

Health Literacy: Fostering Comprehension in Research and Clinical Care

October 27, 2015

1:00-2:30 PM ET

The logo for PRIMER, where the letters are in a serif font and the ampersand is stylized with a white outline and a red interior. The logo is centered on a red background.

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Webinar Objectives

- Define health literacy
- Understand the importance of health literacy in relation to human subjects research, using a case study involving return of results
- Identify key clear communication criteria in the CDC Clear Communication Index
- Identify issues pertaining to clarity and health literacy issues in research documents

Disclaimer

- I am here today representing the work done on return of results working group by the MRCT Center of Harvard and the Brigham and Women's Hospital, which I co-chaired.
- The views and opinions expressed in the following slides should not be attributed to my employer, Merck & Co., Inc.

Health Literacy Overview

- Health Literacy is not the same as ability to read.
 - US: “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”¹
- Even those with adequate health literacy can struggle to understand health information, and appreciate clear communication.
- The complexity of the healthcare system can challenge everyone!

1. U.S. Department of Health and Human Services (HHS). Healthy People 2010. Washington, DC: U.S. Government Printing Office. 2000.

National Statistics on Health Literacy^{1,2}

- According to the results from the 2003 National Assessment of Adult Literacy (NAAL)¹:
 - Only 12% of adults have *Proficient** Health Literacy¹
 - 14% of adults have *Below Basic** Health Literacy¹
 - They were more likely to report health as poor (42%)
 - They were more likely to lack health insurance (28%)

* This reflects the average of 3 NAAL assessment scales: prose, document, and quantitative literacy

1. Kutner M, et al. *The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy* (NCES 2006-483). US Department of Education. Washington, DC: National Center for Education Statistics. 2006.

2. US Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. National Action Plan to Improve Health Literacy. Washington, DC: Author. 2010.

Low Health Literacy: Who's at Risk?

- Health literacy can affect people of all ages, races, incomes, and education levels¹
- Some population groups are particularly vulnerable to health literacy challenges²:
 - The elderly (age 65+)
 - Recent immigrants who do not speak English
 - Minorities
 - Low income
- Application of “universal health literacy precautions” may help to facilitate understanding.

1. U.S. Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. *National Action Plan to Improve Health Literacy*. Washington, DC: Author. 2010.
2. Weiss BD. *Health Literacy and Patient Safety: Help People Understand*. American Medical Association Foundation and American Medical Association. May 2007.

Patient Health Behaviors, Outcomes Linked to Low Health Literacy

Preventive Services¹

- Tend to make less use of preventive care and screenings, such as mammograms and flu shots
- Tend to enter healthcare system later when symptoms and/or disease is more advanced¹

Knowledge & Treatment

- Tend to have less knowledge of their chronic conditions and of their optimal management
- Less likely to ask questions of the provider¹

Utilization

- Generally have more hospital admissions that were potentially preventable, as well as more Emergency Department visits¹

Adherence

- Often do not understand why they need to take medications^{1,2}
- Difficulty affording medications is often not discussed during physician-patient interactions³

1. Nielsen-Bohlman, L., Panzer, A. M., & Kindig, D. A. (Eds.). (2004). *Health literacy: A prescription to end confusion*. Washington, DC: National Academies Press.
2. Weiss BD. *Health Literacy: Health literacy and patient safety: Help patients understand*. The American Medical Association (AMA) Foundation and the AMA. May 2007.
3. Wilson IR, et al. "Physician-Patient Communication About Prescription Medication Nonadherence: A 50-State Study of America's Seniors." *JGIM*. January 2007;22(1):6-12.

Health Literacy Principles (Implementation)

- Plain language
- Use active voice and short sentences
- Formatting to aid comprehension:
 - Headlines to organize information
 - Presentation of “big picture” before the details
 - Descriptive headers and subheadings
 - Limited use of tables and charts
 - Adequate “white space”; 12+ point font
 - Avoidance of text in “all caps”

Numeracy

- The ability to use basic probability and mathematical concepts to explain mathematical and statistical terms.
- Numeracy principles in health literacy focus on simple explanations, instead of using complex fractions, percentages or statistical terms.
- Consider when to include numbers—don't ignore them!
 - Give people the information they need to make their own choices.
 - Providing necessary numbers can increase comprehension.

