

Using ChatGPT to Facilitate Truly Informed Medical Consent

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BROWN
Alpert Medical School

The Promise of Voice AI



Quick Statistics About Voice, Speech, Language

- About 18 million adults have problems with their voice in the past year
- 5% of children have a speech disorder
- About 2 million people in the United States currently have aphasia

AP

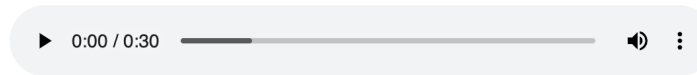
Illness took away her voice. AI created a replica she carries in her phone



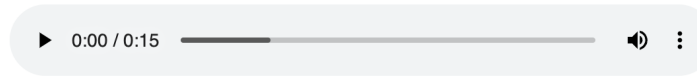


- **Helping patients recover their voice**, for those suffering from sudden or degenerative speech conditions. The Norman Prince Neurosciences Institute at Lifespan, a not-for-profit health system that serves as the primary teaching affiliate of Brown University's medical school, is exploring uses of AI in clinical contexts. They've been piloting a program offering Voice Engine to individuals with oncologic or neurologic etiologies for speech impairment. Since Voice Engine requires such a short audio sample, doctors Fatima Mirza, Rohaid Ali and Konstantina Svokos were able to restore the voice of a young patient who lost her fluent speech due to a vascular brain tumor, using audio from a video recorded for a school project.

1. Current voice

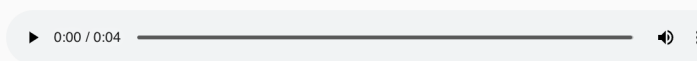


2. Reference audio



3. Generated audio

Talking Ordering

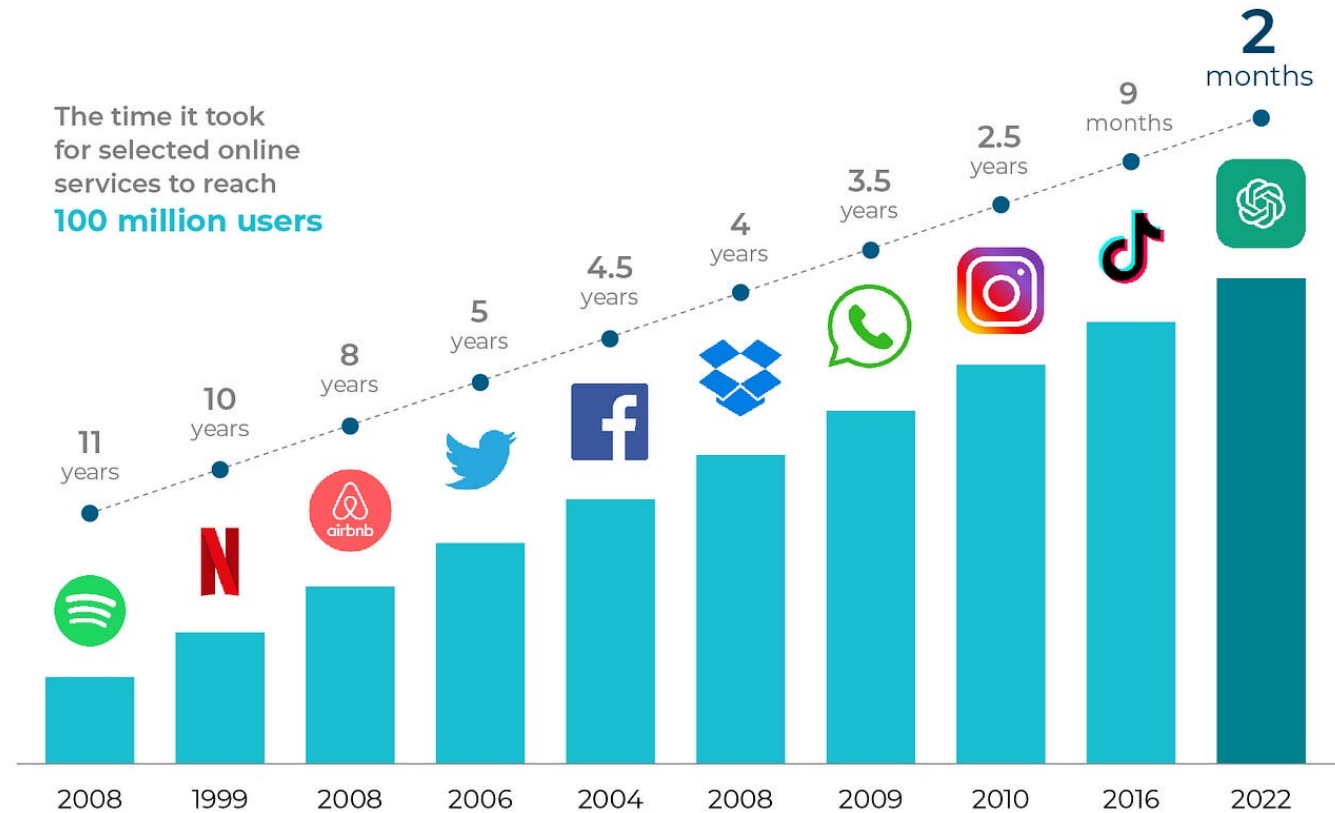


Can I please have a number one with large fries and with a strawberry shake?

Hi everyone, this is what my voice sounds like using OpenAI's new text to speech model called Voice Engine. I was able to use just 15 seconds of a video that I made for a class project to be the reference audio source for the voice you hear right now. What do you think?

The ChatGPT Phenomenon

ChatGPT sprints to 100 million users





Source: World of Statistics



Letter to the Editor

Performance of Three Large Language Models on Dermatology Board Examinations

Fatima N. Mirza^{1 4}  , Rachel K. Lim^{1 2 4}, Sara Yumeen¹, Samer Wahood², Bashar Zaidat³, Asghar Shah², Oliver Y. Tang¹, John Kawaoka¹, Su-Jean Seo¹, Christopher DiMarco¹, Jennie Muglia¹, Hayley S. Goldbach¹, Oliver Wisco¹, Abrar A. Qureshi¹, Tiffany J. Libby¹

