US Centre Summer Research Grant

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Project title: Communication of information about new cancer drugs: the role of the US Food and Drug Administration in protecting public health[1]

A nationally representative randomized survey

Summary of project:

The US Food and Drug Administration (FDA) approves many drugs on the basis of preliminary evidence of safety and efficacy, with often several unresolved uncertainties about how well the drug works at the time of approval. Yet, regulated information for patients and physicians rarely acknowledges these uncertainties.

In this nationally representative randomized survey of US adults, I developed and tested brief statements to communicate the most common sources of uncertainties with new cancer drugs. I then measured the change in participants' decisions and perception of uncertainty after learning about 1 of 5 sources of uncertainty with a new cancer drug's benefits and risks.

Between May 9 and May 14, 2025, 1,105 participants completed this study and were included in the analysis. For 4 of the 5 experimental conditions, participants were less likely to take a new cancer drug after learning about a source of uncertainty with the drug's evidence (pooled effect: 67.4% pre vs 57.3% post; absolute difference 10%, 95% CI:7.3-12.7%; $p<0.0001$; odds ratio 2.98). Learning that the drug had been approved on the basis of an unvalidated surrogate endpoint (absolute difference 14.6%, $p<0.0001$ OR 4.44) and uncertain treatment effect size (absolute difference 12%, $p<0.0001$ OR 3.8) had the largest effect on participants' decisions. Participants expressed strong interest in wanting to know about uncertainties with new prescription drugs.

These findings reinforce the importance of communicating both the evidence and uncertainties associated with new drugs in order to help Americans make informed treatment decisions that are consistent with their preferences.

[1] I gratefully acknowledge Dr Huseyin Naci (London School of Economics), Dr Anita Wagner (Harvard Medical School), Professor Steven Woloshin (Dartmouth College), and Dr Courtney Davis (Kings College London) for their generous feedback on the design of this study.

Table of Contents

List of Tables and Figures

Introduction

The US Food and Drug Administration (FDA) serves as gatekeeper to the largest pharmaceutical market globally. In surveys, Americans report strong beliefs that FDA-approved drugs are highly effective and have low risks of harms.[1] But owing to lobbying from industry and some patient organisations since the HIV/AIDS epidemic in the 1990's, more drugs are now approved despite limited evidence on their efficacy and safety.[2,3] The presumption is that Americans understand and are acceptive of this uncertainty in return for faster access to new drugs.[4–6] This trend is especially pronounced in oncology, where most new cancer drugs are approved before demonstrating any improvements in patient survival or quality of life.[7,8] Follow-up data on these drugs raises even more concerns, as only 20% of fast-tracked drugs eventually demonstrate meaningful improvements in these outcomes for patients.[9]

For Americans to make informed decisions about their health, they need understandable information about the benefits and risks of drugs. The FDA has a legal requirement to communicate this information but currently falls short.[10] Regulated information for patients and physicians often fails to communicate uncertainties about how well new drugs work.[11] For example, whether the new drug is better or worse than standard treatment, whether the drug works equally well for all patient populations, and whether it improves clinically meaningful outcomes that matter most to patients.[12] Insufficient communication may erode trust in regulatory agencies[13,14] and result in uninformed and unwanted treatment decisions.[15,16]

This study focuses on developing and testing strategies that can help the FDA improve its role as safeguarding public health through better provision of information about new drugs. FDA regulations presume that Americans are aware of the uncertainties associated with new drugs, and that patients choosing to take these drugs are making informed decisions that are consistent with their preferences. I empirically test this assumption in a nationally representative sample of US adults by evaluating whether participants change their decision to take a new drug after learning about uncertainties with the drug's benefits and risks.

Methods

This study received ethics approval from the London School of Economics and Political Science (540788). The protocol and analysis were preregistered prior to recruiting participants with ClinicalTrials.gov.

Randomization

Participants were randomized with equal allocation to 1 of 5 experimental conditions upon entering the survey via the Qualtrics software. I evaluated the change in participants' decisions before and after learning about a source of uncertainty with a new cancer drug's benefits and risks. Using a pre-post design, I estimated the within group effect of each experimental condition, and each participant served as their own control.

Participants

A nationally representative census matched sample of US adults were recruited to participate in this survey. Eligible participants were above 18 years of age and fluent in English. Participants were recruited online through CloudResearch; a market research company which engages with hundreds of research panel providers that use various

methods for recruitment. Informed consent was obtained before participants initiated the survey.

Intervention

I developed and tested brief statements to communicate the most common sources of uncertainties with new cancer drugs: (1) single-arm trial designs (non-randomized clinical trials lacking a control group);[17] (2) limited study populations (generalizability of clinical trial evidence);[18,19] (3) limited study durations (long-term benefits and harms);[1] (4) use of unvalidated surrogate endpoints (which often do not reliably predict clinical outcomes);[12] and (5) uncertain treatment effect size (small or uncertain benefit).[20] **Table 1** presents the statements that were tested in the study.

