Health Literacy in Clinical Trials

Critical Conversations

National Academy of Sciences, Engineering and Medicine

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Disclosures

No relevant financial conflicts of interest

Outline

- When, where and how?
  Conversations about clinical trials
- Programs- national and institutional
- Creating a health literate clinical trials environment

Why a clinical trial?

Has she failed multiple therapies – or have the therapies failed her?

* informed verbal and written consent obtained for use of photograph

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Patients learn about clinical trials from their providers

77%

of patients who participate in a clinical trial learn about it from their provider

National Institute of Health. (2016). The Need for Awareness of Clinical Research http://bit.ly/2ogudw6 (Comis, 2009)

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Where these conversations occur

The backdrop

- Health literacy demands placed on patients as soon as they set foot in a hospital or clinic
- Signs, directions, instructions, paperwork can be overwhelming
- Busy clinic, limited time slots

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What's happening in these encounters?

- When, where and how? Conversations about clinical trials
- Is this a good time?
- When is a good time?

Overload of information-difficult to understand and process

New diagnosis, prognosis

Medications, doses, side effects, cost

Impact of family, beliefs, culture, limited English proficiency (LEP)

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The conversations that never occur

The patient perspective

> **I had no idea about clinical trials. It was foreign to me. It's like a foreign word. I had never heard of it before.**

Brown et al J Oncol Pract. 2013 Nov; 9(6): 287–293

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85%

of patients were either unaware that participation in a clinical trial was an option at the time of diagnosis

75%

of these patients said they would have been willing to enroll had they known it was possible

Harris Interactive Survey, 2001

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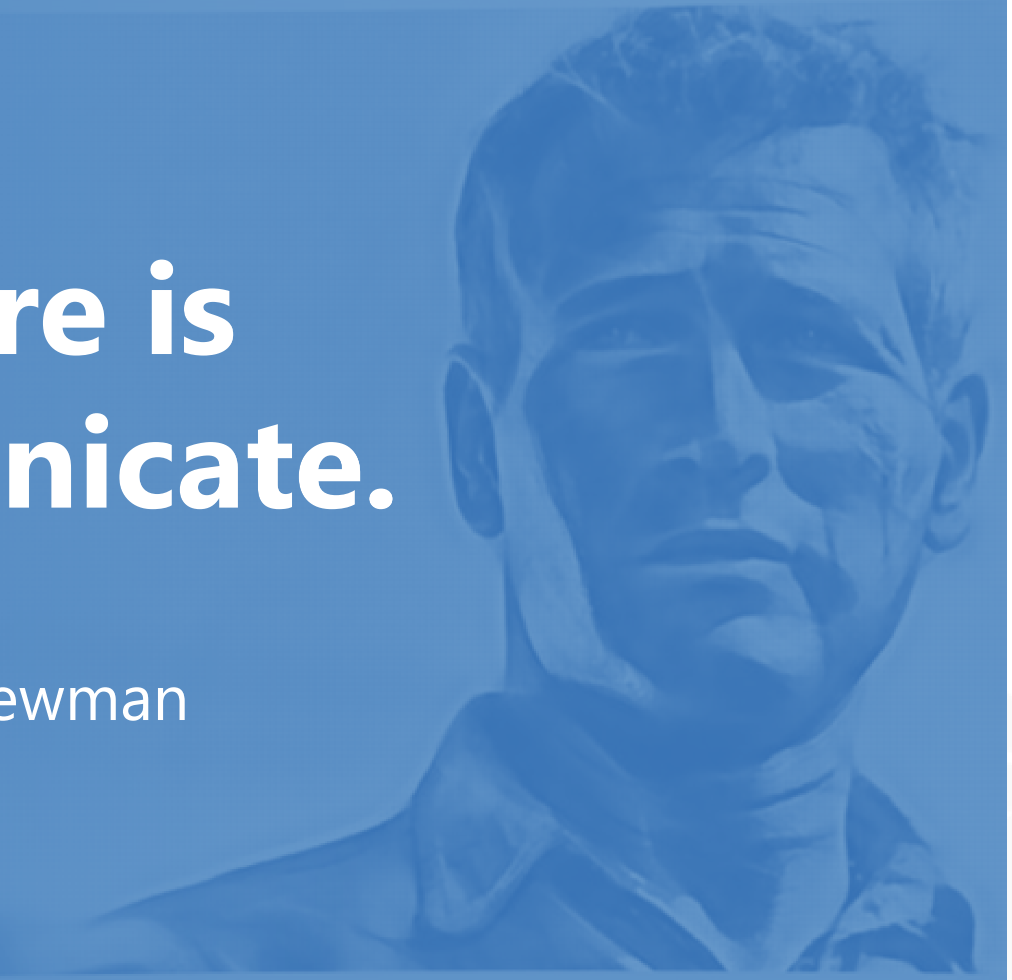
Approximately