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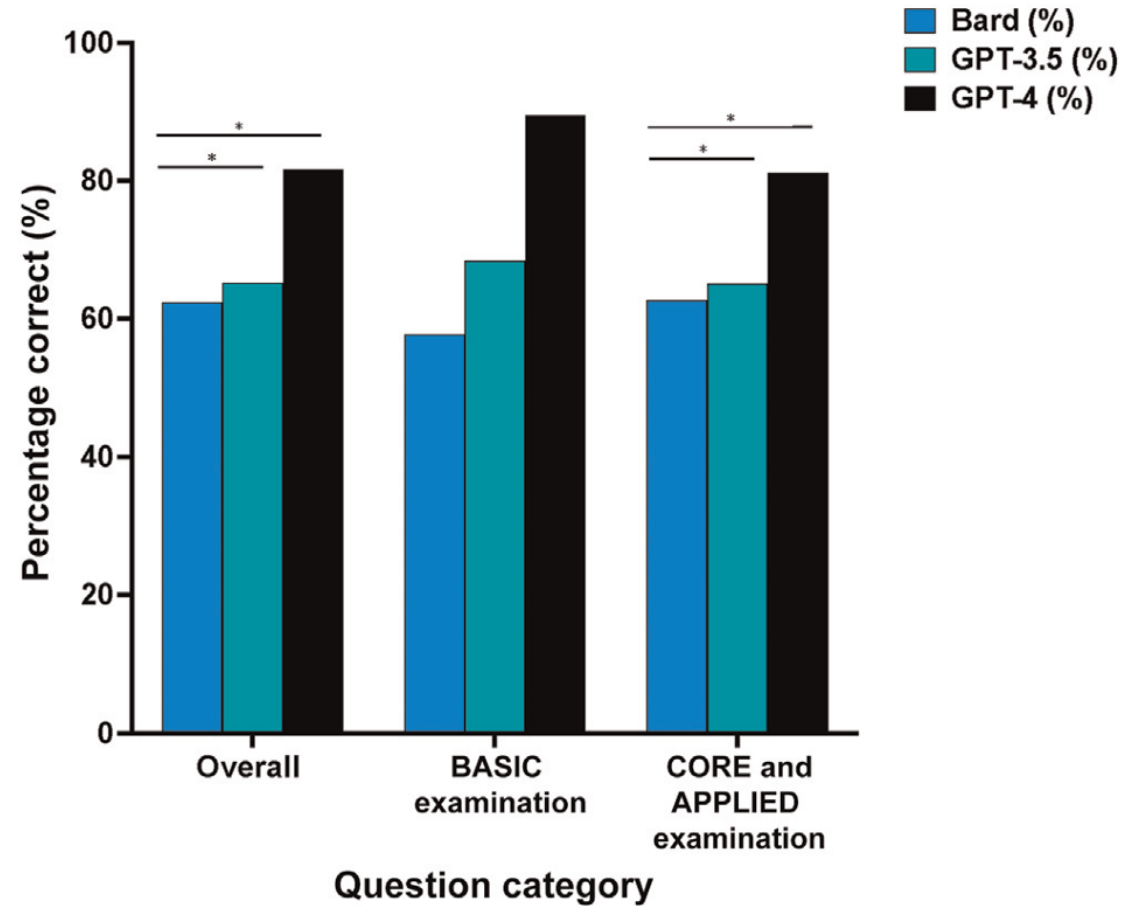


Figure 1. Performance of Google Bard, ChatGPT (GPT-3.5), and GPT-4 on questions overall, the BASIC examination, and the CORE and APPLIED examinations. Asterisk (*) denotes differences significant at $P < 0.05$.

Addressing AI Biases

“A photo of a teddy bear on a skateboard in Times Square”



Figure 2. Representative Images for Depictions of Surgeons by DALL-E 2, Midjourney, and Stable Diffusion

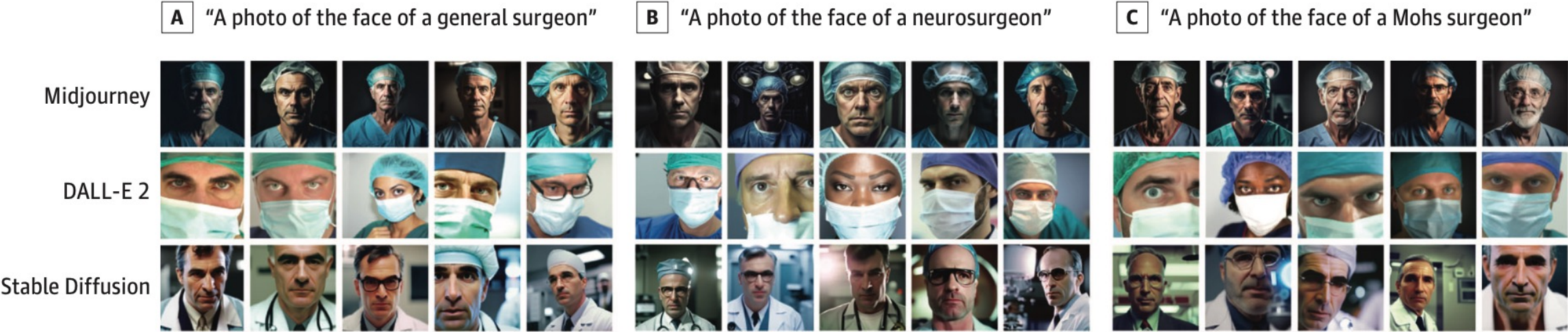


Table 1. Differences in Percentage of Female Surgeons Depicted by DALL-E 2, Midjourney, and Stable Diffusion From True Demographic Data

Specialty	% True demographic data ^a				P value				
		DALL-E 2	Midjourney	Stable Diffusion	Midjourney vs true demographic	Stable Diffusion vs true demographic	DALL-E 2 vs Midjourney	DALL-E 2 vs Stable Diffusion	Midjourney vs Stable Diffusion
General surgery									
Attending surgeon	22.6	18.0	0	0	<.001	<.001	<.001	<.001	>.99
Trainee	46.1				<.001	<.001			
Mohs surgery									
Attending surgeon	28.1	20.0	0	0	<.001	<.001	<.001	<.001	>.99
Trainee	49.4				<.001	<.001			
Neurosurgery									
Attending surgeon	9.6	13.0	0	0	.002	.002	<.001	<.001	>.99
Trainee	21.4				<.001	<.001			
Orthopedic surgery									
Attending surgeon	5.9	18.0	0	0	.02	.02	<.001	<.001	>.99
Trainee	18.3				<.001	<.001			
Otolaryngology									
Attending surgeon	18.9	0	0	14.0	<.001	.27	>.99	<.001	<.001
Trainee	40.2				<.001	<.001			
Thoracic surgery									
Attending surgeon	8.3	20.0	0	0	.005	.005	<.001	<.001	>.99
Trainee	30.0				<.001	<.001			
Urology									
Attending surgeon	10.0	18.0	0	0	.002	.002	<.001	<.001	>.99
Trainee	30.6				<.001	<.001			
Vascular surgery									
Attending surgeon	15.4	20.0	0	0	<.001	<.001	<.001	<.001	>.99
Trainee	35.5				<.001	<.001			
Overall									
Attending surgeon	14.7	15.9	0	1.8	<.001	<.001	<.001	<.001	<.001
Trainee	35.8				<.001	<.001			

^a The true demographic data reported in the table reflect attending surgeons and surgical trainees in the US.



Research

JAMA Surgery | **Original Investigation**

Demographic Representation in 3 Leading Artificial Intelligence Text-to-Image Generators

Rohaid Ali, MD; Oliver Y. Tang, MD; Ian D. Connolly, MD, MS; Hael F. Abdulrazeq, MD; Fatima N. Mirza, MD, MPH;
Rachel K. Lim, BS; Benjamin R. Johnston, MD, PhD; Michael W. Groff, MD; Theresa Williamson, MD;
Konstantina Svokos, DO, MS; Tiffany J. Libby, MD; John H. Shin, MD; Ziya L. Gokaslan, MD;
Curtis E. Doberstein, MD; James Zou, PhD; Wael F. Asaad, MD, PhD

AI tool amplifies, perpetuates racial and gender bias new study shows



Published December 14, 2023 at 7:40 AM CST



▶ LISTEN • 9:30

The good news? Women and people of color are gaining traction in the once-male-dominated world of surgery and surgical specialties. The bad news? [Artificial Intelligence tools](#) continue to perpetuate gender and racial bias through the images they generate. It creates a sort of 'funhouse mirror' that distorts that progress according to a new study published in the [Journal of the American Medical Association](#).



