Health Literacy:
Fostering Comprehension for Research Subjects

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Achieving Excellence in Clinical Research
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Disclosure (Laurie Myers)

- I am here today representing the work done on the return of results working group by the MRCT Center of Brigham and Women's Hospital and Harvard, which I co-chaired.
- The views and opinions expressed in the following slides should not be attributed to my employer, Merck & Co., Inc.
- The opinions contained herein are those of the authors and are not intended to represent the position of Brigham and Women's Hospital or Harvard.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org) and as well as by grants.
- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results, and deliverables.

Objectives

- Define health literacy
- Identify key clear communication criteria in the CDC Clear Communication Index
- Demonstrate relevance of health literacy to clinical research documents
  - Use selected examples from Aggregate Return of Results working group at the MRCT Center
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.”
- 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!


National Statistics on Health Literacy\(^1,2\)

- According to the results from the 2003 National Assessment of Adult Literacy (NAAL):\(^3\)
  - Only 12% of adults have Proficient* Health Literacy\(^4\)
  - 14% of adults have Below Basic* Health Literacy\(^5\)
    - 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

Low Health Literacy: Who’s at Risk?

- Health literacy can affect people of all ages, races, incomes, and education levels\(^6\)
- Some population groups are particularly vulnerable to health literacy challenges\(^7\):
  - 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.

Patient Health Behaviors, Outcomes Linked to Low Health Literacy

- Preventive Services: 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 advanced.

- Knowledge & Treatment: Need less knowledge of their chronic conditions and of their optimal management. Less likely to ask questions of the provider.

- Utilization: Generally have more hospital admissions that were potentially preventable, as well as more Emergency Department visits.

- Adherence: Often do not understand why they need to take medications. Difficulty affording medications is often not discussed during physician-patient interactions.

Health Literacy Principles (Implementation)

- Plain language
- Use active voice and short sentences
- Formatting to aid comprehension:
  - Presentation of the “big picture” before the details
  - Headlines to organize information
  - Descriptive headers and subheadings
  - Limited use of tables and charts
  - Adequate “white space”
  - Minimum of 12-point font
  - Sufficient contrast between font and background color
  - Avoidance of text in ALL CAPS

  For more information: Appendices 3 and 4 of Guidance Document

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”.

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**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.

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**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.

What is the CDC Clear Communication Index (Index)?

• CDC developed the Clear Communication Index for use with public health communication materials
• 4 questions and 20 items based in communication and related sciences that staff can use to develop, assess and score communication products
• Assesses materials in these 7 areas
  – Main Message and Call to Action
  – Language
  – Information Design
  – State of the Science
  – Behavioral Recommendations
  – Numbers
  – Risk

How Was the Index Developed?

❓ How was the Clear Communication Index developed?
  ▪ CDC staff and contract team
  ▪ Multi-step process
  ▪ Questions and items based in scientific literature, staff and consumer testing

❓ How can you use the Index?
  ▪ Design and develop new communication products
  ▪ Assess existing communication products
  ▪ Foster discussion before and during review processes
4 Questions Before Scoring

- Who is your primary audience?
- What do you know about the health literacy skills of your audience?
- What is your primary communication objective?
- What is the main message statement in the material?

PART A: CORE

Domains:
- Main message and call to action
- Language
- Information design
- State of the science

The items in this section (1-11) are always used in scoring.

1. One Main Message Statement

Does the material contain one main message statement?

Yes = 1  No = 0
<table>
<thead>
<tr>
<th>2. Main Message Statement on First Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the main message statement at the top, beginning, or front of the material?</td>
</tr>
<tr>
<td>Yes = 1  No = 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Main Message Statement Emphasized with Visual Cues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the main message statement emphasized with visual cues?</td>
</tr>
<tr>
<td>Yes = 1  No = 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Visual Supporting Main Message Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the material contain at least one visual that conveys or supports the main message statement?</td>
</tr>
<tr>
<td>Yes = 1  No = 0</td>
</tr>
</tbody>
</table>
5. Call to Action

Does the material include one or more calls to action for the primary audience?

