Enhancing the readability and comprehensibility of informed consent forms for research studies

or

How to help participants understand your consent forms

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Health Literacy Research with Diverse Populations

- Multi-method, CBPR research with research partner Caring Health Center (Springfield, MA)
  - Surveys, chart abstracts, home visits, in-depth interviews with African-American, Latinx, Russian-speaking, Vietnamese patients with chronic illness

- Multi-method research on care transitions for pregnant people experiencing hypertensive disorders of pregnancy (Geissler, Attanasio, et al.)
  - In-depth interviews with patients and with MFM, OB/GYN, CNM, and PCP providers
  - Readability review of patient education materials



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The RxHL study: community-responsive research to explore barriers to medication adherence

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Article

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Article

Cultural and translation challenges in assessing health literacy among immigrants from the former Soviet Union

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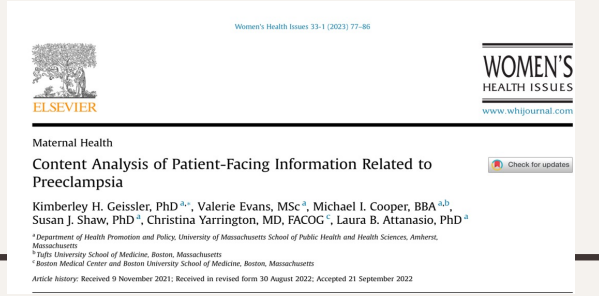

Women's Health Issues 33-1 (2023) 77–86

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WOMEN'S HEALTH ISSUES
www.whijournal.com

Maternal Health

Content Analysis of Patient-Facing Information Related to Preeclampsia

Check for updates

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Overview

- Why does readability matter for consent forms?
- Who is most likely to struggle with consent forms?
- How can I make my consent forms more readable?
- Resources for further reading

What would it feel like to have trouble reading health information?

Try reading these discharge instructions (yes, the font size is intentionally small):

ERUTCNUP SITE CARE

- If you poleved bleeding or sudden swelling at the niorg site:
- Lie down, apply direct pressure above the site. If you poleved bleeding or sudden swelling at the wrist or elbow erutcnup site: sit down and raise your arm above the level of your heart, apply direct pressure above and below the site with the etisoppo hand. If elbanu to stop the bleeding call 911 or have someone drive you to the closest emergency room.
- Numbness and tingling of the detceffa ytimertxe should be detroper to your primary care physician.
- Remove dressing (if elbacilppa) 24 hours after your erudecorp.

Thank you to for this example

University of Virginia Health System | Claude Moore Health Sciences Library

Questions? Find out more at the **Patient & Family Library** or contact Lydia Witman, Patient & Family Library Manager.

hsl.virginia.edu/pfl

Special thanks to the UVA Patient & Family Education Committee, and the Health Literacy Workgroup (Robin Passantino, Cat Harrington, Laura Humbertson, Donna White, Rhode Baptiste, and Cindy Westley).

Thanks to Jason Bennett for design help in the Claude Moore Health Sciences Library.

Why should we care about readability?

- Consent forms are a required and critical part of human subjects protections
- Consent *can* help build rapport rather than deter enrollment

Do we want people to understand consent forms?

- https://earthlymission.com/terms-of-service-apps-reading-time-infographic/
- “The system is perfectly designed to produce the results it gets.”
  - Whose interests are being protected?
  - What information do potential participants need about your study in order to decide to participate?

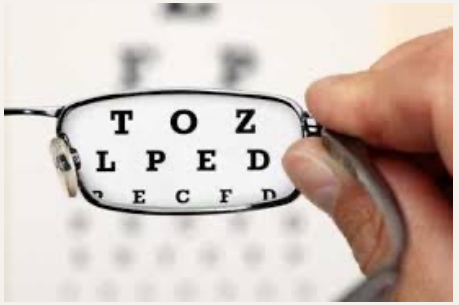
Primary Ethical Standards

1. Respect for persons
    - Includes principles of Autonomy and Competence
        - Research must be voluntary
        - Individuals must be told about and must understand all of the risks and benefits of a study before they agree to participate (informed consent)
        - Individuals must be able to make decisions (competence).
2. Do No Harm
    - Research should aim to minimize harm and maximize benefit
3. Social Justice
    - Benefits must be equitably distributed among participants

Who is most likely to struggle with consent forms? (and what happens next)

Who is most likely to struggle with consent forms?

