HEALTH LITERACY INITIATIVE

A KEY LEVER IN IMPROVING HEALTH

SEPTEMBER 2017

Market Researchers' Responsibility and Opportunity
By the PMRG Health Literacy Initiative Committee

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Low health literacy is related to medication errors, device misuse, lower compliance, and poor health, but is traditionally not considered in market research studies. The purpose of this article is to raise awareness of how health literacy could be used as a lever to improve public health, while challenging market researchers to consider health literacy as both a responsibility and an opportunity in their research designs.

THIS ARTICLE PRESENTS:

I. Evidence of the negative impact of low health literacy on compliance.
II. The challenge low health literacy presents to market research.
III. Results from two market research studies:
    a. Healthcare practitioners
    b. Patients
IV. Market researchers' responsibility and opportunity.
V. The PMRG Health Literacy Initiative's purpose and how to get involved.

I. Evidence of the negative impact of low health literacy on compliance.

Patients' well-being suffers with poor understanding of their health and available treatments. Device and medication misuse can cause problems for patients' health.

FACTS

In the U.S., some 3.8 billion prescriptions are written every year.

More than half of those prescriptions, however, are taken incorrectly or not at all.[2]

In a survey of 1,000 patients, **nearly 75%** admitted to not always taking their medications as directed.[3]

A study of over 75,000 commercially-insured patients found that **30%** failed to fill a new prescription.[4]

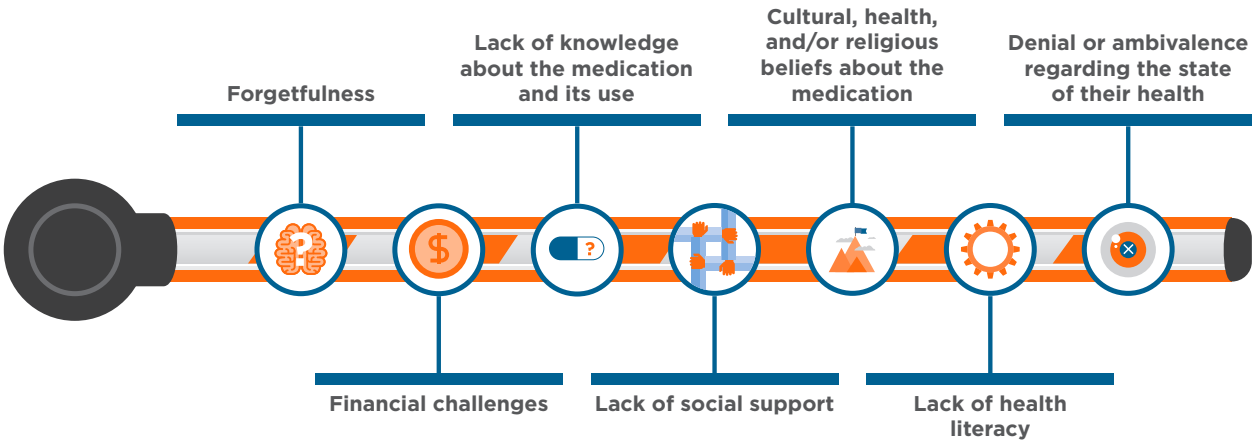
It is estimated that poor compliance costs the US healthcare system $290 billion each year.[5]

> *Every two minutes someone calls a U.S. poison control center about a medication error. They took the wrong dose, took the medicine twice or accidentally took someone else's, among other mistakes.*[6]

> *Researchers found that serious medical errors doubled from 2000 to 2012.*[7]

There are many explanations as to what leads to medication errors, device misuse, and lower compliance. With an aging population, there has been an increase in the number of medications – with different dosing schedules – given to individual patients to treat a variety of chronic medical conditions. This can lead to confusion over treatment schedules. There can also be contraindications among various medications resulting in unintended side effects or other problems affecting adherence to a prescribed plan.