Yes = 1  No = 0

6. Active Voice

Do both the main message and the call to action use the active voice?

Yes = 1  No = 0

7. Language of Primary Audience

Does the material always use words the primary audience would use? See top of Score Sheet for primary audience.

Yes = 1  No = 0
8. Bulleted/Numbered Lists

Does the material use bulleted or numbered lists?

Yes = 1    No = 0

9. Chunks with Headings

Is the material organized in chunks with headings?

Yes = 1    No = 0

10. Most Important Information

Is the most important information the primary audience needs summarized in the first paragraph or section?

Yes = 1    No = 0
11. State of the Science

Does the material explain what authoritative sources, such as subject matter experts and agency spokespersons, know and don’t know about the topic?

Yes = 1  No = 0

Calculate the score for Part A.

Total _____ / 11

Add up the total points for Part A.

PART B: BEHAVIORAL

Answer this question to determine if items 12-14 apply to the material.

Does the material include one or more behavioral recommendations for the primary audience?

If yes – score items 12-14.
If no – skip to Part C.
12. Behavioral Recommendation

Does the material include one or more behavioral recommendations for the primary audience?

Yes = 1
If no, STOP here and don’t score Part B.

13. Behavioral Importance

Does the material explain why the behavioral recommendation(s) is important to the primary audience?

Yes = 1  No = 0

14. Behavioral Direction

Does the behavioral recommendation(s) include specific directions about how to perform the behavior?

Yes = 1  No = 0
Calculate the score for Part B.

Total _____ / 3

Add up the total points for Part B.

PART C: NUMBERS

Answer this question to determine if items 15-17 apply to the material.

Does the material include one or more numbers related to the topic?
   If yes – score items 15-17.
   If no – skip to Part D.

15. Numbers Primary Audience Uses

Does the material always present numbers the primary audience uses?

   Yes = 1   No = 0
16. Lay Explanation of Numbers

Does the material always explain what the numbers mean?

Yes = 1   No = 0

17. Mathematical Calculations

Does the audience have to conduct mathematical calculations?

NOTE: For this item, Yes is scored 0 and No is scored 1.

Yes = 0   No = 1

Calculate the score for Part C.

Total _____ / 3

Add up the total points for Part C.
PART D: RISK

Answer this question to determine if items 18-20 apply to the material.

Does the material present information, including numbers, about risk?
   If yes – score items 18-20.
   If no – skip to Calculate Your Score.

18. Explain Risk
   Does the material explain the nature of the risk?
   
   Yes = 1   No = 0

19. Risks and Benefits
   Does the material address both the risks and benefits of the recommended behaviors?
   
   Yes = 0   No = 1   N/A = N/A

———
20. Probability Explained with Text or Visual

If the material uses numeric probability to describe risk, is the probability also explained with words or a visual?

Yes = 0   No = 1   N/A=N/A

Calculate the score for Part D.

Total _____ /3
OR _____ / 2
(if you answered N/A for only 1 item)
OR _____ / 1
(if you answered N/A for 2 items)

Add up the total points for Part D.

Calculate the Score for the Material

Step 1: Add up the total points that the material earned (this is the numerator).

Step 2: Add up the total possible points that the material could have earned (this is the denominator).

Step 3: Divide the numerator by the denominator and multiply by 100 to get the total score.

_____ / _____ X 100 = ______
How to Interpret Your Score

If the total score is 90 or above:
Excellent! You have addressed many items that make materials easier to understand and use.

If the total score is 89 or less:
Note which items scored 0 points. Use the descriptions and examples in the User Guide to revise and improve the material. Then apply the index again to check your work. You can use the index as many times as you need to revise the material to get a score of 90 or above.

Return of Aggregate Results, MRCT Center of Brigham and Women’s Hospital and Harvard

MRCT Center Mission:
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Return of 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.

Project 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

European Regulation

  - Sponsor of a clinical trial must submit “a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within the defined timelines.”