90% ⚠

of clinical trials fail to meet recruitment goals



> **What we’ve got here is a failure to communicate.**

1967’s “Cool Hand Luke” starring Paul Newman

Health literacy efforts should be prioritized well before the actual clinical trial begins

Efforts usually focused on patients in the trial- informed consent, engagement & retention strategies

Should be prioritized prior to actual recruitment

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Our focus - Addressing key barriers to patient participation in clinical trials

Lack of physician awareness and knowledge of clinical trials

Clinical trial health disparities

- Limited health literacy and LEP
- **100,000 clinical trials operating in the US** –

  African Americans only 5% of all participants

  Latinos only 1% of participants

Joseph et al., 2009; Lloyd et al., 2008 | National Center for Education Statistics, 2006 | The Society for Women's Health Research, 2011

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Our work addresses critical questions

Can we:

- improve health care provider literacy about clinical trials?
- improve physician communication skills related to discussing trials using patient-centered communication?

Can we equip clinical trial sites to recruit minority and limited health literacy patients?

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Programs

National and Institutional

- Disease specific, clinical trial agnostic interventions
- All developed with patient input panels
- Follow evidence-based guidelines from the National Standards for Culturally and Linguistically Appropriate Services

1

Materials to Increase Minority Involvement in Clinical Trials (MIMICT I & II)

- **Provider + Patient education**

2

Patient Advocates for Lupus Studies (PALS)

- **Patient education- Peer based approach**

3

Programs to address Unmet needs and promote Representation of all Participants in Lupus clinical trials using mobile technology for Engagement" (PURPLE)

- **Technology based applications**

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Program #1

Materials to Increase Minority Involvement in Clinical Trials (MIMICT)- Targeting provider literacy about clinical trials

Multifaceted interventions

Combining more than one type of intervention is more effective than single interventions
(Grimshaw et al 1999)

Model builds on three intervention categories

- Educational materials
- Educational outreach
- Patient-focused interventions

Evaluate providers' knowledge, attitudes, self-efficacy, and behavioral intentions to refer minority patients to lupus clinical trials

Assess the feasibility of a clinical trials recruitment model

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U.S. Department of Health and Human Services
Office of Minority Health

The University of North Carolina at Chapel Hill

Combine slides 18, 19 and 20

Educational modules for providers

Interactive videos, transcripts and slides

MODULE A

Referring Patients to Clinical Trials

MIMICT

MODULE B

Lupus Health Disparities and Clinical Trials

MIMICT

MODULE C

Clinical Trials Basics and Barriers to Recruiting African American Patients into Clinical Trials