In 2009, Kaiser Permanente conducted an exhaustive literature review on the topic of non-compliance and found seven patient-related barriers to compliance.[8]



Although high cost of medications is often referenced as a major reason for poor adherence, compliance rates improve only marginally when the cost barrier is removed. Health literacy may be a key lever to improving patients' health.

THE ROLE OF HEALTH LITERACY

The key to understanding and improving compliance is the role of health literacy, which has been defined as "the degree to which individuals have the capacity to obtain, process, understand, [and act upon] basic health information and services needed to make appropriate health decisions."[9] Multiple studies suggest a link between low health literacy and low comprehension.

Research shows only 12% of the population is health literate.[10] People with low health literacy may not understand their health issues (e.g., diabetes, high blood pressure, high cholesterol). This lack of understanding can result in devaluing its treatment, which can negatively impact their health in the long term.

While certain populations are at greater risk for experiencing limitations on their health literacy (e.g., individuals who speak English as a second language), the state is by no means static. Rather, health literacy is dynamic, changing for individuals based on the context of any given situation. Even people with advanced education and reading skills can face health literacy challenges. Consider the stresses imposed by health emergencies. At such times, even the most health literate individual may experience difficulties understanding or processing health information. Simpler and easier-to-understand patient materials, therefore, benefits everyone.

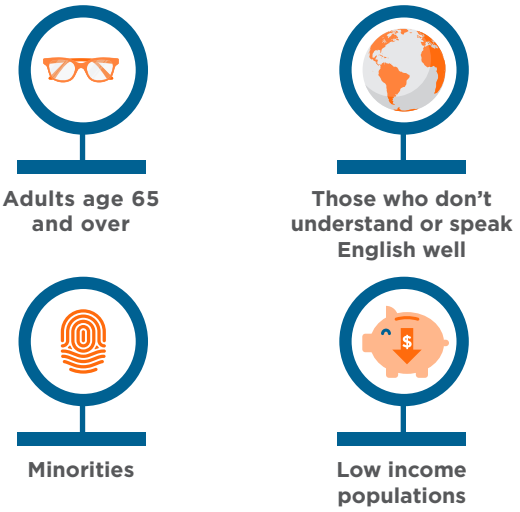
Those with Limited Health Literacy are less likely to understand:[11,12]

- Terminology
- Risks
- Benefits

Lower health literacy has been linked to poorer overall health outcomes.

- Higher rates of hospitalization than in individuals with higher health literacy.[13,14,15]
- Higher mortality rates than in individuals with higher health literacy.[16]
- Though the link is not definitive, the relationship between health literacy and outcomes likely reflects inadequate self-care behaviors.

Many factors affect a person's health literacy skills, including a person's reading skills, age, culture, the complexity of information, and language.[17] Some population groups are particularly vulnerable to health literacy challenges; these include:[18]



II. The Challenge Low Health Literacy Presents to Market Research.

There are four main challenges that low health literacy presents to market research:

Recruitment. Patients with low health literacy are traditionally screened out of samples because researchers want respondents who can understand the information provided in the study and can effectively communicate their feedback. This common practice leads to the exclusion of an important segment of the population. When the study has implications for communications to patients, such as patient education materials or instructions on using a device, this approach is not only deficient in research design, but it also doesn't allow for the learnings that will help create materials that can be better and more easily understood. It is difficult to recruit people with low health literacy and the tools are still being developed. While the Newest Vital Signs (NVS) tool (a tool we recommend for identifying people with low health literacy) has been validated for in person research, it has not yet been validated for online research. Work is ongoing in how to properly screen for health literacy.

Participation. Patients who are lower in health literacy tend to be more reluctant to participate and voice their opinions. This lack of participation arises from lower confidence or embarrassment in their abilities, such as having difficulties speaking, reading, and/or understanding – whether it is a challenge with the English language or medical terminology. Researchers must change the way they collect their data in order to make this work. For example, during in-person research, moderators should provide extended warm-up time at the beginning of the interview to build trust. They should also understand that bland or non-committal participation (e.g., "yes I agree," "no I do not like that") are a signal of potential problems, and thus be prepared to shift activities as needed to get more involved participation and better data.