  Article 37: Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial.

  EU Requires posting laypersons summary to EU Portal – by 2017/2018

Return of results: MRCT Center workgroup

- Academic/Medical Center:
  - Carmen Allenby – MRCT Center
  - Mark Baren – ropes & Gray LLP / MRCT Center
  - Benjamin – Brigham & Women’s Hospital
  - Ascensio De Ramon – Brigham & Women’s Hospital
  - Alla Diggios – MRCT Center
  - Rebecca K. – MRCT Center
  - Holly Henderson Lynch – Harvard Law School
  - Paul Hoffsass – Partners HealthCare
  - Nino Iadanza – University of Padova
  - Alain Joffrain – University of Liege
  - Carmen Major – MRCT Center
  - Zvonimir Sajan – University of Osijek
  - Sarah White – Partners HealthCare
  - Elizabeth Wilcox – Harvard Medical School
  - Sabine Winkler – Harvard Medical School
  - Industry/Trade Associations:
    - Salvatore Minic – PMPA
    - Richard Abergel – EFPIA
    - Elisabetta Consiglio – Novartis Pharma AG
    - Luisa Hagan – Merck Serono
    - Sandra Maye-Collins – Johnson & Johnson
    - Angela Joos – Merck Sharp & Dohme
    - Barbara Kness – Merck
    - Sarah Leonian – Biogen IDEC
    - David Lawrence – Pfizer
    - Cheri Lipman – Pfizer
  - All Others – Merck (CO-CHAIR)

- Institutional Review Boards:
  - David Forster – WIRB Copernicus Group
  - Mary Grier – NE IRB
  - Jim Goodwin – NE IRB
  - Richard Bergstroem – CISCRP
  - Bernhard Baechler – CSGOF
  - Paul Fischbach – Associated Medicine Coalition
  - Zach Hillman – CSGOF
  - Maria Stoltenberg – International AIDS Vaccine Initiative

- Patient Advocates:
  - Nicola Bedlington – European Patients Forum
  - Deborah Collyar – PAIR (CO-CHAIR)
  - David Haerry – European AIDS Treatment Group
  - Cheryl Jernigan – Susan G. Komen
  - Yann LeCam – EURODIS

- Research/Consulting Firms:
  - Barbara Godlewski – The FAIR Company, LLC
  - Gerd Gunz – E12 Consulting
  - Marcello Losso – HIV RAMOS
  - Jane Perlmutter – Gemini Group
  - David Walling – Collaborative Neuroscience
The MRCT Center Tools

An **ROR Guidance Document** for groups wishing to return results including:

- Logistics and detailed processes for results sharing
- Content of research result summaries
- Cultural and health literacy considerations
- Timing

An **ROR Toolkit** including:

- Templates for Phase 1, 2 & 3, studies ending early
- Neutral language guide
- Endpoints language guide

Go to: mrctcenter.org -- Resources -- Return of aggregate results

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**Participant Clinical Trial Results Summaries - Process**

- Write in unbiased and not promotional language
- Obtain review by independent and objective editor(s) and patient representative(s) when possible
- Translate into additional languages consistent with translations of informed consent
- Make available an individual from the study site or neutral informed third party to answer questions for participants
- Make provisions for vulnerable populations and other instances
- Consider as to whether to inform, and whom to inform, in the event of a participant’s death
- Use plain language (sixth-eight grade reading level)
- Apply health and numeracy principles

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**Return of results templates**

- Located in MRCT Return of Results Toolkit
- Templates for Phase 1, Phases 2 and 3, and Trials ending early
- Includes examples
- Incorporates principles of Health Literacy and Numeracy
Participant Clinical Trial Results Summaries - Content

• Thank You
• Title and purpose of the study
• Why the study was done
• Study information (patient population, drugs, start & end date, countries)
• How the study worked (how participants were divided into groups)
• Side effects
• Summary of results
• Final comments (official study title, where to get more information)

