Effectiveness & user experience of digital plain language recommendations in people of different age and health literacy:
Results of three randomized controlled trials and qualitative studies

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On behalf of the eCOVID RecMap team

EBHC, Taormina 26 **|** 10 **|** 2023

Disclosures

- No direct financial conflicts

- GRADE Working Group Co-Chair

- Cochrane Canada - Director

- Guidelines International Network – chair

- Research grants from Canadian Institutes of Health Research (FRN VR4-172741, GA3-177732 & REC 183153)

- Views expressed my own

- RecMap team

Today's talk

Optimizing the presentation of recommendations for different target groups

- Three trials: adults, parents and youth (15 – 24 yrs)
- Overall results

Background

- We typically develop guidelines for people like us:

    Health professionals

- And that is reflected in how we present and word the recommendations

- In the context of the COVID-19 pandemic and in general it became obvious that that's a problem!

- Had done trials to present summaries of systematic reviews to the general population, but not recommendations

- Indeed, very little work on that

Plain Language Recommendation
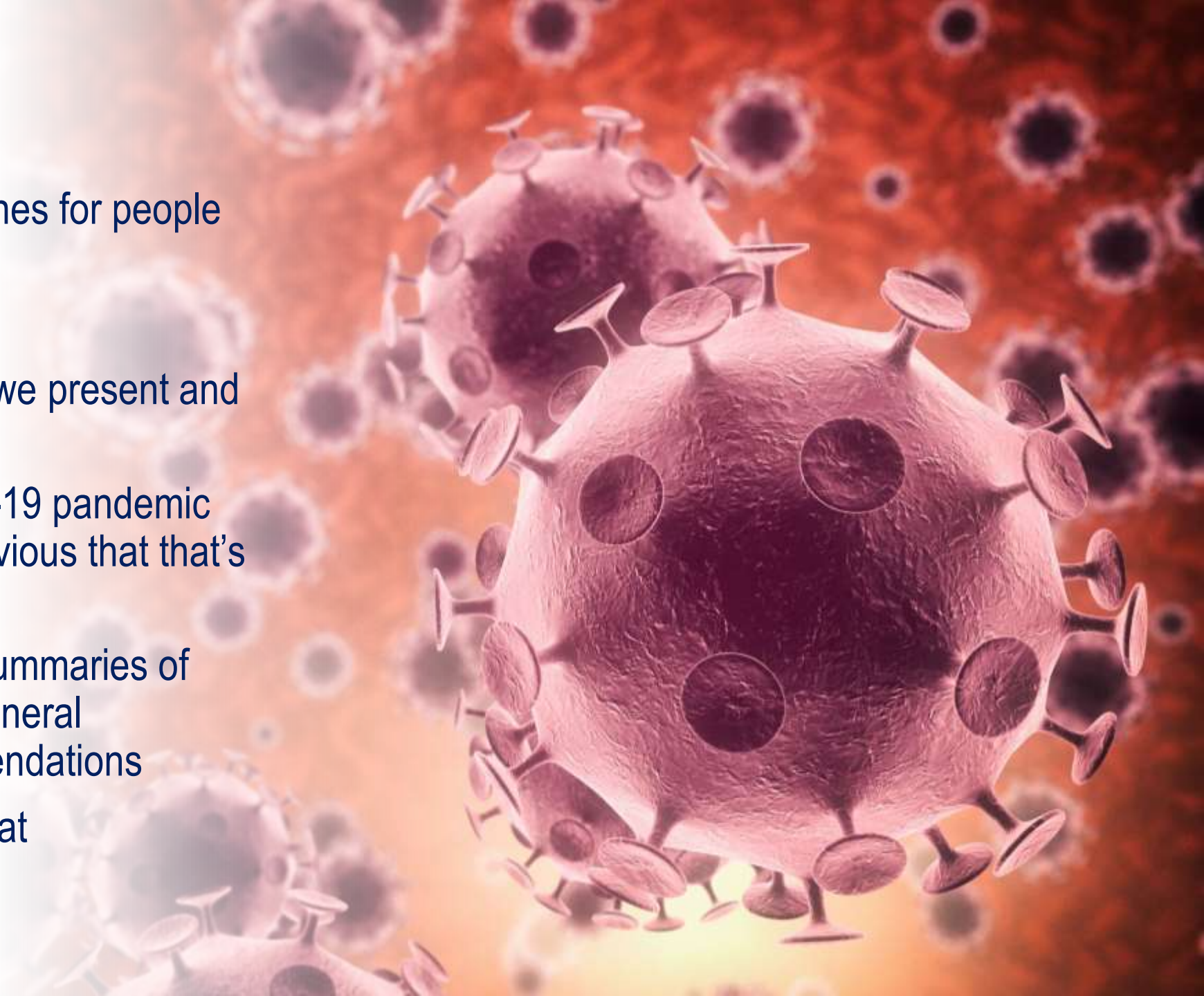
Standard Language Version

This is a recommendation by:
World Health Organization (WHO)

Should people with at least one health condition (comorbidities) that increases their risk for severe COVID-19 get the Pfizer-BioNTech COVID-19 vaccine?

Please note that this information could have changed since its publication date.

Who is this for?

- You have at least one health condition that increases the risk for severe illness when infected with COVID-19
- You are 5 years of age or older
- You do not have an active case of COVID-19

Recommendation

The World Health Organization (WHO) suggests that people with comorbidities that increase their risk for severe illness when infected with COVID-19 should take the Pfizer-BioNTech vaccine to protect against COVID-19. (Published 2022)

[Click here to see where this recommendation came from]

Recommendation strength

Conditional for Pfizer-BioNTech BNT162b2 vaccine

CONDITIONAL

A recommendation can be strong or conditional. When a recommendation is conditional, the majority of people want to follow it, but they may want to talk with their health care professional first.