Numeracy

- Less is more – how critical are the numbers?
 - Omitting unrelated numbers can lead to improved comprehension and higher quality choices.
 - The depth of necessary data may differ.
 - For example, a cancer patient choosing a treatment type will need data regarding effectiveness and survival rates, where a patient wanting to learn how to use an inhaler does not need data on asthma prevalence.
- Summary: “Give the right tool at the right time”.

Cultural Literacy

- Numerous studies have highlighted the under-representation of racial and ethnic minorities in clinical trials.
- Cultural literacy may foster clinical trial participation, and encourage clear communication of results.
- MRCT recommendation: Translate documents if trial participants exceed a certain percentage (e.g. 10%) at a specific trial location. A native speaker should review. Be consistent with the languages used in informed consent documents.

Cultural Literacy

- Certain anatomical and medical terms may need further definition in another language.
- In Spanish, “*Once*” means 11.
- Consider training investigators in cultural sensitivity.
 - Sensitize investigators that culture may have an impact on how participants choose to receive summaries – for instance, they may prefer to have family members present.

Teach Back

- Consider the use of “teach back technique” to confirm comprehension of participants.

A Global Approach to Returning Results (Lay summaries)

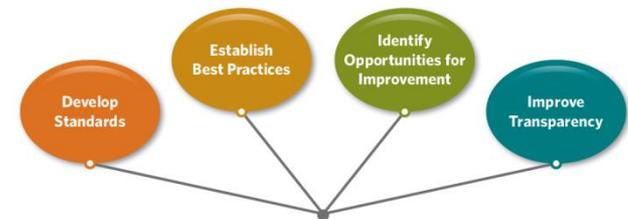
- Membership of the MRCT return of results group includes academics, industry, regulators, patient advocates and patients, CROs, and IRBs/ECs.
- We have partnered with other groups addressing returning results, including Dana Farber Cancer Institute, NIH Alliance Working Group, DIA Lay Summary Working Group, the Alliance for Clinical Trials in Oncology, and CISCRP.
- The working team began as a US working group only. Subsequently established communication channels with EU based stakeholders.

Returning Results - MRCT Mission

- **Goals: Returning Clinical Trial Results to study participants**
 - **Develop standards and best practices.**
 - **Create a guidance document, including templates.**
 - **Address perceived barriers** to widespread implementation.
- Returning results allows sponsors and investigators to recognize and honor the essential contributions and volunteerism of clinical trial participants.
- Expectations of academic, industry, not-for-profit sponsors similar
- Returning results is a key aspect of **Improving Transparency** of clinical trials and **Increasing Public Trust**.

Scope:

Communication and dissemination of summary research results to **individual participants**



The MRCT Center Deliverables

- ***MRCT Center Return of Results Guidance*** for groups wishing to return results including:
 - Content (essential components, source documentation, health literacy considerations)
 - Logistics and detailed processes for results sharing
 - Timing
 - Special considerations
- ***MRCT Center Return of Results Toolkit*** including:
 - Templates for returning results
 - Neutral language guide
 - Endpoints language guide
 - Useful Checklists

<http://mrctcenter.org/return-results>

EMA update

➤ EMA Taskforce

- Has drawn heavily upon the work of the MRCT Center
- Diverse group of members

➤ Scope:

- Communication and dissemination of summary research results to lay public (database)

Content Annex V – EU Layperson Summary

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.158.01.0001.01.ENG

1. Clinical trial identification
2. Name and contact details of the sponsor
3. Main objectives
4. Population of subjects (include eligibility criteria)
5. Investigational medicinal products used
6. Description of adverse reactions and frequency
7. Overall results of the clinical trial
8. Comments on the outcome of the clinical trial
9. Whether follow up clinical trials are foreseen
10. Where additional information could be found

Questions?

Thank you!!

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November conference note:

Return of Results to Participants:

Logistical, Ethical, and Regulatory Considerations
(Advanced Forum for IRB Professionals Track)

November 13 from 2:30-3:45 PM

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