JAMA @JAMA_current · Nov 16, 2023

Study in [@JAMASurgery](#) found that 2 widely used text-to-image generators amplified societal biases, depicting >98% of surgeons as White males, and suggested that feedback is needed to enhance diversity in AI-generated content.



JAMA Surgery @JAMASurgery · Nov 15, 2023

Study highlights the need for strategies to prevent AI text-to-image generators from exacerbating profession-based stereotypes. [ja.ma/3sz9A4e](#) #ILookLikeASurgeon



The Boston Globe @BostonGlobe · Nov 15, 2023

Doctors find AI text-to-image generators perpetuate societal biases



Harnessing AI Responsibly



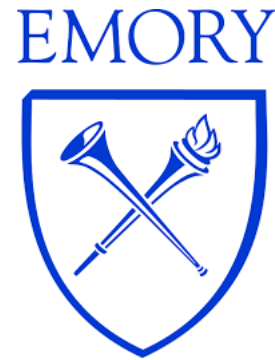
ON THE READABILITY OF SURGICAL CONSENT FORMS

T. M. GRUNDNER, ED.D.

Abstract A great deal of attention has been paid to ensuring that surgical consent forms have valid content, but little effort has been made to ensure that the average patient can read and understand them. Five representative surgical consent forms were analyzed with two standardized readability tests. The readability of all five was approximately equivalent to that of material intended for upper-division undergraduates or graduate students. Four of the five forms were written at the level of a scientific

journal, and the fifth at the level of a specialized academic magazine. I suggest that few consent forms currently in use could pass readability tests. The implication of these findings is that thousands of persons may be undergoing surgery each year on the basis of inadequate consent. The problem has a reasonably simple solution: analysis of all consent forms for readability, and rewriting of those found excessively difficult. (N Engl J Med. 1980; 302: 900-2.)



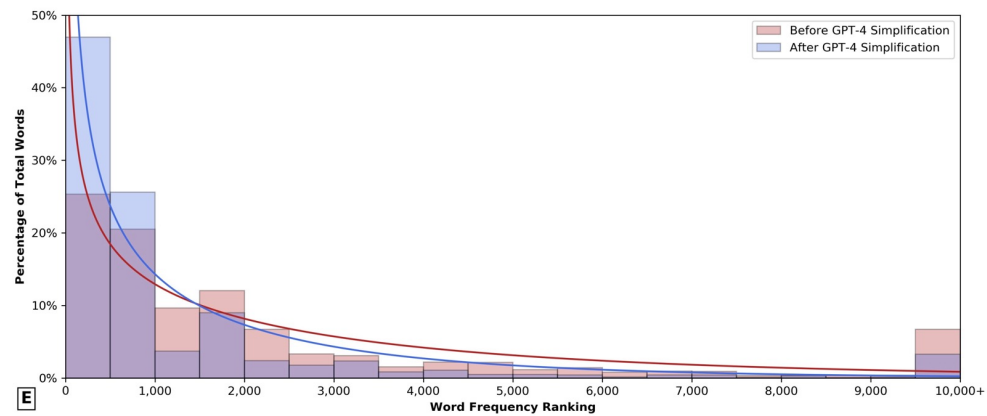
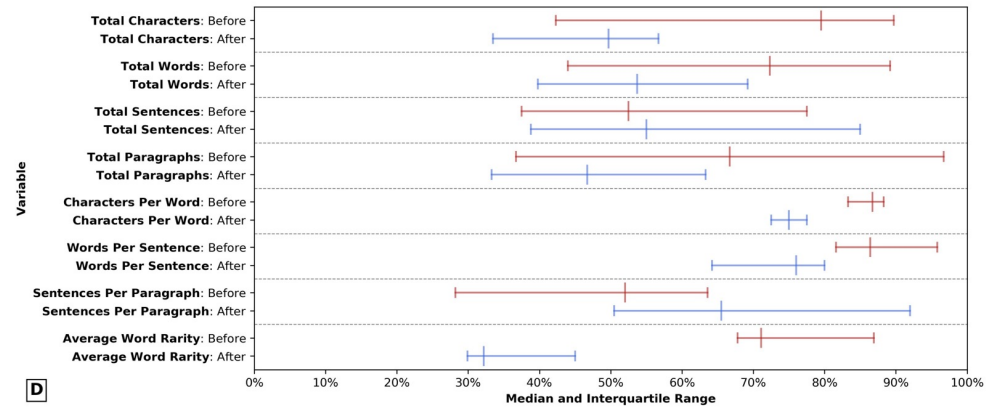
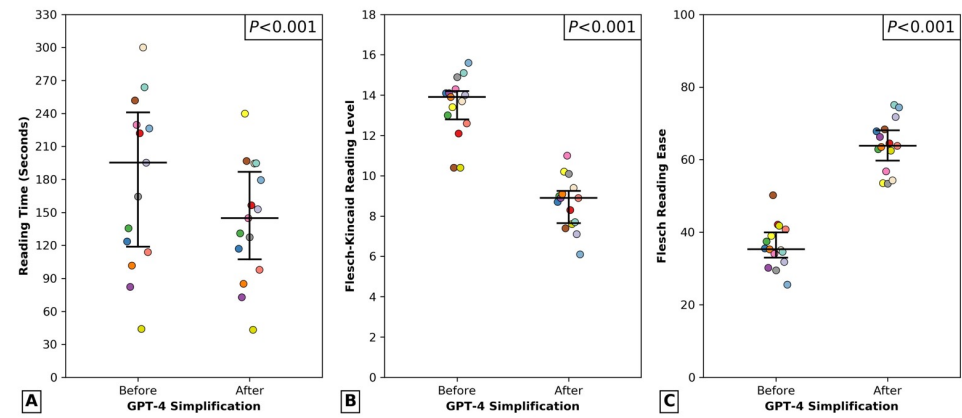