Analysis. Once included into the research, data for low health literacy patients should be analyzed separately from those with adequate literacy to ensure the needs of this at-risk group are not missed. With the proper data collection techniques, researchers should have uncovered the true reactions of the low health literacy group to be included in consideration, rather than being lost in background noise.

Stimuli. The stimuli used in research – which is often closely linked to the actual communication to the patients – should be formatted to follow best practices for health literacy.

Best practices for health literacy

VOCABULARY/LANGUAGE USE

Ensure the vocabulary and language are appropriate for the intended audience

Avoid jargon, abstract words, technical terms, statistics, abbreviations and acronyms

Use words that are familiar to the audience and have 2 syllables or less

SENTENCES/PARAGRAPHS

Use conversational style with an active voice

Use sentences and paragraphs that are short, simple and direct

Avoid large blocks of text

CONTENT/SCOPE

Limit content to essential, "need to know" information

Limit the number of concepts, points and messages

Focus material on behaviors, skills and "how to" information

Provide action-oriented materials, not just facts

GROUPING/CHUNKING

Group "like" information into smaller, logical pieces

Use short, simple and explanatory headings to organize information

FONT SIZE & STYLE

Use a type size that is easy to read and as large as possible (at least 12 point)

Avoid using all caps

WHITE SPACE

Balance white space with words and illustrations

Separate paragraphs and topics with one or two lines

JUSTIFICATION

Leave text flush left and right edges ragged

GRAPHICS

Include graphics that support, emphasize and reinforce important points but don't compete with them

Use graphics that are relevant to the topic and the audience

Avoid complicated diagrams, graphs and technical visuals

Resources

Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2013). CDC Clear communication ndex: a tool for developing and assessing CDC public communication products: user guide. http://www.cdc.gov/ccindex/

Doak, C., Doak, L., & Root, J. (1996). Teaching patients with low literacy skills (2nd ed.). Philadelphia: J.B. Lippincott Copyright ©

Two research studies were undertaken to better understand how market research may be affected by low health literacy challenges, and to quantify the impact that utilization of health literacy best practices may have in market research.

III. Results from Two Market Research Studies.

In an effort to better understand health literacy, the PMRG Health Literacy Initiative (HLI) Committee conducted two market research studies, one with healthcare practitioners and another with patients. As noted above, special efforts were taken to include low health literacy patients who are not usually included in traditional market research studies.

HEALTHCARE PRACTITIONER STUDY (CONDUCTED BY DOCTOR DIRECTORY)

Sample and Method. Physicians (n=100) and pharmacists (n=50) were asked in an online 10-minute survey about compliance and communication with their high blood pressure patients.

Key Findings. In terms of compliance, there is a disconnect between the physicians and the pharmacists. From the physician perspective, most of their high blood pressure (hypertension) patients understand their prescription instructions and are taking their medication as prescribed.

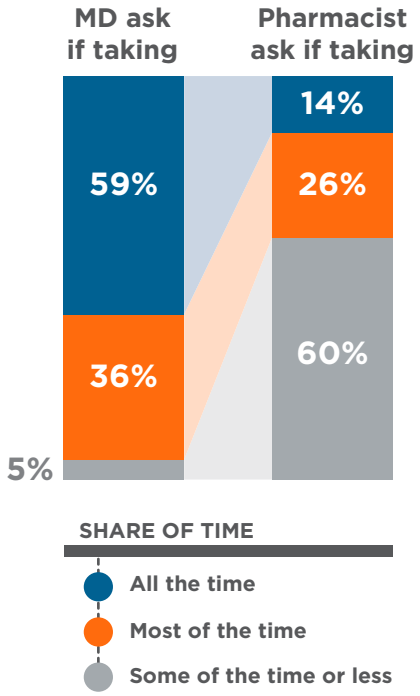
Physicians believe:

- 78% of patients are taking their medication as prescribed.
- 88% understand how to take their medication.