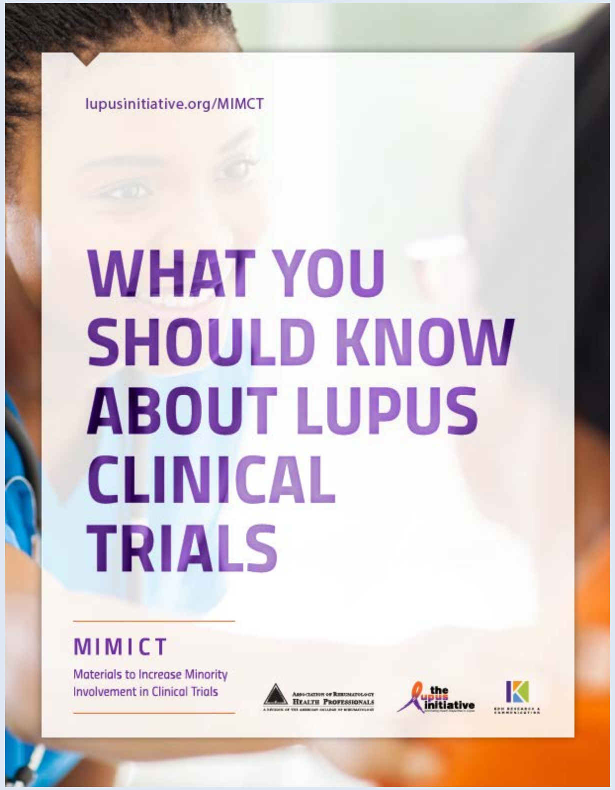
MIMICT

MODULE D

Impact of the Provider-Patient Relationship on Clinical Trial Referrals

MIMICT

Educational materials for patients



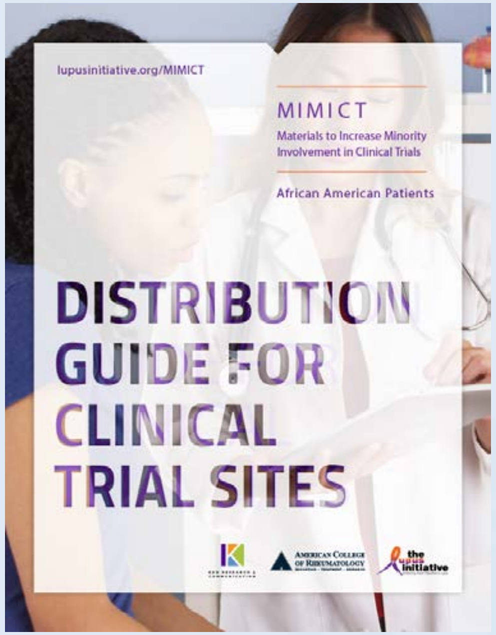
lupusinitiative.org/MIMCT

WHAT YOU SHOULD KNOW ABOUT LUPUS CLINICAL TRIALS

MIMICT

Materials to Increase Minority Involvement in Clinical Trials

Tools for clinical trial sites



lupusinitiative.org/MIMICT

MIMICT

Materials to Increase Minority Involvement in Clinical Trials

African American Patients

DISTRIBUTION GUIDE FOR CLINICAL TRIAL SITES

Click here to download

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- PIs and clinical trials staff reach out to providers and share information about clinical trials
- Empowered providers share information about clinical trials with their patients.
- Patients consider their option and willingness to enroll in a clinical trial

MIMICT 2

Evidence-based and expert-informed practical guidance on how clinical trials sites can most effectively conduct outreach

- PCPs
- Healthcare teams- NPs, PAs, nurses
- Sub-specialists
- Expanding outreach to patients

- Development of culturally and linguistically appropriate materials for Hispanics in addition to African Americans.

Longitudinal study in underserved areas to test the effectiveness of these models

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Program #2

Peer to peer communication- PALS Patient Advocates for Lupus Studies -

Early educational intervention to introduce clinical trials to individuals **before** they have to decide if they want to participate

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an affiliate of
LUPUS RESEARCH ALLIANCE

LuCIN
Lupus Clinical Investigators Network

KDH RESEARCH & COMMUNICATION

EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

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What would motivate you to participate in a clinical trial?

300 individuals with lupus surveyed

>80%

of respondents said that talking with other patients who have taken part in a clinical trial would make them very likely or likely to participate

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Patient (PALS) Advocates for Lupus Studies

Peer support & education program to improve clinical trial awareness and knowledge among people living with lupus

Individuals living with lupus are trained to serve as trial agnostic resource for patients

Training Details

- Online
- Two day in person training

Topics Covered

- Disease
- Clinical Trials
- Peer Counseling Skills

Outcome

- 27 individuals came together for training (PIs, evaluators, facilitators, PALs)

Key Points

- Training materials and program developed with input from individuals with lupus

Patient (PALS) Advocates for Lupus Studies

PALS Semi-Structured Sessions

1	Introduction and get-to-know you
2	Clinical trial basics
3	Clinical trial decision making, benefits and risks of participating in a clinical trial, communicating with, and questions to ask your doctor
4	Informed consent, participating in a clinical trial, patient protections
5&6	Patient-specific concerns/barriers

Study Outcomes

Pre & Post Test Follow Up surveys measure:

1 year follow up

Clinical trial knowledge

Attitudes

Satisfaction

Intentions

Self-efficacy

Program #3

Programs to address Unmet needs and promote Representation of all Participants in Lupus clinical trials using mobile technology for Engagement” (PURPLE)

- Culturally-tailored and to all literacy levels, personalized
- Animations that explain complex study concepts such as randomization and informed consent
- Interactive decision support activities
- Knowledge assessments and surveys, based on “teach back” principles

RTI INTERNATIONAL

PATTERN HEALTH

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Thought provoking time in our evolutionary history

Six of the world's seven billion people have mobile phones - but only 4.5 billion have a toilet