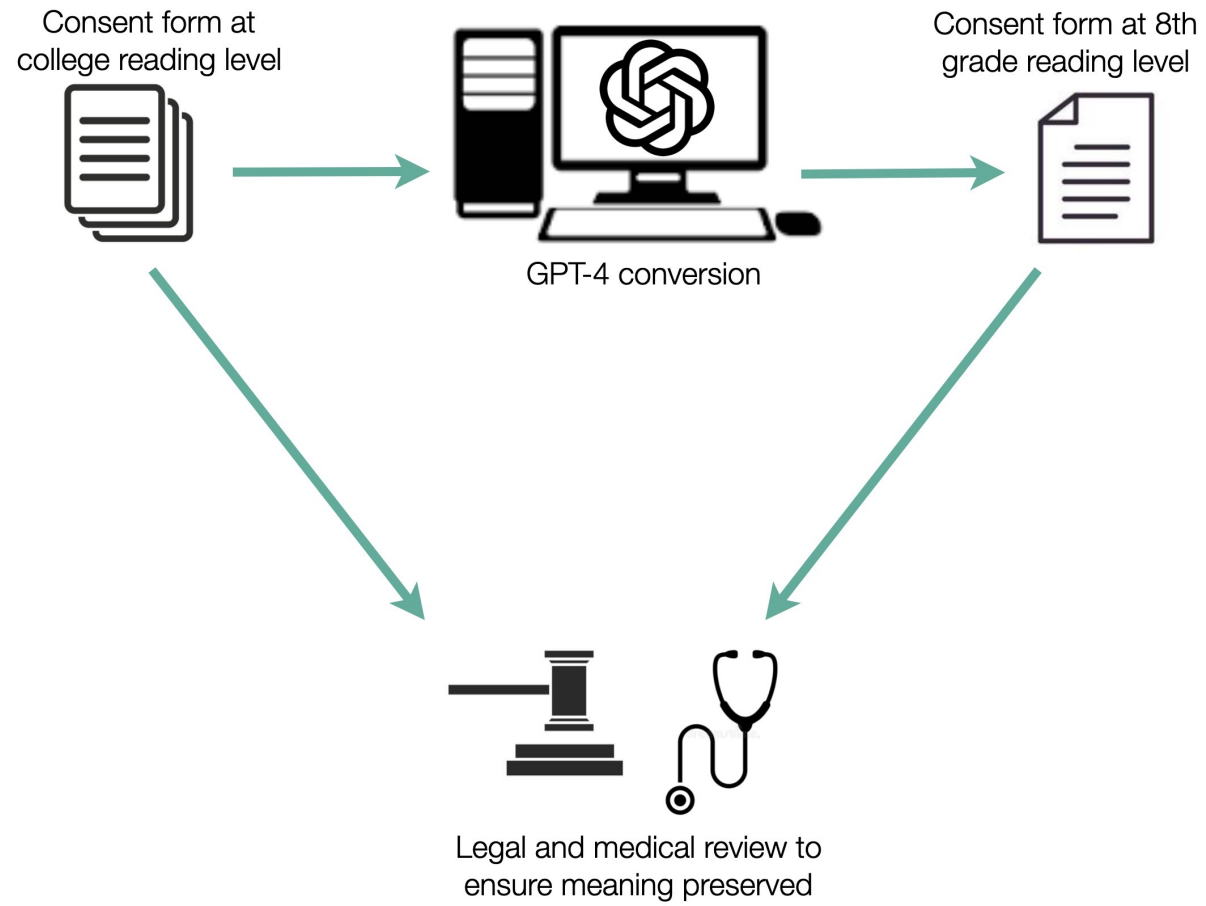
Model
GPT-4

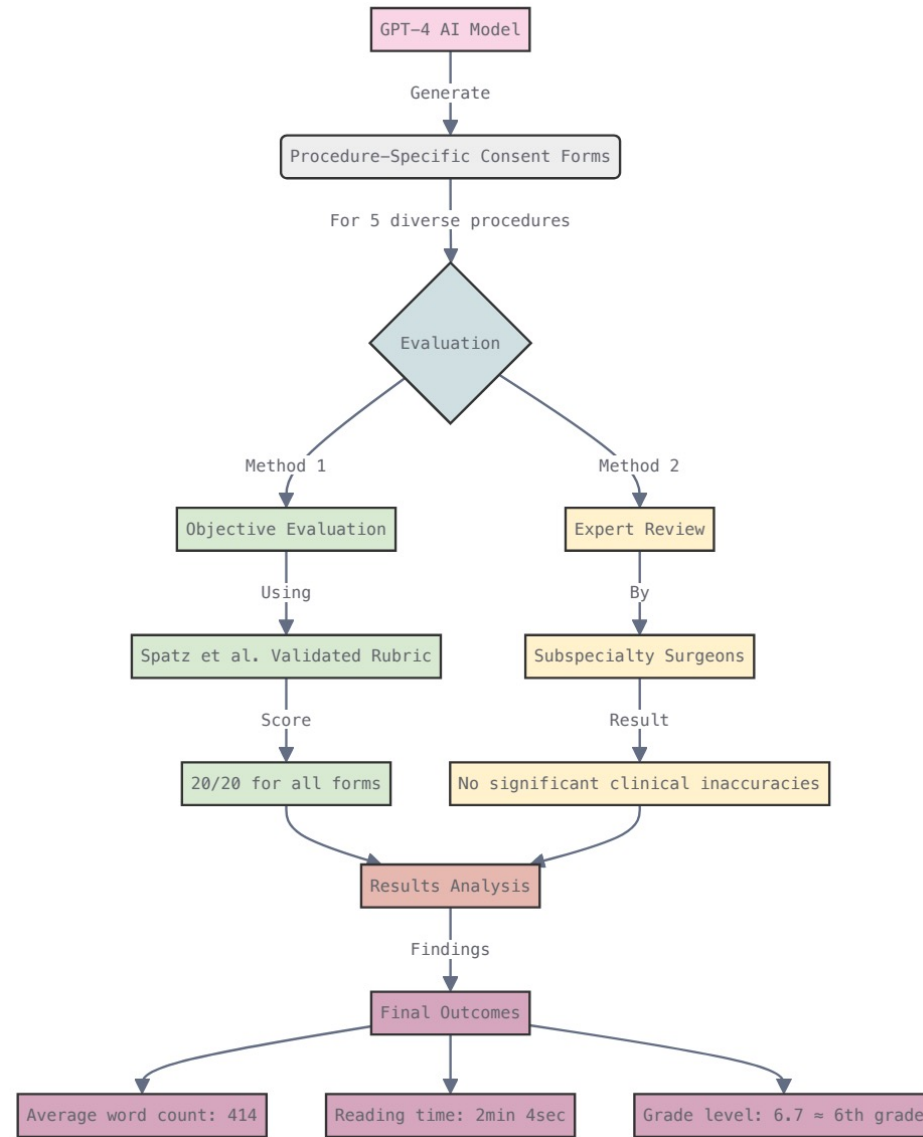
GPT-4 currently has a cap of 25 messages every 3 hours.