Pharmacists provide a less optimistic patient compliance story. Most pharmacists say:

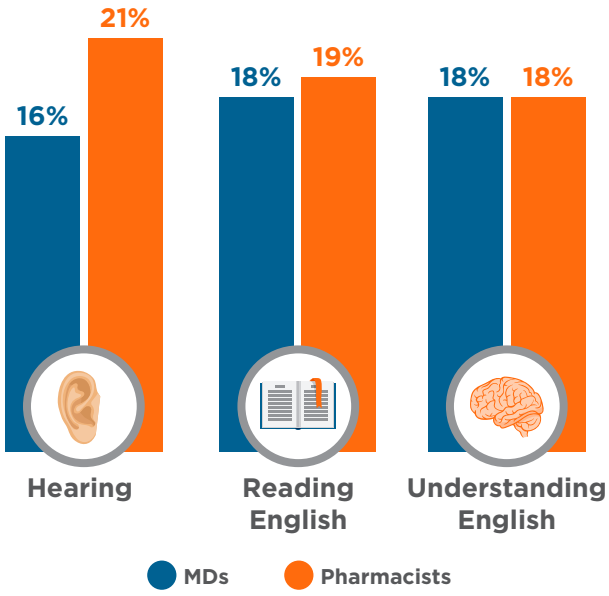
- Up to 24% of hypertensive prescriptions are abandoned.
- Up to 24% of initial starts are not refilled.
- Up to 49% are refilled late.

This gap between physicians and pharmacists perception on patient compliance is concerning, and there is no formal process connecting physicians and pharmacists to allow feedback on medication compliance. In term of communication with the patients, doctors and pharmacists have two different roles. Doctors are focused more on telling patients how to dose and asking if they are taking their medication during follow-up visits when they occur, while pharmacists are not directly asking if patients are taking their medication. There is a gap in care between the roles of physician and pharmacist that widens with low health literacy.



Physicians and pharmacists agree that between 15 and 20% of patients have hearing difficulties or difficulties with understanding or reading English.

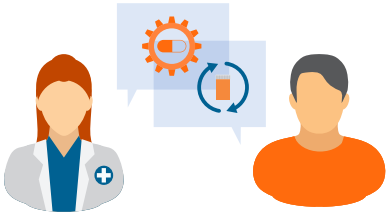
Perceptions of percentof patients having difficulty



Health literacy is not mentioned when physicians are probed as to what triggers them to ask compliance questions of patients. This is the case despite physicians recognizing that some of their patients may experience communication challenges (e.g., hearing difficulties, limited ability to read and/or understand English, etc.).

Triggers to ask About Compliance

About 60% of doctors indicated that there are particular circumstances in which they will ask about drug compliance.



Conversation Triggers

- Lack of efficacy. (26 mentions)
- Patient hasn't called for refills for their Rx. (11 mentions)
- Patient has previously demonstrated lack of compliance. (10 mentions)
- Patient on multiple meds. (9 mentions)
- Cost is a concern for patient. (8 mentions)
- * Perceived health literacy is not a trigger

None of the mentioned triggers validate if a patient understands their diagnosed condition, nor the short and long term benefits of their treatment.

As we see in the above research, non compliance may be worse than physicians are aware because there is no formal feedback for when a patient fills, takes or stops taking a medication. There is no understanding of why a patient doesn't start or stops taking a medication. Without feedback, no follow-up conversations can occur and education on the condition, benefits of treatment, or safety concerns cannot be addressed.

