

Community-based Participatory Research

Part 5: Informed Consent

May 4, 2021

RESEARCH MATTERS **LIVE**



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HRPP (Human Research Protection Program)



ELEMENT I.4.C.

The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

ELEMENT I.1.E.

The organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.



Consent Overview

Nan McMurry, IRB Member

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Subjects as Objects: A Troubled History

- Nazi Experiments on Concentration Camp Inmates
- U.S. Public Health Service Study of Untreated Syphilis (1932-1972)
- Willowbrook Studies (1956-1970)
- Jewish Chronic Disease Hospital Study (1963)



Building Protections for Human Subjects

- National Research Act (1974)
- *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Belmont Report, 1979)
- 45 CFR 46: Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research



Belmont Principles and Consent



Consent: From the classroom to candidacy

Miranda Hill, PhD, MPH & Nathan Hansen, PhD

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AGENDA



BACKGROUND

Transgender women's **social network support** for medication adherence (TRANSSFORM)

- ❑ Transgender woman: broad term used to describe women or people of another feminine identity who were assigned male sex at birth
- ❑ National online social network study



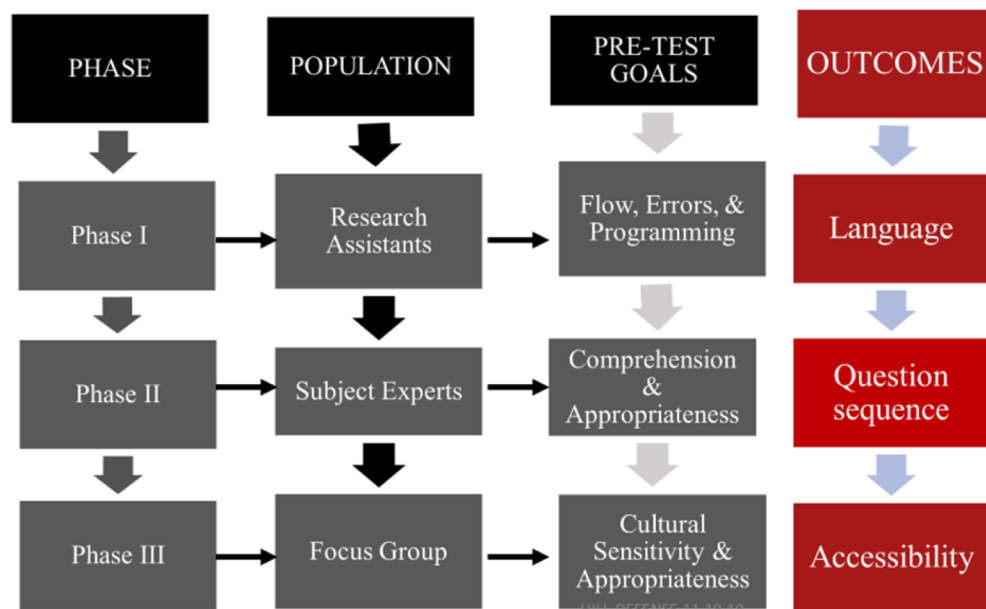
	General Population	US Transgender Population
Poverty	12%	29%
Unemployment	5%	15%

Source: James et al., 2016

Source: James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). Executive Summary of the Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality



BACKGROUND



**HIV+
TRANS
WOMEN
NEEDED**

for a 30-minute
survey on health
& relationships
\$20 Gift Card

take the survey at

<https://www.tinyurl.com/hivtranssupport>

THIS STUDY IS UNDER THE SUPERVISION OF DR. NATHAN HANSEN IN THE DEPARTMENT OF HEALTH PROMOTION & BEHAVIOR @ THE UNIVERSITY OF GEORGIA. FOR MORE INFORMATION CONTACT MIRANDA @ 678.453.6187