Fig. 3 Example of a plain language recommendation summary format for adult participants

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Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing

Interim guidance
First issued 8 January 2021
Updated 15 June 2021
Updated 19 November 2021
Updated 21 January 2022

World Health Organization

Background

This interim guidance has been developed
Immunization at its extraordinary meeting
further updated on 19 November 2021 and

Declarations of interests were collected fr
reported interests can be found on the SAG

The guidance is based on the evidence sun
against COVID-19 (4) and further updated

Annexes (3) which include GRADE and
updated recommendations. All ref
https://www.who.int/groups/strategic-ad

These interim recommendations refer to th
nonproprietary name (INN) is Tozinameran
the subsequent text the vaccine will be ref

On 31 December 2020, BNT162b2 was g

Morbidity and Mortality Weekly Report

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021

Katy R. Woodworth, MD[1]; Danielle Moulia, MPH[1]; Jennifer P. Collins, MD[1]; Stephen C. Hadler, MD[1]; Jefferson M. Jones, MD[1]; Sujan C. Reddy, MD[1]; Mary Chamberland, MD[1,2]; Doug Campos-Outcalt, MD[3]; Rebecca L. Morgan, PhD[4]; Oliver Brooks, MD[5]; H. Keipp Talbot, MD[6]; Grace M. Lee, MD[7]; Beth P. Bell, MD[8]; Matthew F. Daley, MD[9]; Sarah Mbaeyi, MD[1]; Kathleen Dooling, MD[1]; Sara E. Oliver, MD[1]

On November 5, 2021, this report was posted as an MMWR
Early Release on the MMWR website (https://www.cdc.gov/mmwr).
The Pfizer-BioNTech COVID-19 (BNT162b2) vaccine is a
lipid nanoparticle-formulated, nucleoside-modified mRNA vac-
cine encoding the prefusion spike glycoprotein of SARS-CoV-2,
the virus that causes COVID-19. On August 23, 2021, the Food
and Drug Administration (FDA) approved a Biologics License
Application (BLA) for use of the Pfizer-BioNTech COVID-19
vaccine, marketed as Comirnaty (Pfizer, Inc.), in persons aged
≥16 years (1). The Pfizer-BioNTech COVID-19 vaccine is
also recommended for adolescents aged 12–15 years under
an Emergency Use Authorization (EUA) (1). All persons aged
≥12 years are recommended to receive 2 doses (30 μg, 0.3 mL
each), administered 3 weeks apart (2,3). As of November 2,
2021, approximately 248 million doses of the Pfizer-BioNTech
COVID-19 vaccine had been administered to persons aged
≥12 years in the United States.* On October 29, 2021,
FDA issued an EUA amendment for a new formulation of
Pfizer-BioNTech COVID-19 vaccine for use in children aged
5–11 years, administered as 2 doses (10 μg, 0.2 mL each),
3 weeks apart (Table) (1). On November 2, 2021, the Advisory
Committee on Immunization Practices (ACIP) issued an
interim recommendation† for use of the Pfizer-BioNTech
COVID-19 vaccine in children aged 5–11 years for the pre-

is important to protect children against COVID-19 and reduce
community transmission of SARS-CoV-2.

Since June 2020, ACIP has convened 21 public meetings
to review data relevant to the potential use of COVID-19
vaccines, including the Pfizer-BioNTech COVID-19
vaccine.** In addition, the ACIP COVID-19 Vaccines Work
Group, comprising experts in infectious diseases, vaccinology,
vaccine safety, public health, and ethics, has held weekly
meetings to review COVID-19 surveillance data, evidence for
vaccine efficacy and effectiveness, safety, and implementation
considerations for COVID-19 vaccines. Within the EtR
Framework for the Pfizer-BioNTech COVID-19 vaccine for
children aged 5–11 years, ACIP considered the importance
of COVID-19 as a public health problem, as well as benefits
and harms, parents' values and preferences, acceptability,
feasibility, resource use, and equity for use of the vaccine among
children. After conducting a systematic review of published
and unpublished evidence for benefits and harms, the Work
Group used the GRADE approach to assess the certainty of
evidence for outcomes related to the vaccine, rated on a scale of
type 1 (high certainty) to type 4 (very low certainty).†† Work
Group conclusions regarding evidence for the Pfizer-BioNTech
COVID-19 vaccine were presented to ACIP at a public
meeting on November 2, 2021.

Fig. 2 SLV format for youth and adult participants

Goals

Assess the effects of plain language recommendations (PLRs) compared with a standard language versions (SLVs) of COVID-19 recommendations in different age groups and people with different health literacy:

- Understanding

- Usability

- Satisfaction

- Intended behavior

- Preference (by comparing an optimized PLR version to a standard language version)

- Qualitative study

Methods:

- Mixed methods of registered RCTs and qualitative in three populations
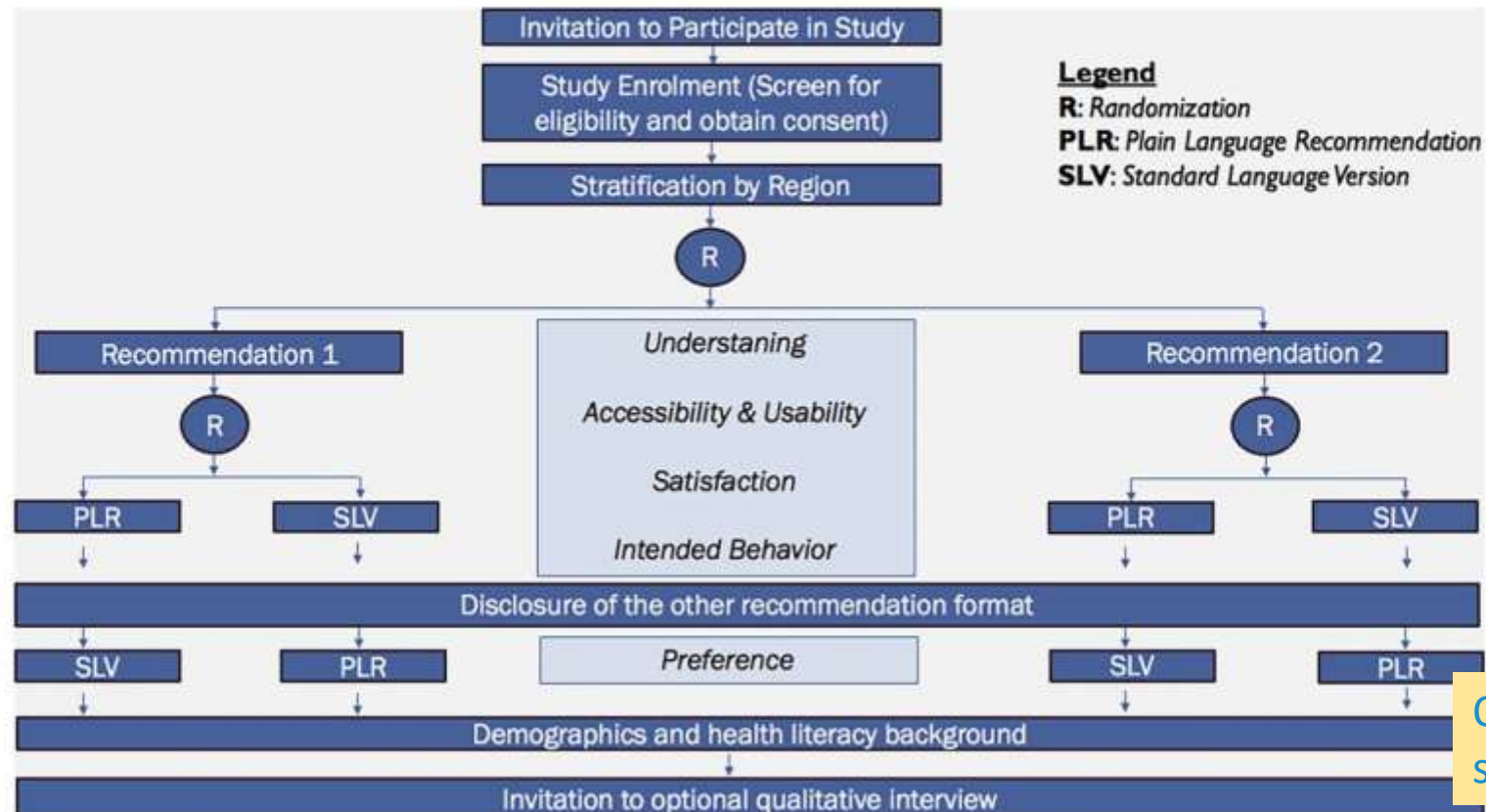- Adults, parents & youth, careful development of protocol with lay people

Fig. 1 RCT flow diagram

3 trials completed

A multi-methods randomized trial found that plain language versions improved adults understanding of health recommendations

Authors:

Shahab Sayfi [1,2,3], Rana Charide[3], Sarah A. Elliott[4,5], Lisa Hartling[4,5], Matthew Munan[4], Lisa Stallwood[6], Nancy J. Butcher[6,7], Dawn P. Richards[8], Joseph L. Mathew[9], Jozef Suvada[10,11,12], Elie A. Akl[3,13], Tamara Kredo[14,15], Lawrence Mbuagbaw[3,16,17,18,19,20], Ashley Motilall [3], Ami Baba[6], Shannon D. Scott[21], Maicon Falavigna[22], Miloslav Klugar[23,24], Tereza Friessová[23,26], Tamara Lotfi[3], Adrienne Stevens[25], Martin Offringa[6,26,27], Holger J. Schünemann[3, 28], Kevin Pottie[2,29]

JAMA Pediatrics | Original Investigation

Plain Language vs Standard Format for Youth Understanding of COVID-19 Recommendations
A Randomized Clinical Trial