Participant Clinical Trial Results Summaries - Example

<table>
<thead>
<tr>
<th>Context</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why the study was done (cont.)</td>
<td>For clinical trials that stop early: This study was stopped earlier than planned. This can happen for many reasons. This study stopped early because [add one of the possible statements below, or your own simple explanation, to this sentence. If there is more than one reason, list all that apply.] ... too many participants had side effects [see below]. ... [drug generic name] did not improve patient results. ... [drug generic name] was not as effective as expected [comparator]. ... [drug generic name] was much more effective than expected. [If applicable, add] The study was stopped so all participants had a chance to take [drug generic name]. ... not enough people joined the study. [Include a statement about what will happen next. ... • For side effects ... • For efficacy ... • For futility ... • Low accrual: ...]</td>
</tr>
</tbody>
</table>

Neutral Language Guide

<table>
<thead>
<tr>
<th>Language to avoid</th>
<th>Language to consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>This study proved...</td>
<td>This study found that... This does not mean everyone in that group had these results.</td>
</tr>
<tr>
<td>This study proved that using &lt;drug A&gt; to prevent &lt;disease/condition&gt; is effective.</td>
<td>This study found that people with &lt;disease/condition&gt; who got &lt;drug A&gt; had &lt;primary endpoint&gt;.</td>
</tr>
<tr>
<td>This means that &lt;Drug A&gt; is better than &lt;Drug B&gt;.</td>
<td>In this study, people who got &lt;drug A&gt; had more &lt;study endpoint&gt; than some people who got &lt;Drug B&gt; with the same health conditions.</td>
</tr>
<tr>
<td>&lt;Drug A&gt; is better tolerated than &lt;Drug B&gt;.</td>
<td>In this study, fewer patients who took &lt;Drug A&gt; had &lt;list specific adverse events&gt; than patients who took &lt;Drug B&gt;.</td>
</tr>
</tbody>
</table>

Similar principles have been suggested by TransCelerate BioPharma:

“Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results”
## Endpoint Descriptions and Examples

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Description of the type of endpoint</th>
<th>Example in simple, plain language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite</td>
<td>A composite endpoint, as the primary endpoint, combines multiple outcomes (e.g., death, getting sick again (relapse), serious event) and test results into one measure of how well the drug/therapy/device works. This is useful when there are many different outcomes that can happen during a trial. This can also be called a combined or multi-part endpoint.</td>
<td><em>The XXX study measured [patients/people] to see if those in Group A (ABC treatment) or Group B (XYZ treatment) lived longer, had fewer heart attacks, or fewer hospital visits for heart failure. These events were measured together (combined) because each one is quite rare. Researchers also wanted to see if the drug worked in patients who had all 3 conditions. The study found that there was no change in the number of events for [patients/people] in Group A or Group B.</em></td>
</tr>
</tbody>
</table>

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## Endpoint Descriptions and Examples

<table>
<thead>
<tr>
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<th>Example in simple, plain language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-Reported Outcomes</td>
<td>This study asked patients about their [list the main purpose of the questionnaire: e.g., symptoms, activity level, quality of life, income and/or happiness] and if the measurement changed based on whether a patient got A or B. The primary endpoint is less XXX based on the YYY scale. This scale measures ZZZ and how this changes over time.</td>
<td><em>Patients answered questions to measure pain, stiffness, and how well people climbed stairs, stood or bent over. Questions were asked during each study visit. About 2 in 4 people (50%) in Group A had less knee pain. About 1 in 4 people (25%) in Group B had less knee pain. This means that patients in Group A (x treatment) had less knee pain than patients in Group B (y treatment/placebo).</em></td>
</tr>
</tbody>
</table>

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## For more information

- CDC Clear Communication Index and resources
  - [www.cdc.gov/healthliteracy](http://www.cdc.gov/healthliteracy)
  - [http://www.cdc.gov/ccindex/](http://www.cdc.gov/ccindex/)

- [Laurie_Myers@merck.com](mailto:Laurie_Myers@merck.com)