treatment.⁵ As a result, tools and interventions to improve understanding of health information for *all* patients must be integrated into written and oral communications among caregivers, public health officials, patients and the general public.

Although the greatest immediate impact may be focusing on the patient-provider relationship, addressing this crisis in a meaningful way must go beyond focusing solely on the doctor/patient dynamic. Holistic approaches that embrace participatory group learning environments, empowerment health education and peer interaction will be equally critical, as will be the involvement of our public and private institutions. Health care providers have the opportunity to effectively communicate with patients during the individual encounters in which

they diagnose, treat or help patients to incorporate preventive health behaviors. On the other hand, information providers have the opportunity to incorporate clear health communication into their informational pieces, written or verbal, to impact the masses being exposed to the information. Larger scale initiatives are examined later in this document, under the section “Where Do We Go From Here.” First, however, is the need to address the basic undercurrent of health literacy and its negative consequences.

Health Care Provider Tools

Create a Blame-Free Environment

It is important for health care providers who encounter an individual exhibiting signs of low health literacy to create a “blame-free” environment in which the individual with low health literacy skill levels can seek help without feeling ashamed or stigmatized.

In a health care environment, there are many clues that should lead the medical staff to suspect a reading difficulty, as discussed earlier in this document. For example, if a patient does not know the names of the medicines that he or she has been taking for a long time or whether he or she makes excuses for not reading the prescription label when asked to do so. These are indications that further assessment may be necessary.

Coping Tips

- If a provider suspects that a patient may have a health literacy problem, he or she might say to the patient, “A lot of people have trouble reading and remembering these kinds of materials (or instructions). Is this ever difficult for you?”
- Having patients repeat the information or instructions as they would tell them to a friend (the “teach-back” method) is an easy way to verify that they understand what they are supposed to do.¹⁴
- It may also be useful to ask the patient, “Is there someone who helps you remember to take your medicine?” That person will often be the surrogate reader for the patient, so the provider should help him or her – often a family member of the patient – to

understand the care instructions so that he or she can reinforce the provider's teaching when the patient is at home.

- Finally, it's often valuable for providers to suggest peer-group environments, such as literacy or health education classes, where their patients will benefit from interacting and being part of a larger community facing similar challenges.

Rethink Spoken Communication

In addition to understanding written communications, adequate health literacy also means that a person can understand and engage in spoken language communication, or dialogue, that occurs in a wide range of health contexts. For example, conversations with physicians, nurses, pharmacists and insurers occur more frequently than they do in written materials. Being able to discuss and ask questions is necessary to all aspects of healthy behaviors and to informed decision-making. There is a large body of research in the areas of sociolinguistics, anthropology and reading research that discusses both the similarities and differences between spoken and written language.

Brown University sociolinguist Christina Zarcadoolas notes that, "There is no one-to-one correspondence between the spoken and the written. One common example of this is that people often understand words, or a string of spoken directions that they cannot understand if read. Similarly, people can sometimes speak in lengthy sentences that they could not read with understanding. People's abilities to use vocabulary and sentence structure in speech usually are a few grade levels above what they can read." ¹⁴

Clearly, knowledge of the important relationship between spoken language competency and reading abilities can be useful to those working in health literacy. More work remains to be done in this area, however.

Information Provider Tools

Revise Written Materials for Greater Understanding

Although innovative alternatives to written materials, such as pictograms, comic strips, videos and graphics-rich computer-based training programs, should be explored more fully, often the use of written materials cannot be avoided. Letters, forms, discharge instructions and even hospital signage all require the use of the written word.

The solution is that written materials for people with low health literacy be aimed at the sixth-grade reading level. Most patient education materials and brochures currently included with medications are written at a 10th-grade reading level or above.¹⁵

Simple words and short sentences, larger type and generous use of “white” (unprinted) space should be used when developing these documents. Complicated medical or technical words should be replaced with simpler choices.