Procedure and outcomes

Participants were given a brief scenario describing a 38-year-old woman diagnosed with non-small cell lung cancer who has tried 2 previous therapies. The scenario explained that only 10% of people in the woman's situation are still alive after 5 years. In the scenario, the woman was told by her doctor about a new drug that was recently approved by the FDA for her disease and that is covered by her insurance. Participants were then given a table summarizing the main benefits and risks of the drug (see Appendix). Data for the hypothetical drug was based on adagrasib (Krazati), a cancer drug that received accelerated approval from the FDA in 2022 for the treatment of locally advanced or metastatic non-small cell lung cancer with a $KRAS^{G12C}$ mutation.

In the pre-intervention phase, participants were asked how likely they would be to take the drug if they were in the woman's position, and how certain they are that the drug would work. Participants were then told that there was more information about the drug, after which participants were randomized to 1 of 5 statements about a source of uncertainty with the drug's evidence. In the post-intervention phase, participants were asked again about their decision to take the drug and how certain they were that the drug would work. Additional questions assessed participants' preferences for communicating information about uncertainty with new drugs.[21]

Results

From May 9 to May 14, 2025, 1,584 individuals were invited to participate in this study; 1,105 (69.7%) completed the survey and met the inclusion criteria (**Figure 1**). Of the 1,105 participants, 65.6% (724/1,105) were women; 35.9% (397/1,105) were 65 years and older, and 68.6% (758/1,105) were white. One-third of participants (340/1,105, 31%) had limited health literacy and 67% (745/1,105) had either been personally diagnosed or had an immediate family member or close friend that had been diagnosed with cancer. Participant characteristics were evenly balanced across the 5 experimental conditions and are summarized in **Table 2**.

Use and trust in prescription drug information

Figure 2 shows the most common sources of prescription drug information used by participants and their trust that information from each of these sources is correct. Physicians were the most common and trusted source of information about prescription drugs, followed by family and friends, and other health news websites (e.g., WebMD, Mayo Clinic). Participants rarely learned about new drugs through print media (e.g., New York Times, Wall Street Journal), while social media was the source with the lowest trust. Overall, 72.3% (95% CI: 69.6-74.9%, 800 of 1,105) of participants responded that it was easy to find trustworthy information about prescription drugs.

Changes in participants' decisions

Figure 3 shows participants' decisions to take a new cancer drug before and after learning about a source of uncertainty with the drug's evidence. Pooled across all experimental conditions, 67.4% (95% CI: 64.6-70.1%, 745 of 1,105) of participants in the pre-intervention phase responded that they would be likely to take the new cancer drug based on the scenario. In the post-intervention phase after participants were randomized to different sources of uncertainty with the drug's evidence, 57.3% (95% CI: 54.4-60.2%, 634 of 1,105) responded that they were still likely to take the drug, resulting in an absolute difference of 10% (95% CI:7.3-12.7%; p<0.0001; OR 2.98; 95% CI: 2.19-4.11).

Learning that the drug had been approved on the basis of an unvalidated surrogate endpoint had the largest effect on participants decisions (67.9% pre vs 53.3% post: absolute difference 14.6%; 95% CI: 7.9-21.2%; p<0.0001), corresponding to an odds ratio of 4.44 (95% CI: 2.1-10.4). The next largest change was among participants that learned that the drug had an uncertain treatment effect size (69.3% pre vs 57.3% post: absolute difference 12%; 95% CI: 5.9-18.1%; p<0.0001; OR 3.8, 95% CI: 1.8-8.5). Comparatively, learning that the drug was studied for a limited duration did not significantly affect people's decisions (63.4% pre vs 53.8% post: absolute difference 5.1%; 95% CI: -0.2-10.5%; p=0.0652; OR 2.0, 95% CI: 0.96-4.3).

Changes in perception of uncertainty

Based on the scenario, only 37.1% (95% CI: 34.3-39.9%, 410 of 1,105) of participants were certain that the drug would work well in the pre-intervention phase. After learning about a source of uncertainty with the drug's evidence, 34.5% (95% CI: 31.8-37.4%, 382 of 1,105) of participants remained certain that the drug would work well (absolute difference 2.5%, 95% CI: -0.1-5.2; p=0.0672; OR 1.29, 95% CI: 0.9-1.7). (**Table 3**).

Overall, 74.2% (95% CI: 71.6-76.7%, 821 of 1,105) of participants thought that the additional information about uncertainty was helpful to their decision, and 90.9% (95% CI: 89.1-92.5%, 1,005 of 1,105) thought that uncertainties with drug benefits and harms should always be communicated. When asked about which sources of uncertainty to communicate, unvalidated surrogate endpoints had the highest consensus (94.1%; 95% CI: 92.5-95.3%).

Conclusions

In this nationally representative survey of US adults, 10% of adults changed their decision and were less likely to take a new cancer drug after learning about a source of uncertainty with the drug's evidence. Participants found the information about uncertainty helpful to their decisions and strongly expressed that uncertainties with new drugs should always be communicated.

This study developed and tested new strategies to help the FDA better communicate the information about new drugs at the time of regulatory approval. The FDA has historically resisted changes to regulated information over concerns that adding further information would overwhelm patients and physicians.[22] Yet, this study shows that brief explanations about uncertainties are effective at improving understanding and decision making. Communicating uncertainties about the effects of new drugs is essential to help the American public make informed and evidence-based treatment decisions.