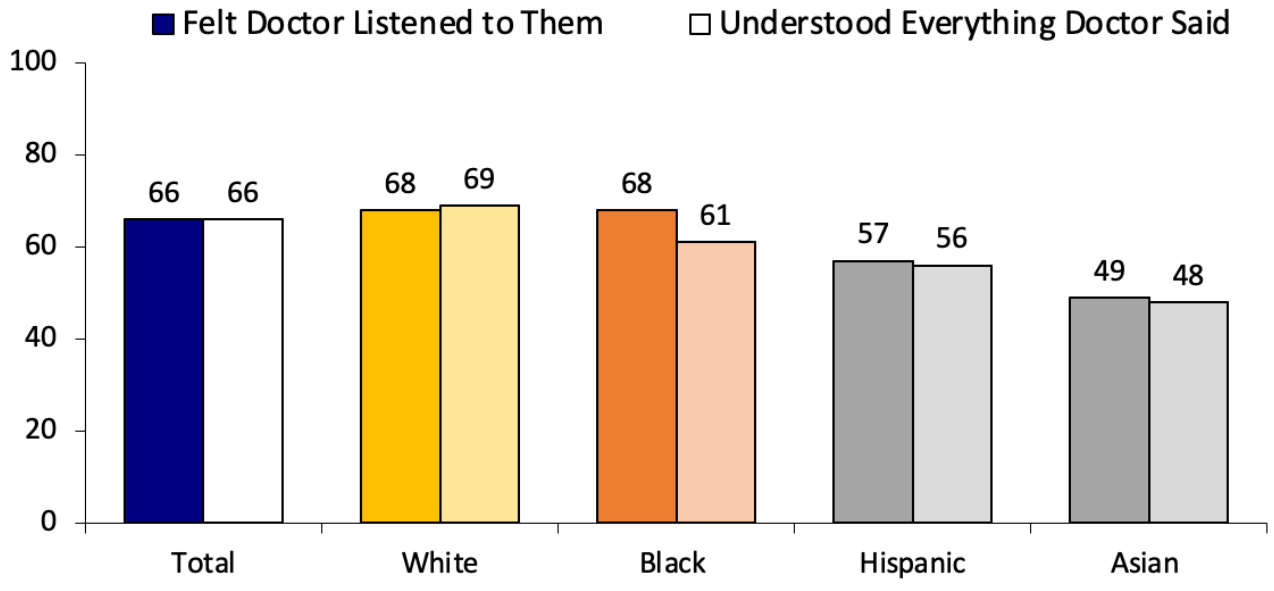
- People with limited education
- People whose first language is not English
- People with limited vision
- People over age 65
- People with poorer self-rated health (Goodman et al. 2013, Kirsch et al. 2002)