Comic-strip formats have been found to be very useful for presenting a range of patient information and self-care regimens to patients with low health literacy skills.⁵

When using comic-strip formats or other forms of illustration, however, care should be taken to ensure that readers don't find the materials condescending. The objective for any pictorial or simple image is the same as it is for written materials, that is, to deliver key messages. Images, therefore, should focus on desired behavior rather than on medical facts, and the information should be both culturally sensitive and personally relevant.^{15,16}

Existing Health Literacy Initiatives

Over the past two decades, more and more health care organizations and institutions are recognizing that low health literacy is having an impact on the nation's health. Some provider organizations (including hospitals and health clinics), payer organizations (including health insurance companies and federal and state funding organizations), pharmaceutical companies and disease-focused organizations are addressing health literacy challenges in varying ways.

Some of the basic efforts these organizations are undertaking include:

- Simplifying the language in printed materials.
- Designing print materials in several languages.
- Hiring multilingual staff.
- Creating more culturally sensitive materials.
- Offering cultural sensitivity training for staff.

Pfizer's Commitment to Health Literacy

Pfizer is fully committed to raising awareness of the health literacy issue, and the company is actively committed to developing real-world strategies for addressing – and overcoming – this national public health problem. Pfizer has supported more than five years of research (in both academic and clinical settings) to determine the causes of inadequate health literacy, the scope and impact of the problem, and to begin to develop workable solutions.

Some of the company's health literacy efforts include:

- Creating a strategic partnership with the American Medical Association Foundation [AMAF] to raise awareness and understanding of health literacy among physicians and other health care professionals and to develop tools that will improve communications with patients. Pfizer has awarded a two-year grant to the AMAF that will be used to develop a tool kit and a Web site, and grants to support physician-focused health literacy programs and media outreach efforts.

- Supporting programs to build the health literacy research base, to provide training on health literacy issues to health care organizations and voluntary health associations, and to communicate the importance of health literacy to the public.
- Applying the Pfizer Principles for Clear Health Communication to patient education materials developed for all consumer communications related to diseases and products and providing these materials, along with customized training in their use, to health care and advocacy groups.
- Supporting the Florida Health Literacy Study, a clinical trial at the University of South Florida, designed to determine the most effective interventions for improving health outcomes for patients with diabetes or hypertension.
- Conducting community-based initiatives with national patient advocacy groups in association with the National Health Council and other health-related organizations.
- Sponsoring an annual national conference on health literacy.
- Awarding research grants to health care and academic institutions to develop and test health literacy interventions.

All of these programs represent the first steps in a far-reaching Pfizer health literacy initiative that will continue to grow in strength and influence as this public health issue becomes a public health priority.

No one organization can advance health literacy alone. By leveraging the work of the many organizations that are addressing this issue, Pfizer serves as the convener of a new coalition that is hoped to radically impact the nation's health. The Partnership for Clear Health Communication is a coalition of national organizations that are working together to promote awareness and solutions around the issue of low health literacy and its effects on health outcomes. The Partnership Steering Committee includes the following organizations:

American Federation for Aging Research
 American Medical Association Foundation
 American Nurses Association
 American Pharmacists Association
 American Public Health Association
 David Baker, MD
 California Literacy, Inc.

National Alliance for Caregiving
National Alliance for Hispanic Health
National Association of Community Health Centers
National Coalition for Literacy
National Council of La Raza, Institute for Hispanic Health
The National Council on the Aging
National Health Council
National Medical Association
Janet Ohene-Frempong, MS
Partnership for Prevention
Pfizer Inc
ProLiteracy Worldwide

WHERE DO WE GO FROM HERE?

There is no quick fix for low health literacy, but the involvement and collaboration of providers of information and providers of care will be essential in order to raise awareness and develop solutions to improve clear health communication between patients and providers. The movement to enhance health outcomes through improved health literacy is gaining momentum. The participation of government, health care professionals and companies, patient advocacy groups, and community-based organizations and the health care system will broaden the reach of the issue of health literacy. For example, the federal government might implement health literacy demonstration programs as part of Medicare and Medicaid to help improve health outcomes.