Research

ELSEVIER

Journal of Clinical Epidemiology 161 (2023) 8–19

Journal of Clinical Epidemiology

ORIGINAL ARTICLE
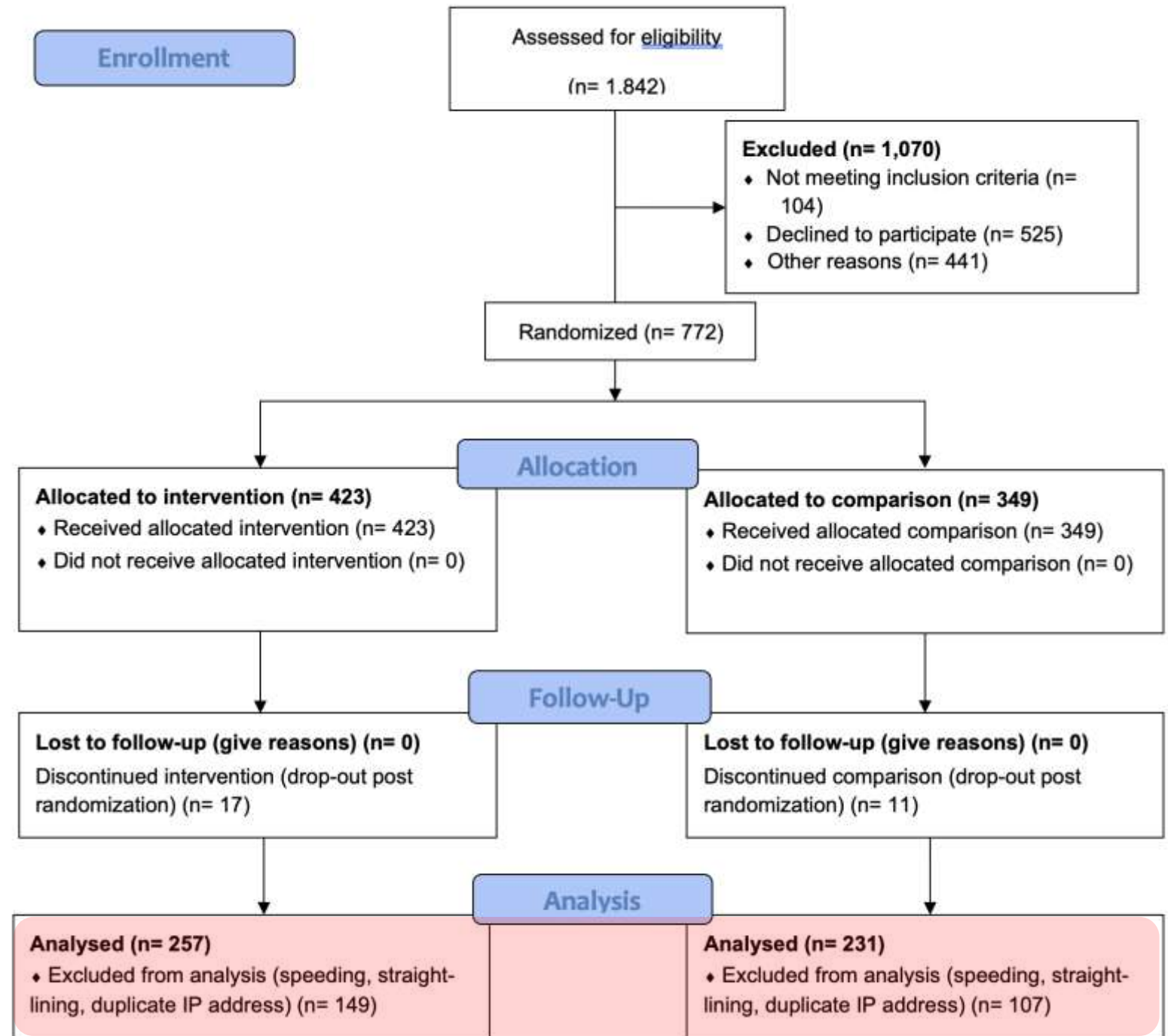
A multimethods randomized trial found that plain language versions improved parents' understanding of health recommendations
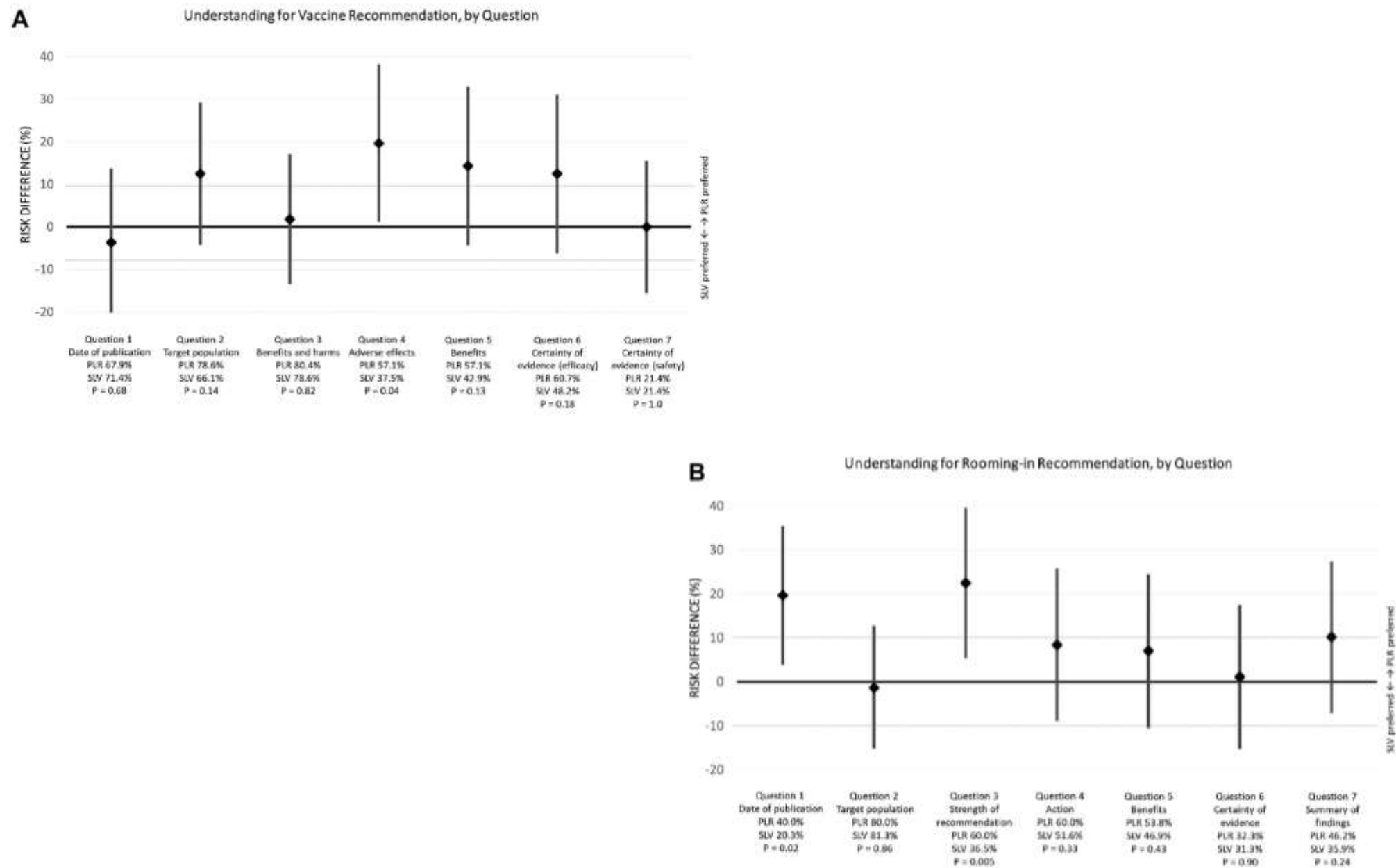
Sarah A. Elliott[a,b], Shannon D. Scott[c], Rana Charide[d,e,f], Lisa Patterson-Stallwood[g], Shahab Sayfi[h], Ashley Motilall[d,e,f,i], Ami Baba[g], Tamara Lotfi[d,e,f,j], Jozef Suvada[i], Miloslav Klugar[k], Tamara Kredo[l,m,n], Joseph L. Mathew[o], Dawn P. Richards[p,q], Nancy J. Butcher[g,r], Martin Offringa[g,s,t], Kevin Pottie[u], Holger J. Schünemann[d,e,f,j], Lisa Hartling[a,b,v]