Patient Study.
(Fielded by MarketVision Research)

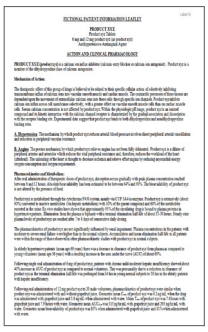
For the patient study, the objectives were to:

- Assess individuals' health literacy.
- Assess comfort with filling out medical forms.
- Determine how an individual's health literacy impacts their ability to read a medication label.

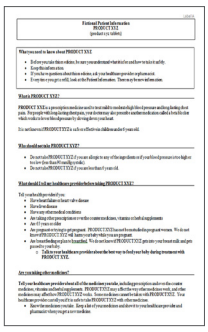
Sample. Research was conducted with 805 patients, half of whom had high blood pressure (hypertension) and half among the general population. Special recruitment was in place to ensure adequate numbers of patients with low income and low education. Respondents completed a 10-minute online survey.

Method. Although the Newest Vital Sign (NVS) has only been validated for in-person research, we adapted the tool for online use. A component of this research was used to understand how the NVS may be administered online. The measure used was a series of 6 questions about an ice cream nutrition label. Later in the survey, respondents were given a series of five questions about a drug label. Respondents were grouped into adequate vs. limited health literacy based on their score. Half of each group was randomly given the traditional label and half was randomly given the optimized label.

Traditional Label



Optimized Label

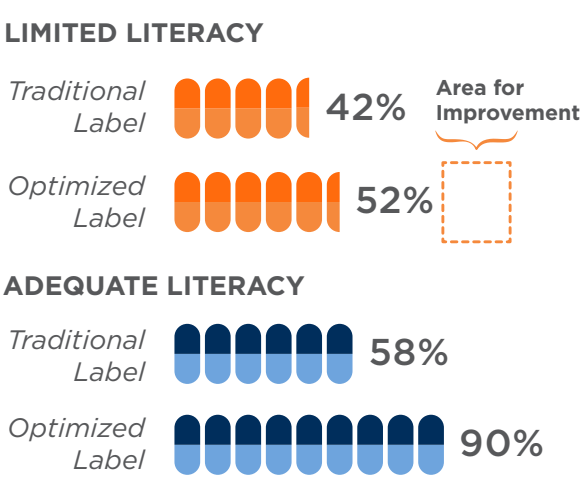


Stimuli. For the purposes of this study, the traditional pharmaceutical label was modified into the optimized label by following some of the health literacy best practices described in the list above. This was a proof of concept study, to allow us to document the effect a minimum change would have. If this were an actual market research study for a product to be launched, we would recommend engaging a health literacy consultant and conducting research with people who have low health literacy.

Key Findings. Contrary to expectations, the improved label did not have a big effect among those with low health literacy, with only slightly improved comprehension of the product label. This highlights the importance of additional work such as including low health literacy respondents in research and hiring a health literacy consultant to achieving a better result for this group. Most surprising to us, the biggest positive effect on comprehension was seen among those who had adequate health literacy. The comprehension level was raised by over 30%, to a level indicating that almost everyone with adequate health literacy understood the basics about the drug. This illustrates a side benefit of including those with low health literacy in our research – that by doing so we will improve comprehension for all.

This patient study shows the need to:

- Include low health literacy patients in the sample design.
- Separately analyze performance of low health literacy patients.
- Carefully craft patient communications using best practices and expert consultation.



Health literacy can be a key lever in improving patients' health. With some simple techniques, comprehension can increase, which could lead to improved compliance, as well as reduced medication errors and device misuse.

IV. Market researchers' responsibility and opportunity.

As discussed, there are four challenges that low health literacy presents to market research:

- **Recruitment.** Are special efforts used to include them in the sample?
- **Participation.** Are special techniques used to gain their true reactions?
- **Analysis.** Are their results scrutinized vs. dismissed as background noise?
- **Stimuli.** Were the tested materials formatted optimally?