These health literacy program elements would be particularly important in the development of documents such as the Health Employer Data Information Set (HEDIS), which is used by the National Committee for Quality Assurance (NCQA) to accredit health plans.

HEDIS documents could then be used to encourage the development and use of materials that facilitate patient understanding of health care information.

Other Efforts to Explore

Additional government efforts might include:

- Federal funding of research to better understand the scope of the health literacy problem.
- Adding health literacy evaluations and other quality improvement interventions into Medicare's current requirements for provider certification.
- Including in Medicare's *Current Beneficiary Survey* questions that assess patients' health literacy skills.
- Creating health literacy Centers of Excellence through the Health and Human Services (HHS) Agency for Health Care Research and Quality.
- Creating a clearinghouse for best practices related to addressing low health literacy.
- Helping create opportunities for increased partnerships between health and adult education researchers and practitioners.

Future research should focus on optimal methods of screening patients to identify those with poor health literacy, investigating the connections between clinical outcomes and increased costs associated with poor health literacy, determining the causal pathway between poor health literacy and health outcomes, and developing effective health education techniques.¹³

A Look Into the Future

The most effective way and a great initial step to make an impact in the short term is through patient-provider relationships. But there is so much more that needs to be done to ensure that health literacy truly is eradicated.

A true public health vision for health literacy would be one that goes beyond a focus on doctor/patient interaction; examines and addresses the social and cultural factors that impact health literacy; seeks the promotion and protection of health, and the elimination of health inequalities as a primary goal of society both in the United States and worldwide.

A commitment from public, voluntary, academic and business organizations to promote and protect public health through enhanced health literacy will empower far greater segments of the population to protect their own health and the health of others by equipping them to understand and act on health information. With this collective level of commitment from our social institutions, the emerging – and potentially devastating – public health crisis of low health literacy can be reversed, ultimately benefiting the nation’s health.

An emerging public health movement to eradicate *low health literacy*, which is preventing millions of Americans from successfully managing their health and, ultimately, leading better quality lives, is just beginning. A prophetic look into the future finds a society capable of understanding and acting upon health information as a result of action and intervention taken on behalf of those able to impact the health of large segments of our population.

Appendix I: Principles for Clear Health Communication

Pfizer, in consultation with Leonard and Cecilia Doak of Patient Learning Associates Inc.,¹⁶ Clear Language Group and other health literacy experts has developed Principles for Clear Health Communication that focus on key directives for developing written materials for patients.

Pfizer's Principles are:

- **Base the content on a written objective. Explain the purpose and limit the content.**

Explain the purpose and benefits from the patient's point of view.

Use the objective to limit the content.

Outline the sequence of topics.

Emphasize desired patient actions and behaviors.

Review key points.

- **Involve the reader.**

Create interaction with the reader/viewer.

Provide examples for concept, category and value judgment words.

Make the document culture-, age- and gender-suitable.

- **Make it easy to read.**

Use conversational style with active voice, and common words and context.

Break up complex topics.

Use "road signs" and "chunking."

- **Make it *look* easy to read.**

Allow lots of "white space" on each page; no dense text.

Use cueing to direct reader/viewer attention to key points.

Provide sharp contrast and large type.

- **Select visuals that clarify and motivate.**

Select realistic visuals; omit distracting details.

Use active captions.

For example, witness how mammography exam information is delivered in Example A – a medical model – and Example B – a patient-centered model based on the Principles.

Which do you believe is easier to understand?

EXAMPLE A (original, medical model)

An extra step: Mammography

Women in the three high-risk categories – aged 50 or older, 40 or older with a family history of breast cancer, aged 35 or older with a personal history of breast cancer – may consider an additional routine screening method. This is *X-ray mammography*.