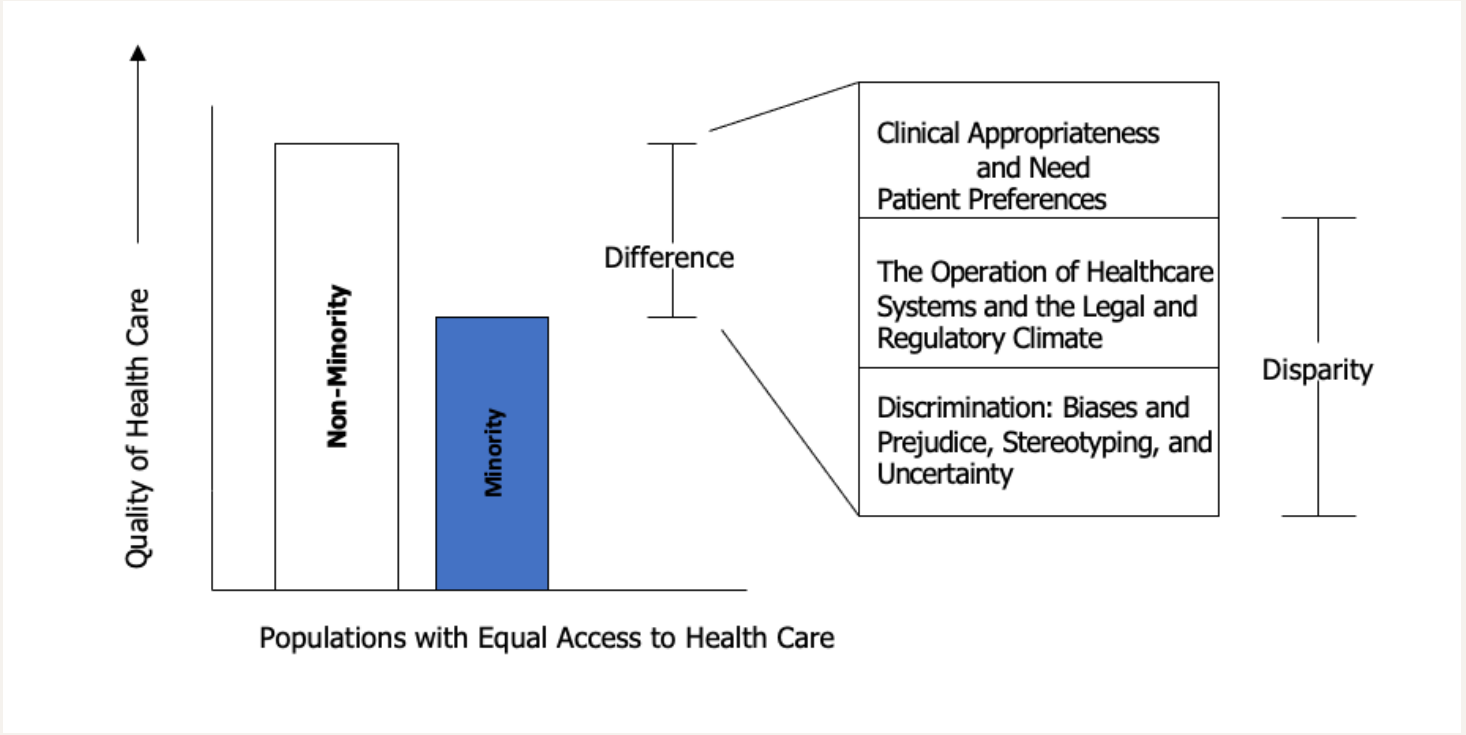
Minority patients are less likely to feel their doctor listened to them than whites

Percentage of adults ages 18 to 64 reporting ease of communication during doctor visits, 2001



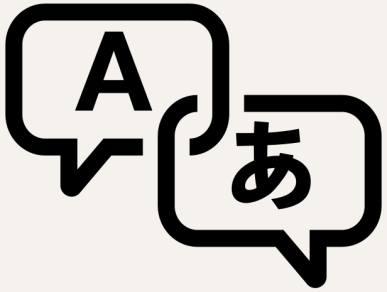
Source: The Commonwealth Fund. Health Care Quality Survey. 2001.

Differences, Disparities, and Discrimination:



Source: IOM,Unequal Treatment, 2002

How can I make my consent forms more readable?



Translate consent forms into participants' first language

How many people will take part in this study?
The final sample size for the study will include a total of 450 persons, up
each group.

What benefits can I expect from being in this study?
You should not expect any benefit from taking part in this study. In othe
and CHW support have been shown to improve medication adherence
control. Results of this study will inform future strategies to improve me
among people of diverse cultures with hypertension.

What risks, side effects or discomforts can I expect from being in
The risks of participating in this study include loss of confidentiality and
emotional distress if you find the interview questions are sensitive. If yo

Có bao nhiêu người sẽ tham gia nghiên cứu này?
Cỡ mẫu cuối cùng cho nghiên cứu sẽ bao gồm tổng cộng 450 người, tối đa 225 ngườ
trong mỗi nhóm.

Tôi có thể mong đợi nhận được những lợi ích gì khi tham gia nghiên cứu này
Quý vị không nên mong đợi nhận bất kỳ lợi ích nào từ việc tham gia nghiên cứu này.
nghiên cứu khác, sự hỗ trợ của dược sĩ và nhân viên y tế cộng đồng đã được chứng
thiện độ tuân thủ dùng thuốc và kiểm soát huyết áp. Kết quả của nghiên cứu này sẽ
thông tin cho các chiến lược trong tương lai để cải thiện độ tuân thủ dùng thuốc ở n
cao huyết áp thuộc các nền văn hóa khác nhau.

Tôi có thể gặp những rủi ro, tác dụng phụ hoặc bất tiện nào khi tham gia ngh
Những rủi ro khi tham gia vào nghiên cứu này bao gồm mất tính bảo mật và gặp tình
thẳng tâm lý hoặc cảm xúc nếu quý vị thấy các câu hỏi phỏng vấn là nhạy cảm. Nếu c

Use Plain Language

Medicaid Eligibility

This example was created for training and is not official agency text.