Online trials: adults

Enrollment

Assessed for eligibility (n= 1.842)

Excluded (n= 1,070)
- Not meeting inclusion criteria (n= 104)
- Declined to participate (n= 525)
- Other reasons (n= 441)

Randomized (n= 772)

Allocation

Allocated to intervention (n= 423)
- Received allocated intervention (n= 423)
- Did not receive allocated intervention (n= 0)

Allocated to comparison (n= 349)
- Received allocated comparison (n= 349)
- Did not receive allocated comparison (n= 0)

Follow-Up

Lost to follow-up (give reasons) (n= 0)
Discontinued intervention (drop-out post randomization) (n= 17)

Lost to follow-up (give reasons) (n= 0)
Discontinued comparison (drop-out post randomization) (n= 11)

Analysis

Analysed (n= 257)
- Excluded from analysis (speeding, straight-lining, duplicate IP address) (n= 149)

Analysed (n= 231)
- Excluded from analysis (speeding, straight-lining, duplicate IP address) (n= 107)

A

Understanding for Vaccine Recommendation, by Question

B

Understanding for Rooming-in Recommendation, by Question

Fig. 2. Results for understanding questions by recommendation: (A) vaccine, (B) rooming-in. *Abbreviations*: SLV, standard language version; PLR, plain language recommendation.

Parents

Table 2. Primary and Secondary Outcomes

Outcome[a]	PLR[b] mean (SD)	SLV[b] mean (SD)	Difference (95% CI)	P value
Understanding (primary outcome)				
Total correct answers (0-7)	3.96 (2.02)	3.33 (1.88)	0.63 (0.13 to 1.12)	0.014
Accessibility/usability				
Q1. It was easy to find the information I needed.	4.76 (1.59)	4.15 (1.71)	0.61 (0.19 to 1.03)	0.005
Q2. It was easy to understand the information.	5.02 (1.54)	4.28 (1.52)	0.74 (0.35 to 1.13)	0.0002
Q3. The information could help people make a decision.	5.10 (1.49)	4.73 (1.59)	0.37 (−0.02 to 0.76)	0.07
Q4. The order/format of the presented information made it easy to understand the recommendation.	5.09 (1.54)	4.23 (1.60)	0.86 (0.46 to 1.26)	<0.0001
Q5. People could use and apply this information.	5.07 (1.52)	4.62 (1.52)	0.46 (0.07 to 0.84)	0.02
Q6. I can use this information without additional instructions or help.	4.86 (1.66)	4.67 (1.45)	0.19 (−0.20 to 0.59)	0.34
Accessibility/Usability: Total Mean Score	4.98 (1.32)	4.45 (1.29)	0.54 (0.21 to 0.87)	0.002
Satisfaction				
Q1. How satisfied are you with the presentation of the information (e.g., order of information, location of information, etc.)?	5.03 (1.43)	4.37 (1.56)	0.67 (0.29 to 1.05)	0.0006
Q2. How satisfied are you with the length of the document?	5.19 (1.39)	4.49 (1.48)	0.70 (0.33 to 1.06)	0.0002
Q3. How satisfied are you with the design of the document (e.g., colors, font, etc.)?	5.00 (1.52)	4.28 (1.54)	0.73 (0.34 to 1.11)	0.0003
Satisfaction: Total mean score	5.07 (1.31)	4.38 (1.37)	0.70 (0.35 to 1.04)	<0.0001
Behavior				
Have you already followed this recommendation in any way?	71/121 (59%)	78/120 (65%)	−6.3 (−18.6 to 5.9)	0.31
If you have not followed this recommendation, how likely is it that you would follow it now?	4.75 (1.65)	5.04 (1.61)	−0.29 (−0.81 to 0.24)	0.28
How likely is it that you would share this recommendation with other people you know?	5.29 (1.61)	5.16 (1.63)	0.13 (−0.28 to 0.54)	0.53
Preference	4.93 (1.96)[c]	5.17 (1.80)[c]	−0.23 (−0.71 to 0.24)	0.34