Mammography uses radiation (X-rays) to create an image of the breast on film or paper called a *mammogram*. It can reveal tumors too small to be felt by palpation. It shows other changes in the structure of the breast that doctors believe point to very early cancer. A mammogram usually consists of two X-rays of each breast, one taken from the top and one from the side. Exposure to X-rays should be carried out to assure that the lowest possible dose will be absorbed by the body. Radiologists are not yet certain whether there is any risk from one mammogram, although most studies indicate that the risk, if it does exist, is small relative to the benefit. Recent equipment modifications and improved techniques are reducing radiation absorption and, thus, the possible risk.

EXAMPLE B (revised, patient-centered model)

What is a mammogram and why should I have one?

A mammogram is an X-ray picture of the breast. It can find breast cancer that is too small for you, your doctor, or nurse to feel. Studies show that if you are in your forties or older, having a mammogram every 1 to 2 years could save your life.

How do I know if I need a mammogram?

Talk with your doctor about your chances of getting breast cancer. Your doctor can help you decide when you should start having mammograms and how often you should have them.

Why do I need one every 1 to 2 years?

As you get older, your chances of getting breast cancer get higher. Cancer can show up at any time – so one mammogram is not enough. Decide on a plan with your doctor and follow it for the rest of your life.

Where can I get a mammogram?

To find out where to get a mammogram:

- Ask your doctor or nurse.
- Ask your local health department or clinic.
- Call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER.

Pfizer is committed to including the Principles for Clear Health Communication in the development of its patient-directed communications, and the company is encouraging and training other organizations to use the principles in the development of their own health information materials for a wide range of consumer audiences.

Renowned health and literacy experts, Leonard and Cecelia Doak, in addition to contributing to the development of Pfizer's principles, have created their own list of five principles:

- Define the behavioral objective(s) of the material.
- Determine the key information points the reader needs in order to achieve the behavioral objective(s).
- Select the most appropriate presentation method(s) (e.g., audio, audiovisual, print, radio, TV, interactive computer programs).
- Decide on the reading level of the material if you select a print presentation.
- Organize the topics in the way the person will use them.

In addition, the National Institutes of Health, along with the National Cancer Institute, have created the following guidelines for developing print materials:

- Define the target audience.
- Conduct target audience research.
- Develop a concept for the product.
- Develop content and visuals.
- Pretest and revise draft materials.

Likewise, CMS (formerly HCFA) has produced a six-step model for developing and testing print materials:

- Identify the goal and intended audience.
- Do research to learn about the audience and issues.
- Develop and test the materials.
- Distribute the materials.

- Assess the overall effectiveness.
- Use feedback to make further improvements.

While differing in certain ways, all of these guidelines share a common approach of developing clear, easy-to-read materials that are tailored to the needs of the target audience.

Appendix II: The Fry Testing Readability Formula

Reading skills in terms of U.S. school grade levels can be closely approximated by a formula. These formulas, however, do not take into account many important factors that contribute to making something easy or hard to read, such as how logical the writing is, or how conceptual or abstract the information is. Formulas, for the most part, are applicable to narrative language (running text) but not to lists, charts and tables. The majority of formulas establish readability based on two factors:

- The number of difficult words (usually words with three or more syllables) in a sample. Difficult words mean more syllables in the sample and a higher grade level.
- The average length of sentences. Longer sentences with more words than in the average sentence translate to a higher grade level.

While many formulas – both manual and computerized – exist, Pfizer has chosen to use the Fry formula as part of its Principles for Clear Health Communication. Fry was selected because it:

- Is easy to use and takes only about 15 to 20 minutes to obtain results.
- Uses reasonably small sample sizes (100 words), making it suitable for both short and long documents.
- Reveals which types of words and sentences are difficult.
- Is well-recognized within the reading community.
- Is not copyrighted.

Fry specifies sample sizes of 100 words each. Except for very short pieces, three or more samples are selected and then an average is calculated. The reason for selecting three samples is that the readability levels are often not uniform throughout the text. One could be misled if only one sample were used. For more information about the Fry Formula, consult:

http://www.pfizerhealthliteracy.org/part4using_readability_formulas.pdf

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