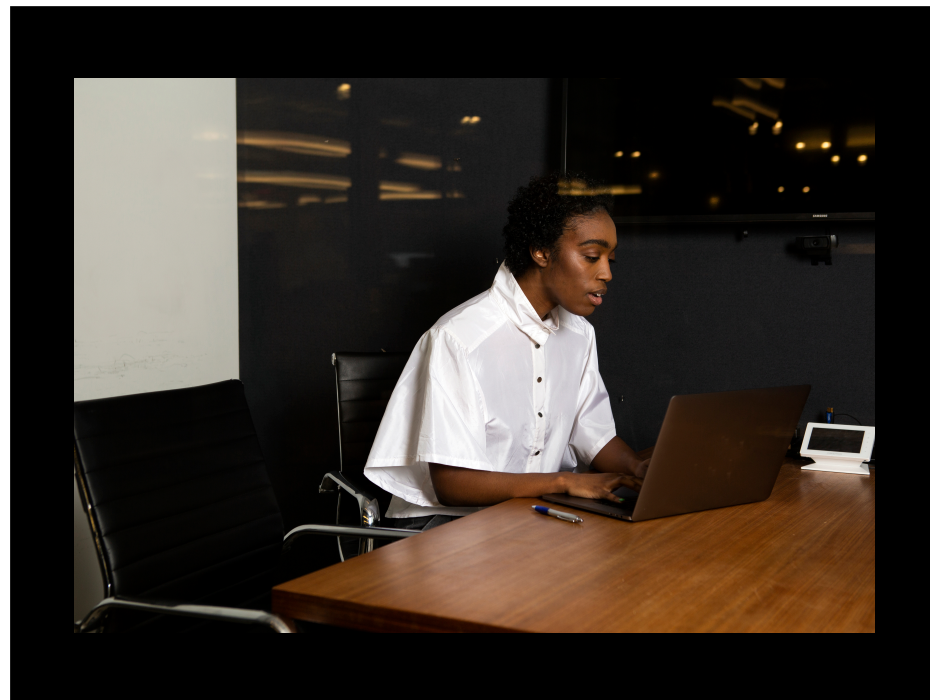
COMMUNITY ENGAGEMENT & CONSENT

Sustained community engagement led to changes in recruitment & consent

- ☐ Partnership with local provider
- ☐ Observations
- ☐ External expert review of materials

Conclusion: the consent form was not appropriate for people with lower educational attainment and literacy levels

Advice: learn about readability scores & downgrade the reading level from graduate-level to middle school



COMMUNITY ENGAGEMENT & CONSENT

Readability formulas

Measure the ease of reading a certain text or page lay-out

- ☐ Number of words
- ☐ Sentences (number of letters or syllables)

Score

- ☐ Reading ease
- ☐ Grade level

Goal: ↑ information accessibility

Limitations

- ☐ Comprehension debacle
- ☐ Conflicting scores



Rudolph Flesch's Reading Ease Formula, Flesch's Grade Level, J. Peter Kinkaid's Flesch-Kinkaid Index, Robert Gunning's Fog Index, The SMOG Readability Formula, & New Dale-Chall formula