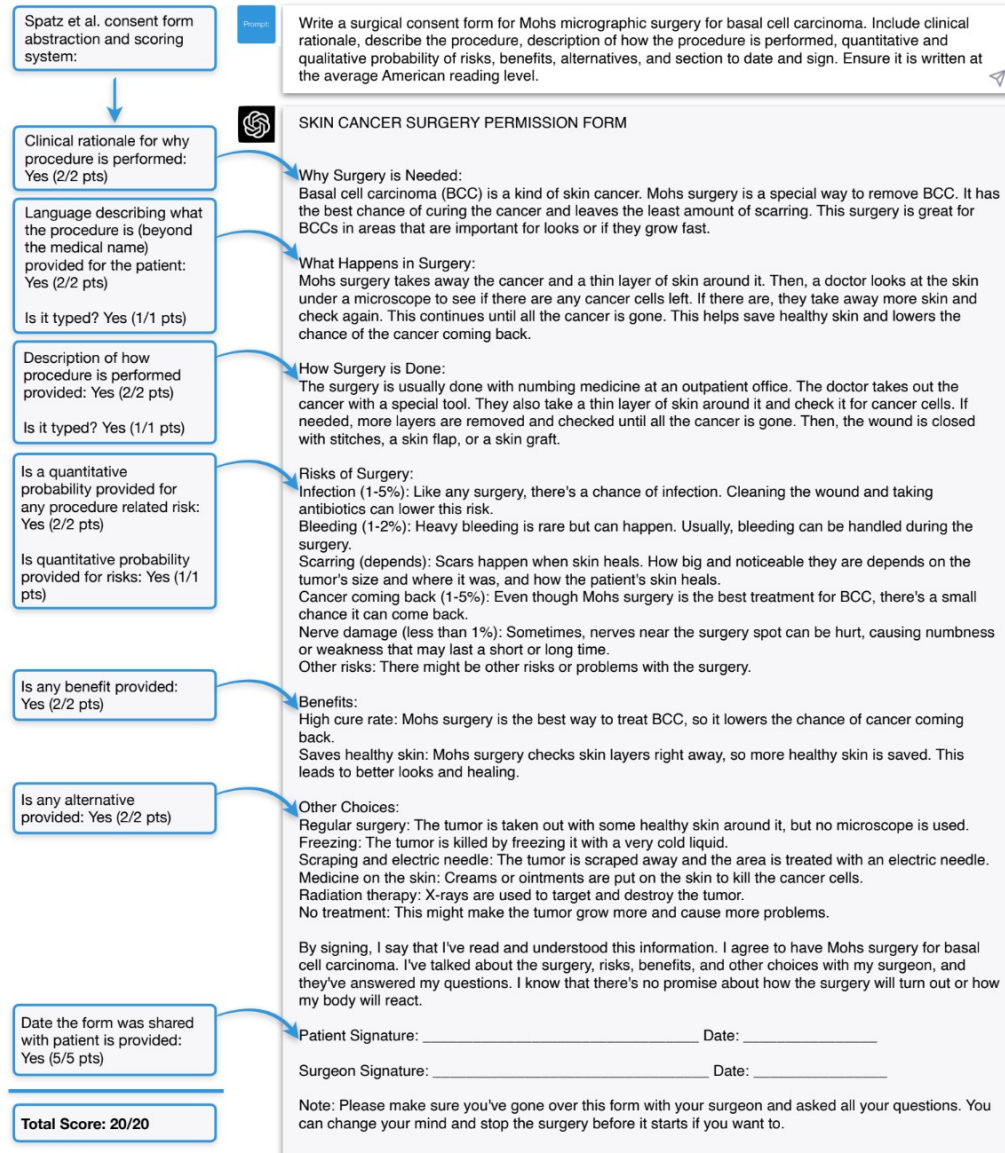
While preserving content and meaning, convert this consent to the average American reading level:

I give permission to my health care professionals (who are listed on the back of this form as the performing provider), to do the procedure(s) listed on the back of this form, with anesthesia and/or sedation if that is needed. Anesthesia or sedation medicine will be given by the health care professional, anesthesiologist, or other trained health care staff who work under appropriate supervision.










[nature](#) > [npj digital medicine](#) > [articles](#) > article

Article | [Open access](#) | Published: 08 March 2024

Bridging the literacy gap for surgical consents: an AI-human expert collaborative approach

[Rohaid Ali](#) , [Ian D. Connolly](#), [Oliver Y. Tang](#), [Fatima N. Mirza](#), [Benjamin Johnston](#), [Hael F. Abdulrazeq](#), [Rachel K. Lim](#), [Paul F. Galamaga](#), [Tiffany J. Libby](#), [Neel R. Sodha](#), [Michael W. Groff](#), [Ziya L. Gokaslan](#), [Albert E. Telfeian](#), [John H. Shin](#), [Wael F. Asaad](#), [James Zou](#) & [Curtis E. Doberstein](#)

[npj Digital Medicine](#) **7**, Article number: 63 (2024) | [Cite this article](#)

**Theory will only take you so
far**



Original Surgical Consent

Acknowledgment of Informed Consent: Surgical Procedure
You have the right to be informed about the surgical procedure(s) which your provider recommends so that you can make an informed decision whether or not to undergo the procedure(s). The purpose of this form is to provide written acknowledgment of your consent.

Name of Provider(s) Performing Procedure(s):
I voluntarily authorize the provider, as well as his/her partner, assistant, or designee qualified to perform the surgical procedure(s) described below:

Primary procedure(s) to be performed: _____

Laterality (Left, Right, Bilateral, N/A) (required): _____

Additional procedure(s) to be performed (if applicable): _____

Laterality (Left, Right, Bilateral, N/A) of Additional procedure(s): _____

Department of Anesthesia to provide services (Yes or No, required): Yes No

If "Yes" - My provider has explained common risks associated with this surgery or procedure(s). I understand that the procedure(s) may involve such risks and may include adverse effects from the administration of anesthesia, conscious sedation, or medications I receive. I understand that these risks also include allergic reactions, bleeding, blood clots, burns, infections, adverse side effects of drugs, loss of sensation, loss of vision, loss of limb function, paralysis, stroke, brain damage, heart attack, loss of bodily function and death. I understand that there may be other unforeseen risks or complications of the procedure(s) and/or anesthesia, as well as risks related to my recovery.

If "No" - My provider has explained common risks associated with this procedure(s). I understand that the procedure(s) may involve such risks and may include adverse effects from the administration of conscious sedation, or medication(s) I receive. I understand that these risks also include allergic reactions, bleeding, blood clots, infections, loss of bodily function and death. I understand there may be other unforeseen risks or complications of the procedure(s), as well as risks related to my recovery.

If a healthcare worker receives an occupational exposure to my blood or body fluids during the procedure and I am unable to provide consent at the time of the exposure, I consent to an immediate HIV blood test so that the healthcare worker can receive prompt initiation of antiretroviral therapy.

I understand that genetic or diagnostic testing may be done on tissue, fluids, or organs removed during surgery. I understand that this is a teaching facility, and that the hospital may use remaining portions of tissue, fluid, or organs that are not sent for genetic or diagnostic testing for teaching, research, or scientific progress or other alternative purposes of Rev. 04/2023

You have the right to be informed about the surgical procedure(s) which your provider recommends so that you can make an informed decision whether or not to undergo the procedure(s). The purpose of this form is to provide written acknowledgment of your consent.

Flesh-Kincaid Reading Level: 12.1 | Words: 45 | Average syllables per word 1.6

My condition and the above procedure(s) have been described to me. Alternative treatments for my condition and the risks of alternative treatment or no treatment at all have been explained. I understand that during my surgical procedure(s) my provider may decide that there are additional surgeries or procedures which may be required, and I consent to those surgeries or procedures which in my providers' professional judgement are necessary. The potential need for blood transfusions was explained where appropriate, along with a discussion of the potential risks, benefits, and alternatives to transfusion.

Flesh-Kincaid Reading Level: 14.7 | Words: 93 | Average syllables per word 1.8

Simplified Surgical Consent

Understanding and Agreement
You have the right to know about your surgery and other treatments. This form is your agreement in writing.

I give permission for this provider and their partner, helper, or someone they choose to do the surgery listed below.