Adults

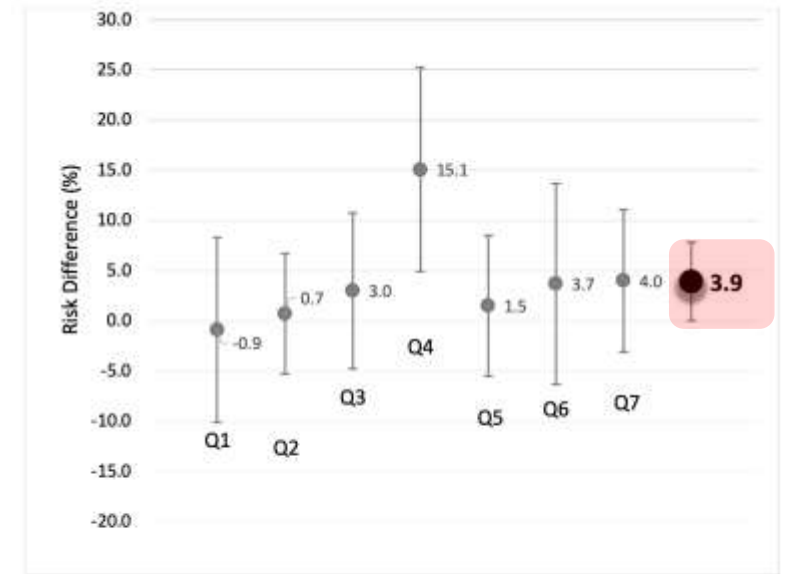
Figure 2. Risk Differences (%) and 95% CIs for correct responses to 7 questions measuring understanding, and Total difference * for WHO recommendation.
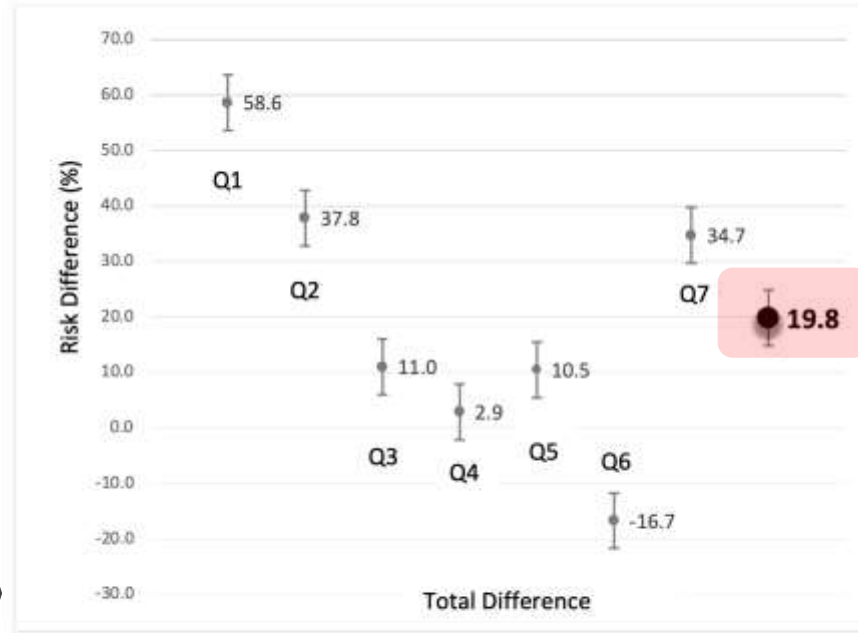
Figure 3. Risk Differences (%) and 95% CIs for correct responses to 7 questions measuring understanding, and Total difference * for CDC recommendation.
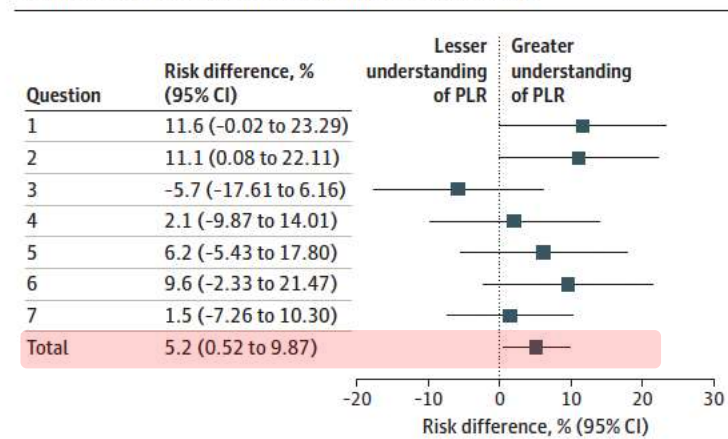
*Positive Risk Difference scores indicate greater understanding for the PLR over SLV

Youth

Figure 2. Risk Differences and Total Mean Difference for Correct Responses to 7 Questions Measuring Understanding

Question	Risk difference, % (95% CI)	Lesser understanding of PLR / Greater understanding of PLR
1	11.6 (−0.02 to 23.29)	
2	11.1 (0.08 to 22.11)	
3	−5.7 (−17.61 to 6.16)	
4	2.1 (−9.87 to 14.01)	
5	6.2 (−5.43 to 17.80)	
6	9.6 (−2.33 to 21.47)	
7	1.5 (−7.26 to 10.30)	
Total	5.2 (0.52 to 9.87)	

Risk difference, % (95% CI)

Squares represent risk differences, and horizontal lines represent 95% CIs. PLR indicates plain language recommendation.

Table 2. Results of Secondary Outcomes Comparing Mean Score Difference of PLR With SLV

Secondary outcomes	Group score, mean (SD)[a] PLR (n = 137)	SLV (n = 131)	Mean difference (95% CI)
Accessibility and usability	5.12 (1.1)	4.78 (1.3)	0.34 (0.05 to 0.63)
Satisfaction	5.24 (1.3)	4.85 (1.5)	0.39 (0.06 to 0.73)
Intended behavior[b]	5.24 (1.6)	5.02 (1.7)	0.22 (−0.20 to 0.74)

Abbreviations: PLR, plain language recommendation; SLV, standard language version.

[a] Scores were 1 to 7 based on the number of correct responses.

[b] Denominator for the SLV arm was 92 and for the PLR arm was 90.

our ability to observe the expected difference in understanding between groups but also suggests that there is room for improvement and that we made some progress in communication of recommendations. While the 5.2% improvement in