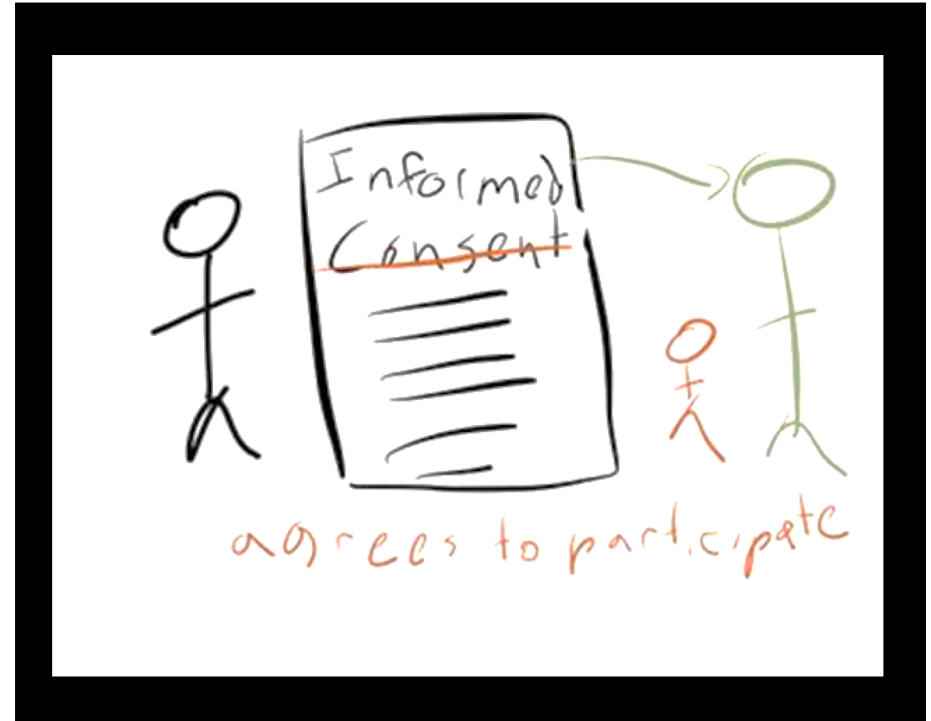


BEFORE

- ☐ Graduate-level vocabulary
- ☐ Long statements & text strings
- ☐ Passive voice
- ☐ College reading level

AFTER

- ☐ Plain language
- ☐ Succinct bullet points for each section
- ☐ Active voice
- ☐ 8th grade reading level



BEFORE

Your involvement is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled. The decision to take part (or not take part) in the research will not affect your treatment or health care services. If you decide to stop or withdraw from the study, the information that can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return, or destroy the information

AFTER

About the study

- ☐ This study is voluntary
- ☐ You can stop at any time and still get paid for participating
- ☐ Taking the survey (or not) won't affect your health services
- ☐ If you want to stop, we will keep your data (unless you tell us that you want it to be deleted)



REFLECTION & RESOURCES

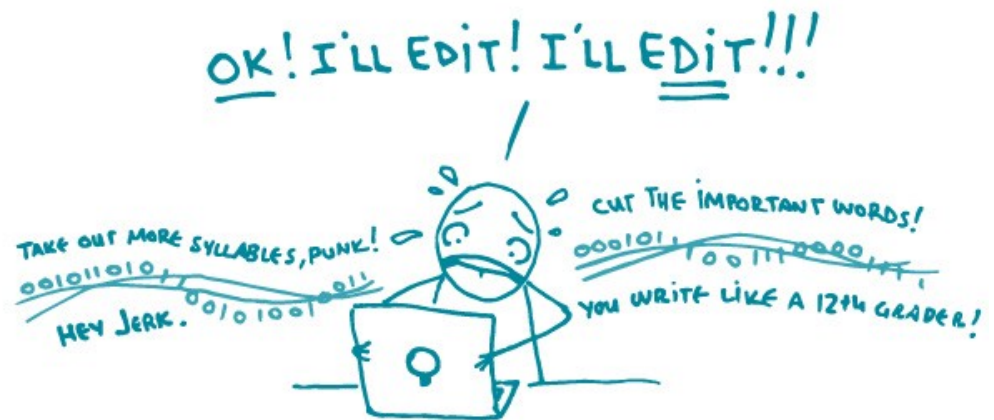
Lessons

- ❑ Community engagement & cultural humility are critical to consent
- ❑ Change is hard, but necessary
- ❑ Ask, Listen, Act, & Advocate

