MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Introduction -

Adoption of Health Literacy Best Practice to Enhance Clinical Research: A Workshop

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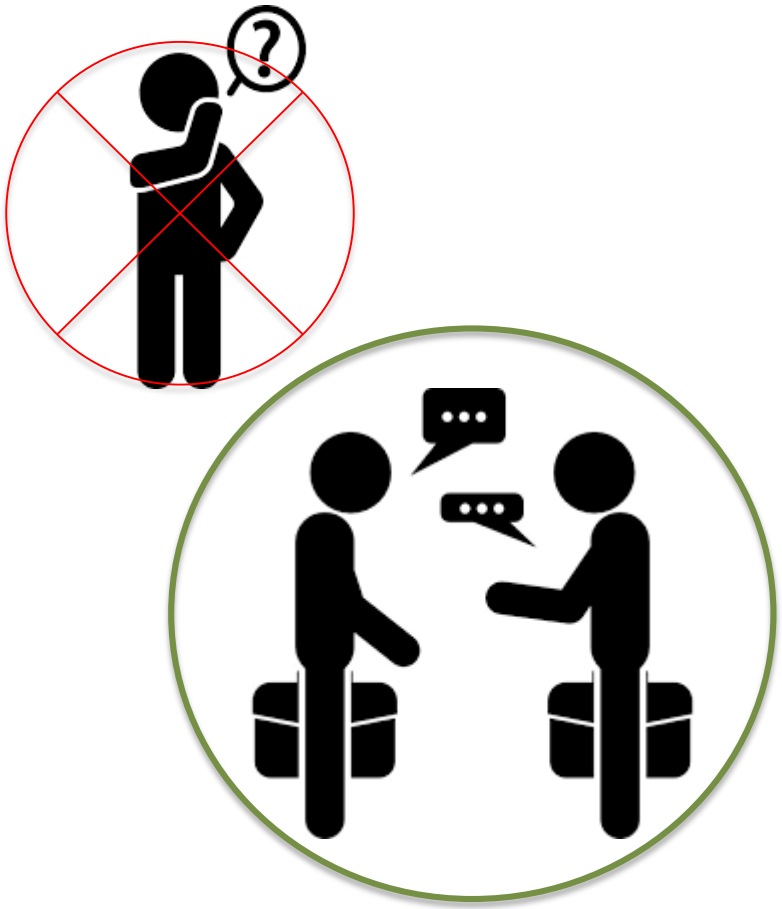
The health literacy, clinical research and clinical care continuum

- Diagnostics, treatments, and therapies are the result of research.
- Research must include participants who reflect the affected population, or those intended to utilize the intervention.
- There are legitimate and varied reasons why individuals have concerns about research that should be addressed as a precondition to consideration of participation in research.
- Communication depends upon a common understanding, shared exchange of information, and trust.
- Health literacy, including plain language, numeracy, imagery, and design, can help support communication and understanding.

Comprehension is the responsibility of the communicator



- It is not the responsibility of the person receiving information to try to make sense of it.
- The communicator is responsible for sharing information in a way that is understood by the intended audience.
- The audience should be comfortable not knowing, communicating any lack of understanding, and asking questions.
- And it is a greater problem for individuals whose preferred language is other than English.
- It is a systems problem.

Health literacy to enhance clinical research

- Understandable health information and shared-decision making applies in research - important recruitment and consent conversations must be undertaken from a foundation of an understandable research content that can lead to values-concordant decision-making.

- Health literacy can help increase engagement in research
  - Demonstrates respect for the potential participant
  - Supports justice

- HHS Common Rule and FDA both require “information that is given to the subject or the representative shall be in language understandable to the subject or the representative.”
  - And that includes not only the informed consent, but recruitment materials, participant instructions, patient-reported outcomes, surveys, plain language summaries, and other.

Health literacy to enhance *culturally competent* clinical research

- Health literate communications must be culturally and linguistically appropriate for the population, and there is wide variation among different populations, not only geographically.
- Outreach to the communities must be authentic and include those communities as partners
- Shared use of standard terms is helpful.
- Getting this right is helpful for everyone.

  - What do participants, patients, and caregivers need to make the informed decisions?
  - What do health care providers need to make research a part of their conversations?
  - What do researchers and clinical research stakeholders need to support participants before, during, and after a research study?