Main surgery: _____

Site (Left, Right, Both, N/A): _____

Other surgery (if needed): _____

Site for other surgery (Left, Right, Both, N/A): _____

If a healthcare worker comes into contact with my blood or body fluids during the surgery and I can't give my consent, I agree to an immediate HIV blood test to help the healthcare worker.

I know that some might be done on tissue or organs removed during surgery. I understand that this is a teaching hospital, and leftover samples might be used for teaching, research, or science, or might be frozen away. The hospital will try to keep me informed.

There may be people watching my surgery or treatment. There may also be extra technicians to monitor the surgery.

I don't have to agree to the surgery or treatment until I have all the information I need. I confirm that this has been done.

You have the right to know about your surgery and other treatments. This form is your agreement in writing.

Flesh-Kincaid Reading Level: 4.6 | Words: 19 | Average syllables per word 1.4

My health issue and treatments have been explained to me. I know about other treatment options and the risks of not getting treatment. I understand that I might need more surgeries or treatments during my surgery. I agree to this. If I might need a blood transfusion, I've been told about the risks and benefits.

Flesh-Kincaid Reading Level: 5.2 | Words: 55 | Average syllables per word 1.4

Stakeholder Review of AI-Generated Surgical Consent Form

 **Timeline:** April to July 2023

 **Key Institutional Stakeholders:**

- Strategic Operations
- Patient advocate
- Risk management
- Legal
- Surgical Executive Committee:
 - Surgical leads
 - Anesthesia leads
 - Perioperative leads

 **Approach:** Comprehensive review by key stakeholders across various departments

Addressing Concerns in AI-Generated Consent Form Implementation

⚠️ Concerns Raised

1. Potential introduction of biases into AI output
2. Determining authority for approving consent form wording
3. Need for similar initiative for other patient-facing literature

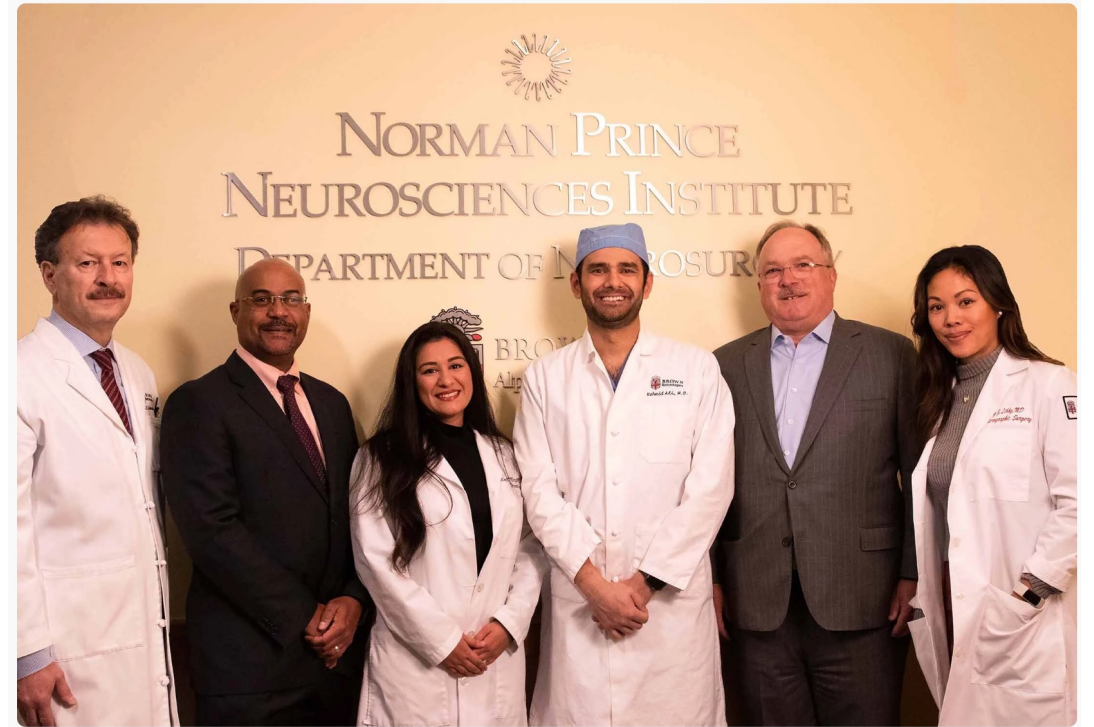
✅ Resolutions

1. Implemented multiple human expert reviews
2. Final approval assigned to risk management team
3. Proceeded with surgical consent, planned future expansion

The Boston Globe

Before and after: See how ChatGPT helped local doctors make medical forms easier to understand

By Maggie Scales Globe Correspondent, Updated August 23, 2023, 1:15 p.m.



From left: Dr. Ziya Gokaslan, Dr. Dean Roye, Dr. Fatima N Mirza, Dr. Rohaid Ali, Mr. John Fernandez, Dr. Tiffany J Libby




















Eric Topol @EricTopol · Jan 11

Important practical use of [#GPT4](#) for helping to make "informed consent" informed



CASE STUDY

Using ChatGPT to Facilitate Truly Informed Medical Consent

Fatima N. Mirza , M.D., M.P.H.,^{1,2} Oliver Y. Tang , M.D.,³ Ian D. Connolly , M.D.,⁴ Hael A. Abdulrazeq , M.D.,^{1,2} Rachel K. Lim , B.A.,¹ G. Dean Roye , M.D.,^{1,2} Cedric Priebe , M.D.,^{1,2} Cheryl Chandler , M.S.N., R.N., C.N.L., C.P.H.R.M.,² Tiffany J. Libby , M.D.,¹ Michael W. Groff , M.D.,⁵ John H. Shin , M.D.,⁴ Albert E. Telfeian , M.D., Ph.D.,^{1,2} Curtis E. Doberstein , M.D.,^{1,2} Wael F. Asaad , M.D., Ph.D.,^{1,2} Ziya L. Gokaslan , M.D.,^{1,2} James Zou , Ph.D.,⁶ and Rohaid Ali , M.D.^{1,2}

Received: September 19, 2023; Revised: October 22, 2023; Accepted: October 23, 2023; Published: January 10, 2024

Abstract

Informed consent is integral to the practice of medicine. Most informed consent documents are written at a reading level that surpasses the reading comprehension level of the average American. Large language models, a type of artificial intelligence (AI) with the ability to summarize and revise content, present a novel opportunity to make the language used in consent forms more accessible to the average American and thus, improve the quality of informed consent. In this study, we present the experience of the largest health care system in the state of Rhode Island in implementing AI to improve the readability of informed consent documents, highlighting one tangible application for emerging AI in the clinical setting.