Resources

<https://www.plainlanguage.gov/>

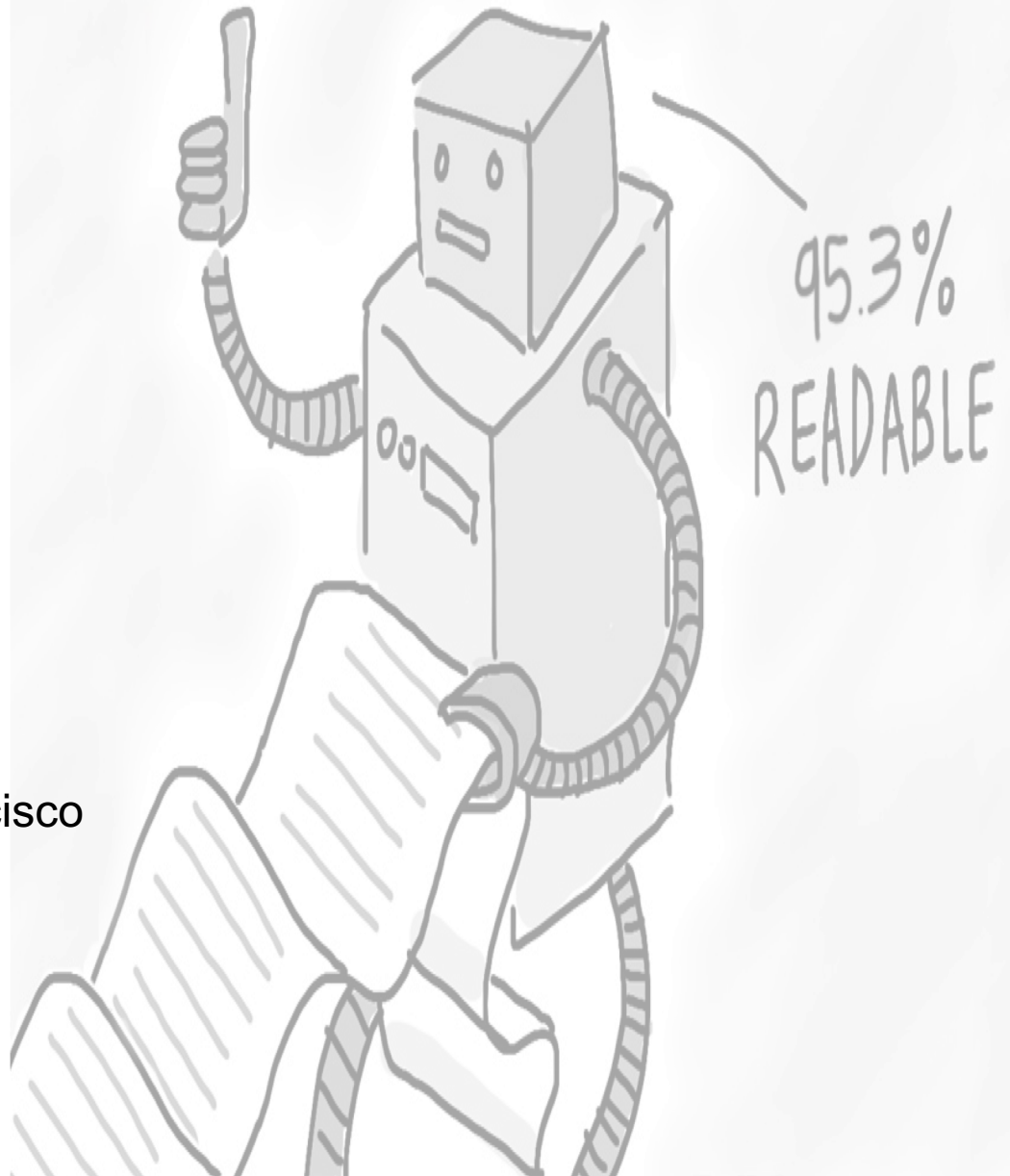
<https://readabilityformulas.com/>



THANKS!

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Health Literacy and Consent

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21.06.2015 05:59



A theory of mind problem



Gallagher HL, et al. *Neuropsychologia*. 2000;38(1):11-21. doi: 10.1016/s0028-3932(99)00053-6. PMID: 10617288.



Health literacy



Pleasant (2014)
Rademakers & Heijmans (2018)



Health autonomy

PATIENT-CENTERED CARE

Willingness to engage in healthcare and recognition of one's ability to take health-related action.