U.N. report (2013)

https://www.forbes.com

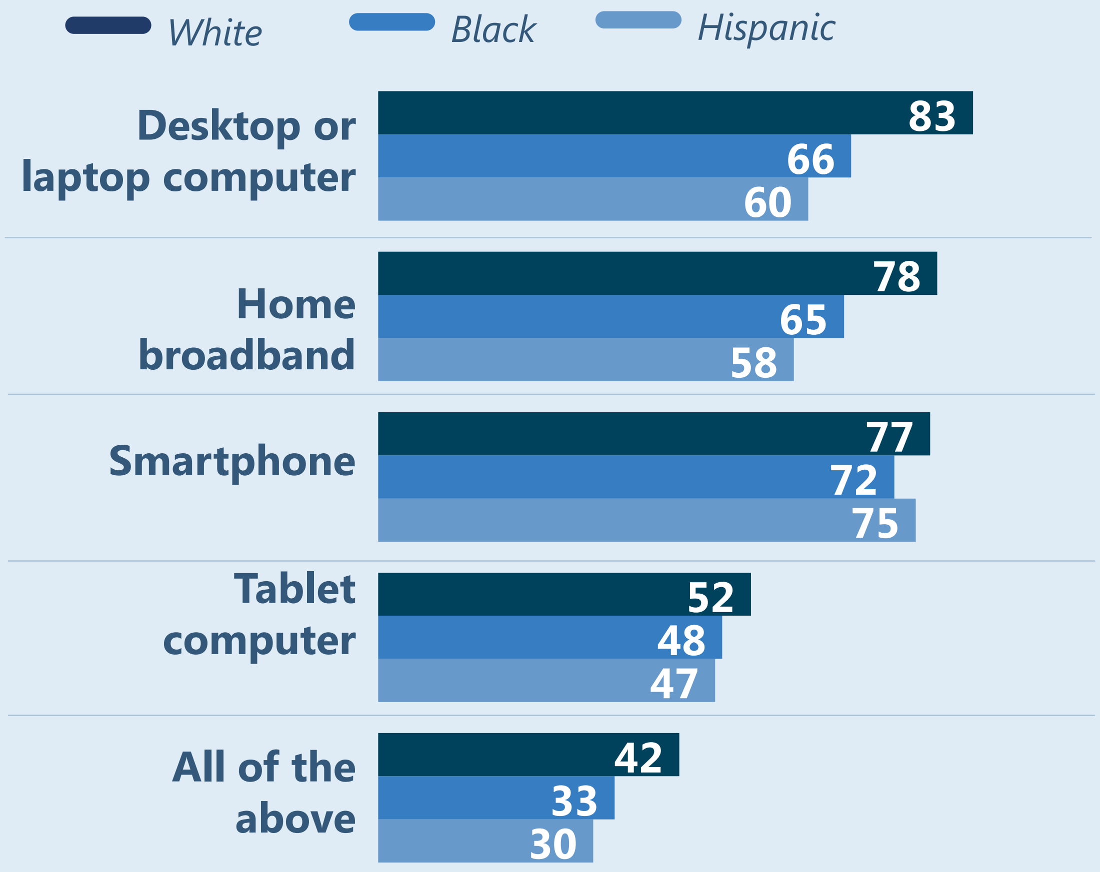
Bridging the gap- Smartphones help blacks, hispanics

- 22% hispanics and 15% of blacks are "smartphone only" internet users
- Lack home broadband but own a smartphone
- 9% of whites fall into this category

Blacks and Hispanics are more likely than whites to rely on their smartphones to look up health information

Blacks and Hispanics own mobile devices at similar rates to whites

% of U.S. adults in each group who say they have...



Notes: White and blacks include only non-Hispanics are of any race.
Source: Survey conducted Sept. 29-Nov 6, 2016. **PEW RESEARCH CENTER**

Doctors are a trusted source of health information

Patients consistently rate their own doctors as their most trusted source of health information, yet most physicians do not have sufficient time or resources to discuss clinical trials

First of its kind to educate patients about clinical trials through interactive content using custom-built physician avatars modeled after patients' real-life treating physicians

Hesse, B. W., Moser, R. P., & Rutten, L. J. (2010). Surveys of physicians and electronic health information. NEJM, 362(9), 859–860

Creating a health literate clinical trials environment - Adapting "Universal precautions"

Educate all patients about clinical trials-

- Check implicit biases at the door
- Advocate for **consideration** of participation, rather than to encourage participation
- Resources to help individuals make informed decisions

Educate providers about clinical trials

Outreach targeted towards patients and providers

Communication

Expanding organizational health literacy

- Informed consent: multi-step
- Customizable templates FAQs for patients
- Research personnel training "Teach back" for patients and for research personnel
- Language competency, bilingual staff, professional interpretors
- Consent forms and supplementary info in other languages

AHRQ (DeWalt et al., 2010)

Desired outcome of health literacy in clinical trials

Dynamic state influenced by how well WE deliver information that matches patients' abilities, needs and preferences

Informed decisions = Empowered patients

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