✖ Before

Medicaid: Apply if you are aged (65 years old or older), blind, or disabled and have low income and few resources. Apply if you are terminally ill and want to receive hospice services. Apply if you are aged, blind, or disabled; live in a nursing home; and have low income and limited resources. Apply if you are aged, blind, or disabled and need nursing home care, but can stay at home with special community care services. Apply if you are eligible for Medicare and have low income and limited resources.

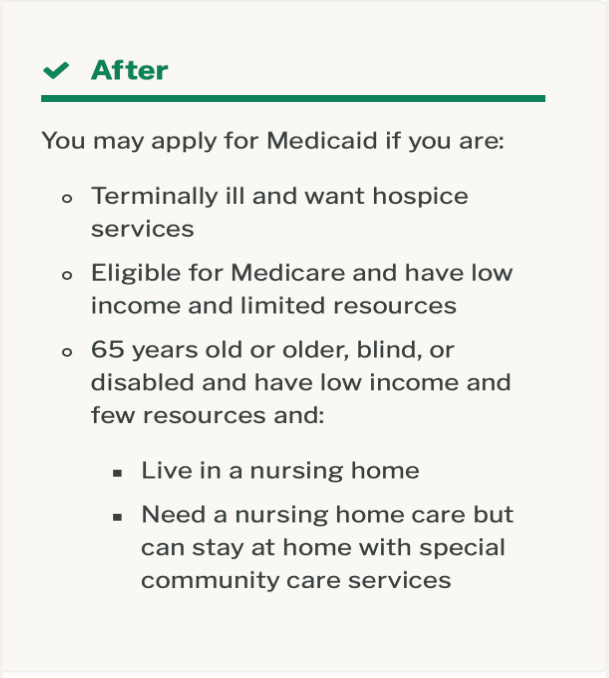
✔ After

You may apply for Medicaid if you are:

- Terminally ill and want hospice services
- Eligible for Medicare and have low income and limited resources
- 65 years old or older, blind, or disabled and have low income and few resources and:
  - Live in a nursing home
  - Need a nursing home care but can stay at home with special community care services

Plain language writing features:

- Lists, headers, tables and other elements that make information easy to follow
- Reader-centered organization
- “You” and other pronouns
- Active voice, not passive
- Short sentences and paragraphs
- Common, everyday words
- Examples



Patient-centered communication for consent forms

- Place yourself in patients' shoes: what would *you* want to know?
- Use analogies to explain complex ideas
  - e.g., "a coin toss" for randomization
- **Don't** avoid or soft-pedal risks
- **Do** emphasize contribution to knowledge, especially for minoritized participants

Example 1

Original	**Revised**
• Grade level = 13.0 • Reading Ease = 39.9 • 20% passive sentences	• Grade level = 6.1 • Reading Ease = 79.5 • 0% passive sentences
If you agree to **participate**, we will **arrange a screening interview** with you at our research clinic. **During this interview, you will be asked** to do some tasks that measure your thinking and problem-solving **abilities and answer questions** about your **medical history and occupational history**. If you are willing, a trained technician will **obtain a blood sample of approximately** two tablespoons. This visit should take **approximately** two hours. If you are eligible **to participate in the study**, every two years we will **repeat the initial assessment procedures** at the Center for Health Studies**, and we will periodically review** your medical record to see if there is a change.	If you agree to **be in the study**, we will **schedule a visit** at our research clinic. **At this visit, we will ask you** to do some tasks that measure your thinking and problem-solving **skills. Then, we will ask you** questions about your **health and your work history.** If you are willing, **we** will **take about** two tablespoons **of blood from your arm**. This visit should take **about** two hours. If you are eligible **for** the study, we will ask you to **come in for a similar visit and blood draw** every two years**. We will also check** your medical record **from time to time** to see if there is a change.

Conclusion:
Like universal access, plain language helps everybody

- Ensuring understanding ≠ “dumbing it down”
  - Increased comprehension is the goal of plain language
- “Data suggest that having institutional review boards recommend or require evidence-informed consent practices may be an effective way to increase their use.” (Solomon et al. 2022)

Resources

- Fry readability formula
  - Calculates grade level using syllables per word for 100-word chunks of text
- https://www.plainlanguage.gov
  - Provides training, examples, and overviews of federal laws and policy governing access to information (not health care-specific)
- https://www.health.state.mn.us/data/irb/plainlang.html
  - Provides before/after examples of plain language consent forms and many other resources
- https://www.gabrielledickson.com/infographic-informed-consent

For more information:
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Questions?