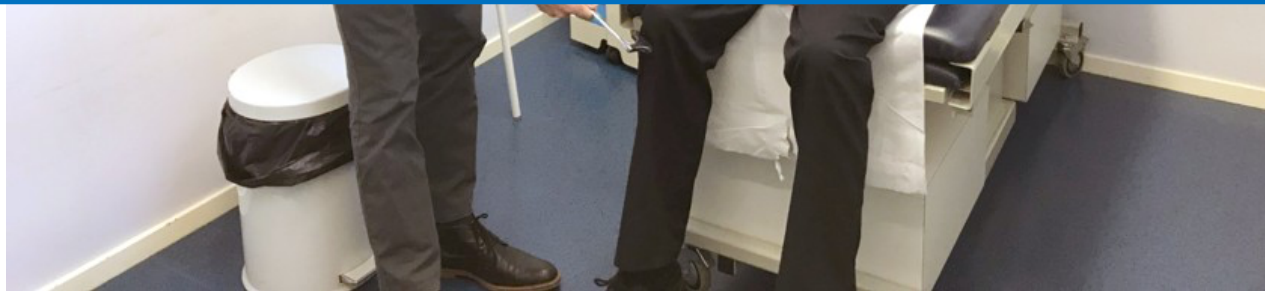
Concept by Sachin Jain, Art by Matthew Hayward © 2014 All Rights Reserved



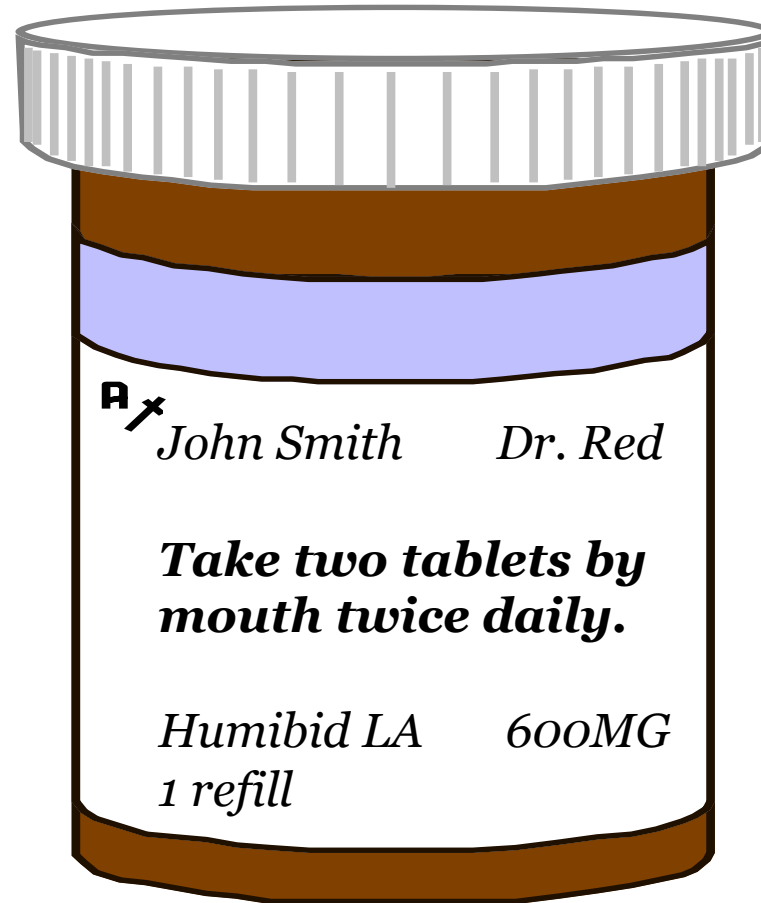
Shared decision making



Collaborative process where patient and healthcare provider arrive at a treatment decision, together.