- Baseline understanding: about 45% complete correct answers, increase about 5%

Preplanned IPD meta-analysis

- 997 participants
- 488 adults, 268 youth & 241 parents
- 515 (52%) PLR format & 482 (48%) SLV format
- Lower English proficiency correlated with lower understanding
- Otherwise, no major subgroup effects (interaction with one rec)
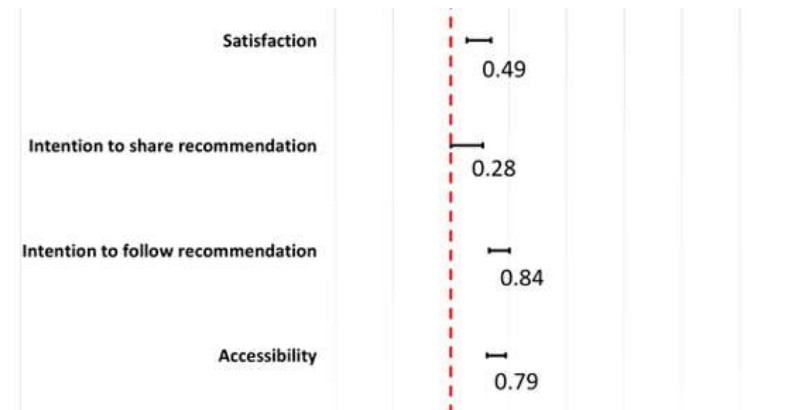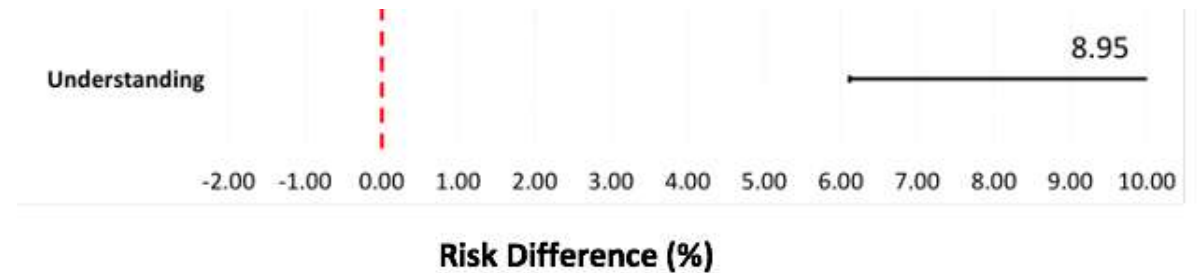
Other outcomes: mean scores of questions with 7 point score

Participants' preference for the presentation format

Qualitative findings
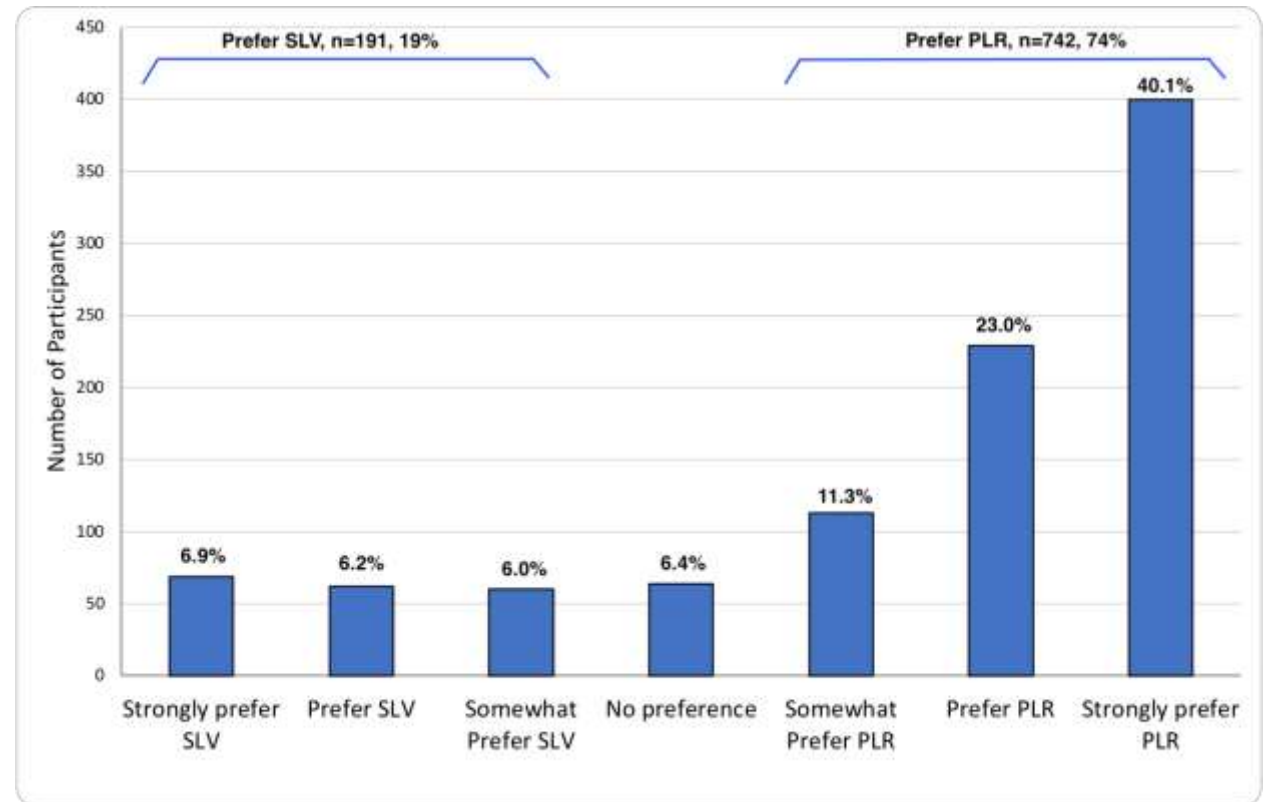
Table 3. Themes from parent interviews