Clinical Implications of Consent Form Readability

Study Methodology: Analysis of Federally Funded Clinical Trials



Data Source:

Comprehensive analysis using data from ClinicalTrials.gov



Study Scope:

All interventional clinical trials completed in the United States on or before January 1, 2023



Inclusion Criteria:

- Results posted online
- Accessible informed consent forms

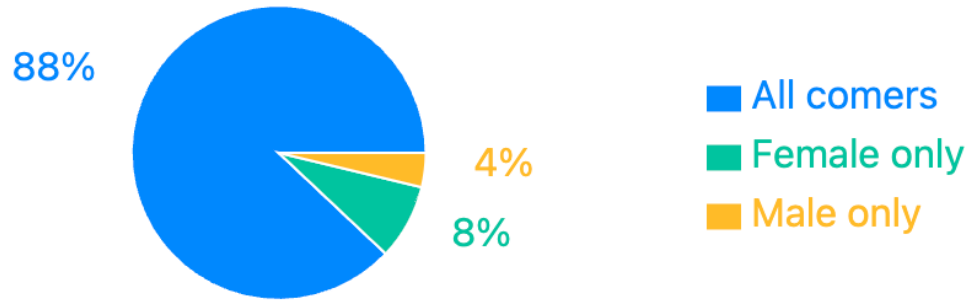


Focus:

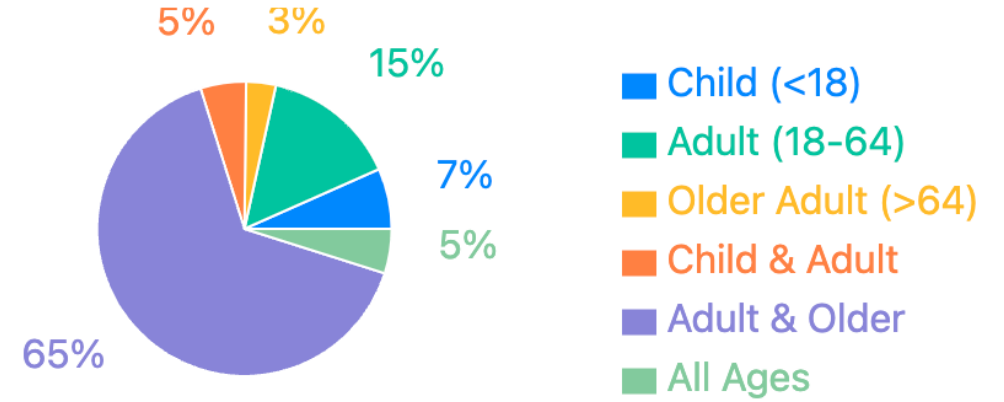
Studies sponsored by the National Institutes of Health (NIH) or other U.S. federal agencies