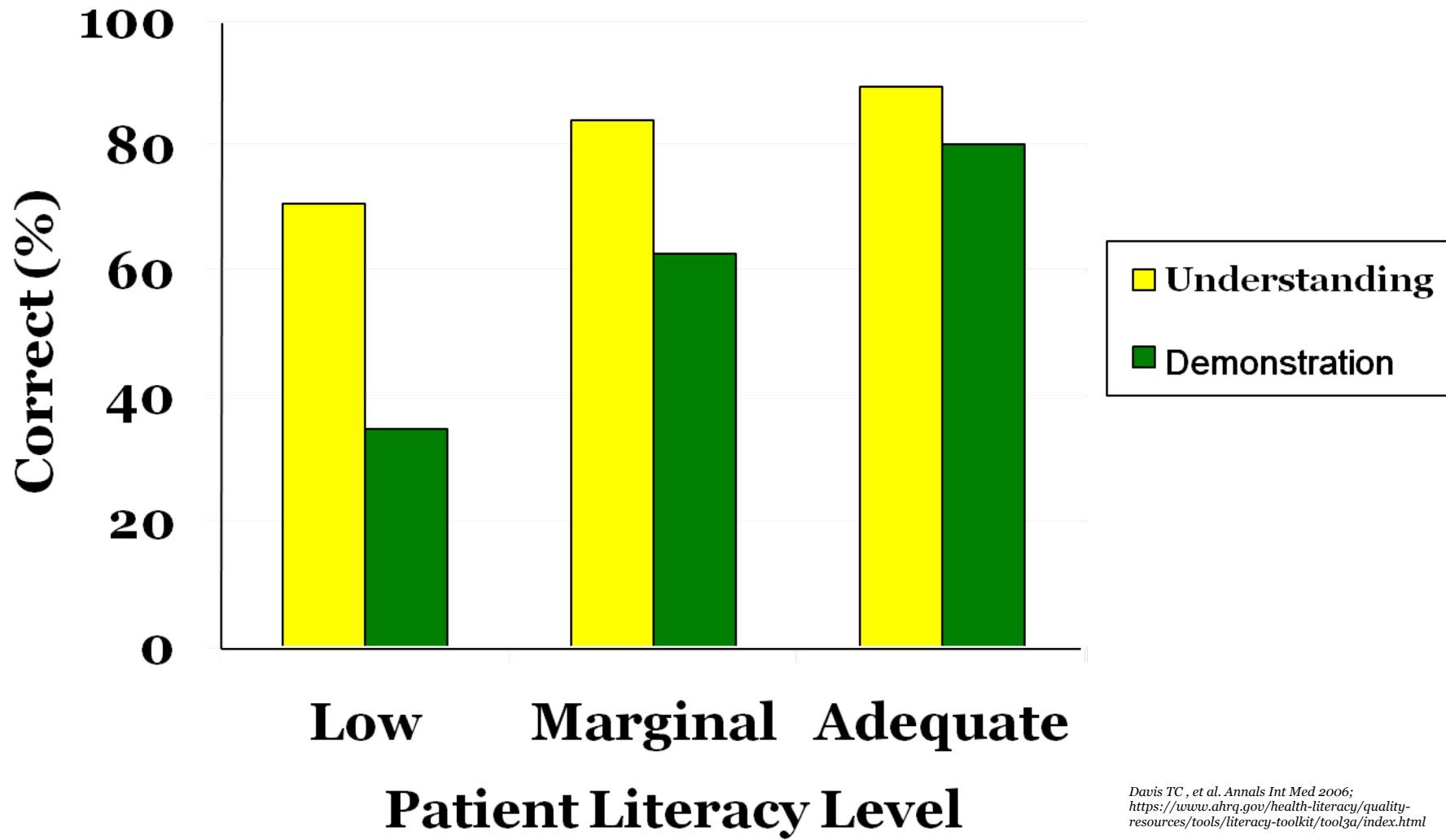
An illustration



<https://www.ahrq.gov/health-literacy/quality-resources/tools/literacy-toolkit/tool3a/index.html>



An illustration



Davis TC, et al. Annals Int Med 2006;
<https://www.ahrq.gov/health-literacy/quality-resources/tools/literacy-toolkit/tool3a/index.html>



And consent?

1. Think about the theory of mind problem.
2. Collect data from your participant.
3. Change your process.
4. Test your process.
5. Codify your process.
6. Time, complexity, etc.



Wrap-up