As researchers, we are responsible for the proper design, execution, and analysis of our studies. The research may be flawed if low health literate patients are not considered.

Beyond your responsibilities as a market researcher, consider your opportunity to provide added value to your client, as well as your client's client. Armed with the above knowledge, you are empowered to help move the industry towards better market research, and ultimately higher levels of patient health.

V. The PMRG Health Literacy Initiative's Purpose and How to Get Involved.

The PMRG Health Literacy Initiative (HLI) provides today's leaders in healthcare marketing research with the tools and understanding required to address the needs of all patients. By providing education, resources, and training, the PMRG HLI works to drive change within our industry and at the FDA. This change will ultimately reach and empower patients to take control of their own health and to better understand their conditions and treatments. This initiative is a collaboration of members across the healthcare industry including manufacturers, payers, and agency organizations. This collaboration is essential to ensure the HLI is about the improvement of healthcare for patients, and that it benefits the entire healthcare industry.

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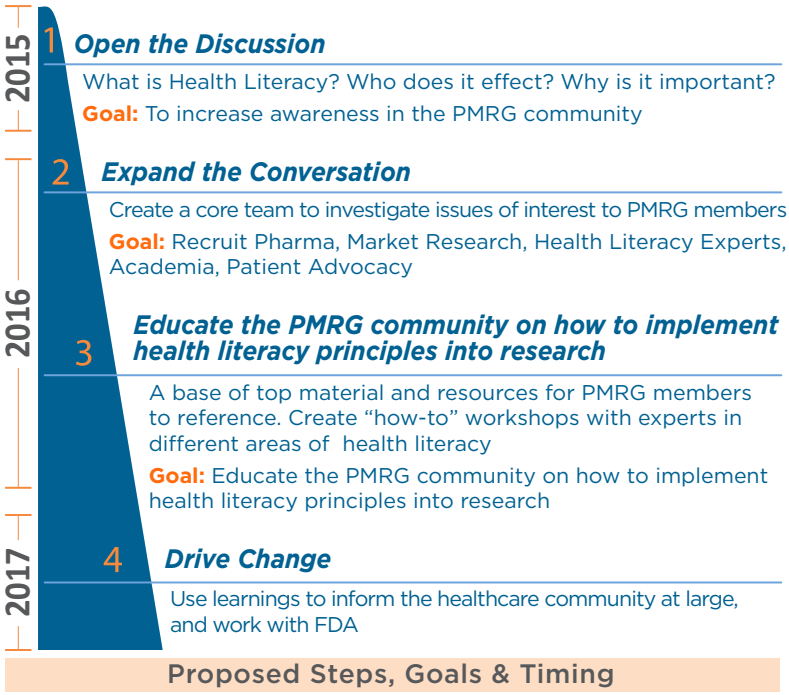
Heather Collins, PRC (Baltimore Research); Tom Donnelly, PhD (MarketVision Research); Scott von Lutcken (Merck); Lynn Ricker (KnowVanta); Jeffrey C. Adler, PRC (Vault Consulting); Heather Turkoz (UCB); William Stone (Sommer Consulting); Karen Tibbals; and John Ewing (formerly of Everyday Health/Doctor Directory). An additional special thanks to the committee members who also contributed to this article: Donna Wray (TGaS Advisors); William Leopold (Life Sciences at CMI); Daria Bakina Delta Marketing Dynamics; Sherry Fox (The Planning Shop International); Jim Kirk; Suzanne McMahon (Merck); Michelle Blechman (Astellas); Amit Patel (Medical Marketing Economics); and Bob Graff (MarketVision Research)

The PMRG Health Literacy Initiative welcomes you to:

- Connect with us to join the group or to get more information: https://www.pmrg.org/MemberResources/HealthLiteracyInitiative/tabid/1273/Default.aspx.
- Partner with us on future studies.
- Consider health literacy in your market research study design so as to not inadvertently exclude low health literacy patients from your sample.



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