Theme/Element	Definition	Attributes	Supportive participant quotes
Findability and accessibility	What boundaries prevent users from accessing information?	- Strong marketing campaigns are required - Colors, highlighting, and device differences impact accessibility - Should be hosted somewhere with high traffic	"Some of the coloring [on SLV] like it was hard to read for me because I have some sensory difficulties, so I found like the highlighting and the red lettering tricky for me." Participant_001 "I'll go to the websites of some of like you know, the more credible organizations like John Hopkins or the Mayo clinic, or CDC." Participant_003
Usefulness and value	What information has practical application for the user?	- Format preferences are based on cultural context - Information for decision-making is helpful - Journal articles/scientific layouts are only helpful for those with a science background	"You don't want to go to a committee and you start talking about effect size of this if you would understand what that, that will translate to." Participant_012 "I would definitely share the [PLR] with friends or colleagues that might not have a science background but if I knew for sure that they had that background I'd probably give them [the SLV]." Participant_011
Usability	What components improve or impede the ease of use?	- Appearance differs on computers vs. mobile device	"[the PLR] On the phone it didn't display it very good. I had to move around my device a lot to try to and then a few times I turned it around so it was horizontal, that was better, but I still had to scroll over." Participant_002
Credibility	What elements contribute to appearing trustworthy?	- Citations in footnotes, consistent branding, and visible logos from health agencies improve credibility	"I'm not sure who's presenting the information to me which might be nice to have just even like an emblem [on PLR]." Participant_010 "I'm curious to know where [the PLR] recommendations are coming from right, so that I know whether to follow them or not but I want to see how that data came about." Participant_001
Desirability	What components do end users want, or have a positive response to?	- Diagrams and lists are preferred - Short paragraphs preferred	"I wouldn't want to go into long details [like SLV], explain paragraphs and you know a long scientific laboratory experiment." Participant_004

SLV, standard language version; PLR, plain language recommendation; CDC, Centers for Disease Control and Prevention.

Plain Language vs Standard Format for Youth Understanding of COVID-19 Recommendations — Original Investigation Research

Table 3. Themes and Concepts Emerging From 14 Participants From the Qualitative Study

Theme, concept	Participant perceptions	Representative quotation
Presentation		
Aesthetics	Almost all felt that the PLR was more aesthetically pleasing and friendly for the lay public relative to the SLV, commenting on the visual appeal of the PLR format	"[The PLR] is easier to read and it's more appealing to the eyes. I like the color, and the font size is bigger."
Formatting	All stated that the PLR format was easier to understand and navigate when reading health information and appreciated the PLR's formatting and layout	"The colors [of the PLR] are beautiful, but the thing I like the most is that it is like in bullet form like I know what I'm going to read next and what information I'm going to get if I click there, so that's the thing I like."
Length	The majority of participants commented on the length of the SLV format, which was overwhelming for many	"[The SLV] is just words and words and words, and I feel like I'm in like my research course and I'm reading a lot, but in the [PLR] there's a lot of...white space which I like and...it's just more clear and neat."
Content		
Understandability	All participants felt that the PLR format gave them a better understanding of the health recommendation	"For a lay person to understand [the PLR] is a lot easier, like there are simpler words; it doesn't seem as complicated as if you go to the long document."
Comprehensiveness	Almost all youths felt that the PLR provided a comprehensive overview of the topic	"I thought [the PLR] was much more concise and clear what they wanted to convey, and I think it was more tailored to the reader in terms of what's important and meaningful to them."
Complexity	When reading the SLV, the majority of participants had issues with the complexity of the language and information	"The sentences are hard to understand with a lot of scientific jargon, even for someone like myself, like I'm going into my third year of medical school."
Usability		
Navigation	When using the formats to locate key information, almost all participants noted that the [PLR] was easier to navigate; yet, many participants cited having issues with finding information in the SLV format, including a few who decided to use the "find" command to answer questions in the survey	"I'm looking for information that's relevant to me and things I have questions about, but the [PLR] just makes it a lot easier." "I'd have to read really into [the SLV], in order to find the recommendations, but I'd still have to read a lot, because the recommendation word comes up on a lot of pages."
Efficiency	For the majority of participants, the efficiency of the PLR format made it more appealing to use	"I think [quickness] definitely is important because people don't want to spend a lot of time necessarily searching for information when there is another option available where it's presented really quick."
Formatting	Several participants also noted various formatting and technological features of the PLR	"On the side [of the PLR], there's the legend and then, when you press on it, then like you'll automatically scroll down to the category that you want, and then the title of each category is big compared to the rest of the font underneath so it stands out more, and I can find it quickly."
Credibility		
Trustworthiness	Despite the strong preference of participants toward the PLR for consuming information, the majority of youths mentioned that the PLR lacked credibility, indicating that having the SLV would improve the overall credibility	"I just feel like the [PLR] just doesn't look as credible, you know,...because it, it looks like anybody wrote it or like I wrote it." "I would say [I would use the PLR], because I mean it seems like the [PLR], it's very organized and it's easier and faster to find the answers that you're looking for, and if it is coupled with like references and like that source (SLV) I think I would probably use the [PLR]."
Sharing	Almost all participants suggested that the PLR format would be more appropriate to share with their friends, family, and the general youth audience but only if the information is trustworthy	"[I would share the PLR] just because it's quicker and not everyone's interested in knowing, like all the details, but again, like I would only feel comfortable sharing with my family and friends if I knew it was like legit, like if it was real."
Decision-making	Half of the participants stated that if they had to choose one to make decisions about their health, they would rather use the SLV as it seemed more credible and detailed	"In that case, if I want to have like as much information as I can possibly have, I would use the [SLV], because I think it's more reliable and it has like kind of more information, even though it's like the same thing, but yes in that case I would use the [SLV], even though it's kind of boring."
Suggested improvements		
Aesthetics	Several participants suggested aesthetic improvements for the format	"I think it's good, I think the font size is a little bit tiny for me. Maybe not necessarily tiny, but it seems to be out of proportion because the subtitles are so large and then the actual blurbs are tinier. Maybe it's also because the colors are different, like the headings' colors, the background, that is a little bit different, so there is a little bit of contrast there, but it's not a big deal."
Accessibility	A few participants suggested to ensure that the PLR has accessibility features consistent with any relevant regional or national accessibility guidelines	"The only other thought that I would have is just from like an accessibility standpoint for both documents, just making sure that if they're like online that they're accessible to people with like screen readers and stuff like that so having those open boxes—like I'm not a professional in that like I don't know how it works—but I just know some people who have used it, and so I think whenever you're presenting information, it's important to go through those accessibility features, make sure that they can be used online."

Summary

- PLRs improved understanding and other key outcomes
- Further optimization possible → qualitative study lots of suggestions for improvement
- Future: Wording issues, address real decisions or health outcomes
- One version for all target audiences!