U.S. Federally Funded Clinical Trials Summary

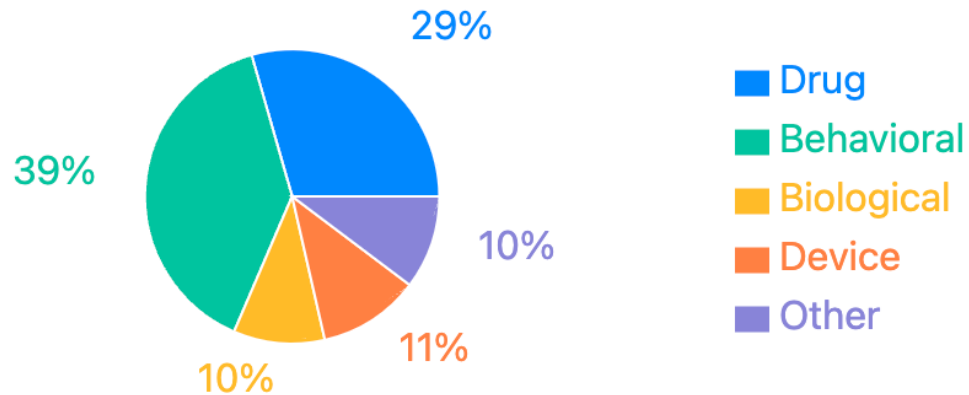
Participant Gender



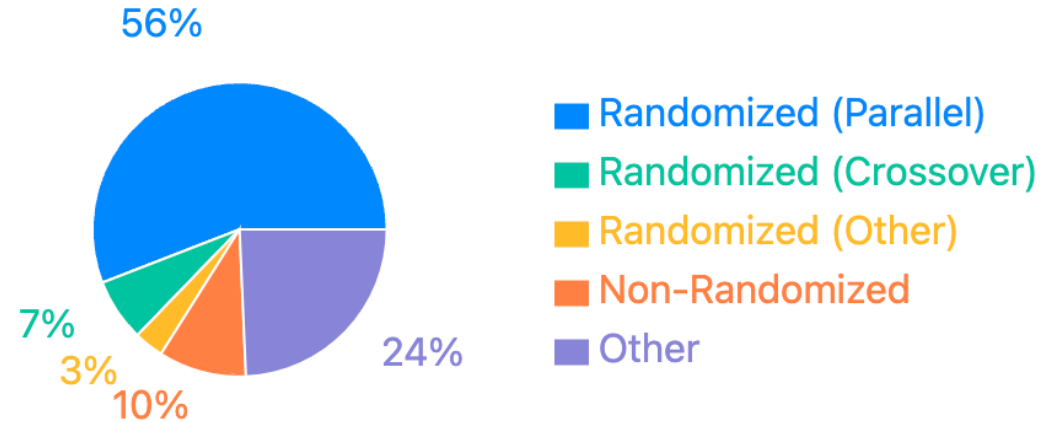
Participant Age



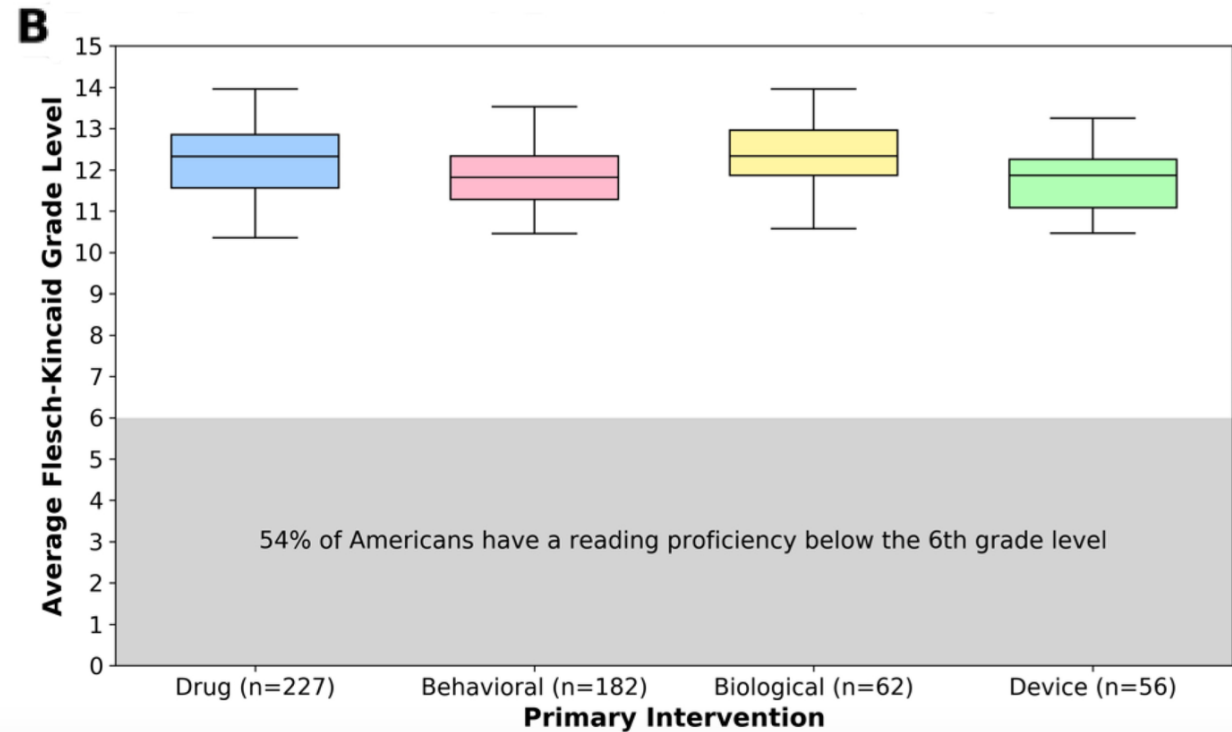
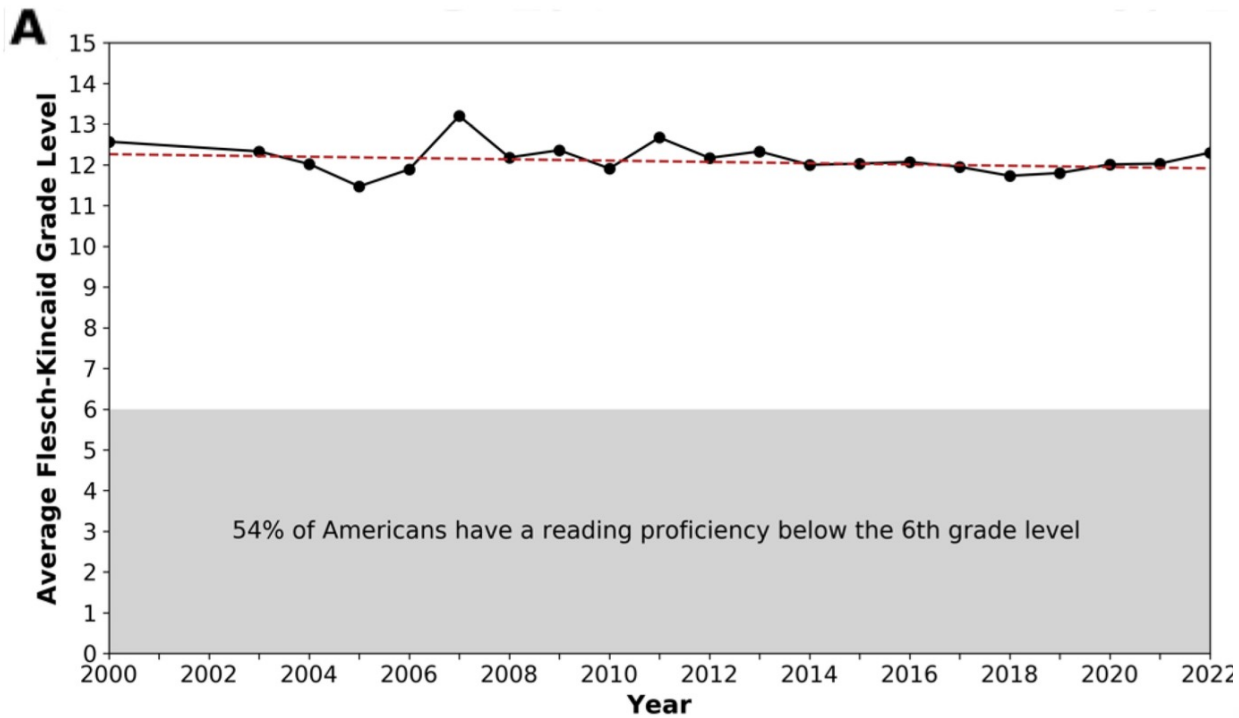
Primary Intervention



Study Design



798 Federally Funded Clinical Trials (2000-2023)



Consent Form Readability and Trial Dropout Rates

Key Findings

- › Each additional Flesch-Kincaid Grade Level increase in consent form:

16% higher dropout rate

(IRR 1.16, 95% CI 1.11-1.21, $p < 0.001$)

Analysis Method

Risk-adjusted zero-inflated negative binomial model

Factors Considered:

- › Enrollment
- › Subject age
- › Study design
- › Oncologic trial status
- › Subject gender
- › Primary intervention
- › Study phase
- › Consent form length

Consent Form Readability and Trial Dropout Rates

Key Findings: Readability

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- › Study phase
- › Consent form length

Key Findings: Pages vs. Readability

- › Unadjusted analysis: Number of pages significant (IRR 1.29, 95% CI 1.27-1.30, $p < 0.001$)
- › Risk-adjusted model: Number of pages not significant (IRR 1.01, 95% CI 0.99-1.03, $p = 0.305$)

Interpretation

The complexity of the language, rather than the length of the document, may be driving the association with dropout rates.

Potential Factors: Consent Form Complexity and Dropout Rates

Misaligned Expectations

Complex forms may lead to poor initial understanding, resulting in participants enrolling without fully grasping trial requirements.

Surprise and Dissatisfaction

Participants struggling with complex forms may experience unexpected challenges with study requirements or side effects.

Erosion of Trust

Complex language could diminish trust between researchers and participants, particularly among those with lower health literacy.

Reduced Engagement

Difficulty understanding initial consent may lead to less empowerment to ask questions, resulting in disengagement over time.

Note: These hypotheses require further investigation. They highlight the importance of clear, accessible communication throughout the entire trial process, not just at enrollment.

Study Limitations and Considerations



Correlation vs. Causation

While our model shows a strong association between readability and dropout rates, we cannot infer causation from this observational data.



Types of Attrition

Our analysis doesn't distinguish between different types of attrition, such as:

- Active withdrawal
- Loss to follow-up

These may have distinct underlying causes.

Implications for Clinical Trials



Participant Comprehension

Complex consent forms may unintentionally exclude or confuse potential participants, especially if written above average reading levels.



Resource Allocation

Participant dropout represents a significant use of resources that could potentially be mitigated.



Study Validity

Higher dropout rates can impact statistical power and validity, crucial for trials with rare conditions or small sample sizes.







Ethical Considerations

Ensuring truly informed consent is crucial. Dropouts due to misunderstanding may indicate a failure to meet this ethical standard.

Note: Addressing these considerations could improve trial outcomes and ethical standards.

Future Directions

-  Addressing readability in consent forms has significant potential impact on clinical trials.
-  AI coupled with expert human oversight could simplify consent forms while maintaining accuracy and appropriateness.
-  Improved readability could lead to better participant retention and enhanced diversity in studies.
-  Clear communication in consent processes can uphold ethical obligations and potentially improve research quality and applicability.

Key Takeaway: Focusing on readability is crucial for the design and implementation of clinical trials, potentially leading to more inclusive, efficient, and impactful clinical research.

Shaping the Future with Your Expertise

Team

Brown

Rohaid Ali
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Toki Oyelese
Jared Fridley
Prakash Sampath
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Hael Abdulrazeq
Oliver Tang
Rachel Lim

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John Shin
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Ian Connolly

BWH

Mike Groff
Ben Johnston

Lifespan

John Fernandez
Dean Roye
Paul Galamaga

Yale

Cheryl Zogg

Stanford

James Zou
Eric Wu

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Open AI Team



BROWN
Alpert Medical School