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Table 1: Statements communicating different sources of uncertainties with new drugs that were developed and tested in the study

Source of uncertainty	**Statement about uncertainty**
Single-arm trial	Because Zenova has not been compared to other treatments, it is unknown if Zenova is better, the same, or worse than other treatments for non-small cell lung cancer.
Limited study duration (Long-term benefits and harms)	Since patients given Zenova were followed for a short time, the longer-term benefits and harms of taking Zenova are unknown.
Limited study population (generalizability)	Zenova has not been studied in patients similar to Alex (patients with her race and ethnicity). It is unknown whether Zenova will work and what harms it will have for patients like her.
Unvalidated surrogate endpoint	Zenova has only been shown to shrink the size of tumors. It is unknown whether Zenova improves how patients feel or how long they live.
Treatment effect size (magnitude of therapeutic benefit)	It is unknown whether patients with non-small cell lung cancer will notice an improvement with Zenova.

Figure 1: Participant recruitment and randomization (CONSORT flowchart)

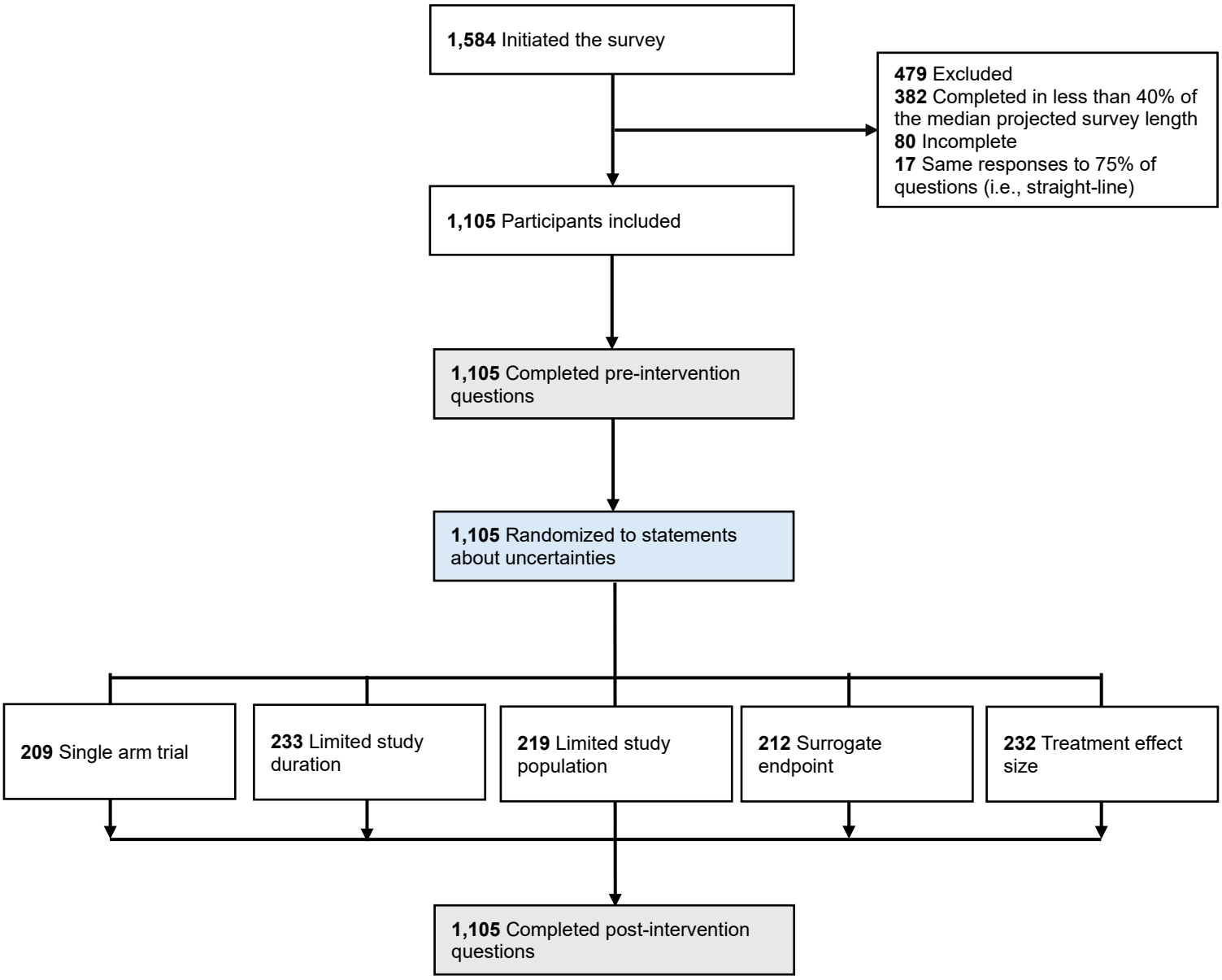


Table 2: Participant characteristics

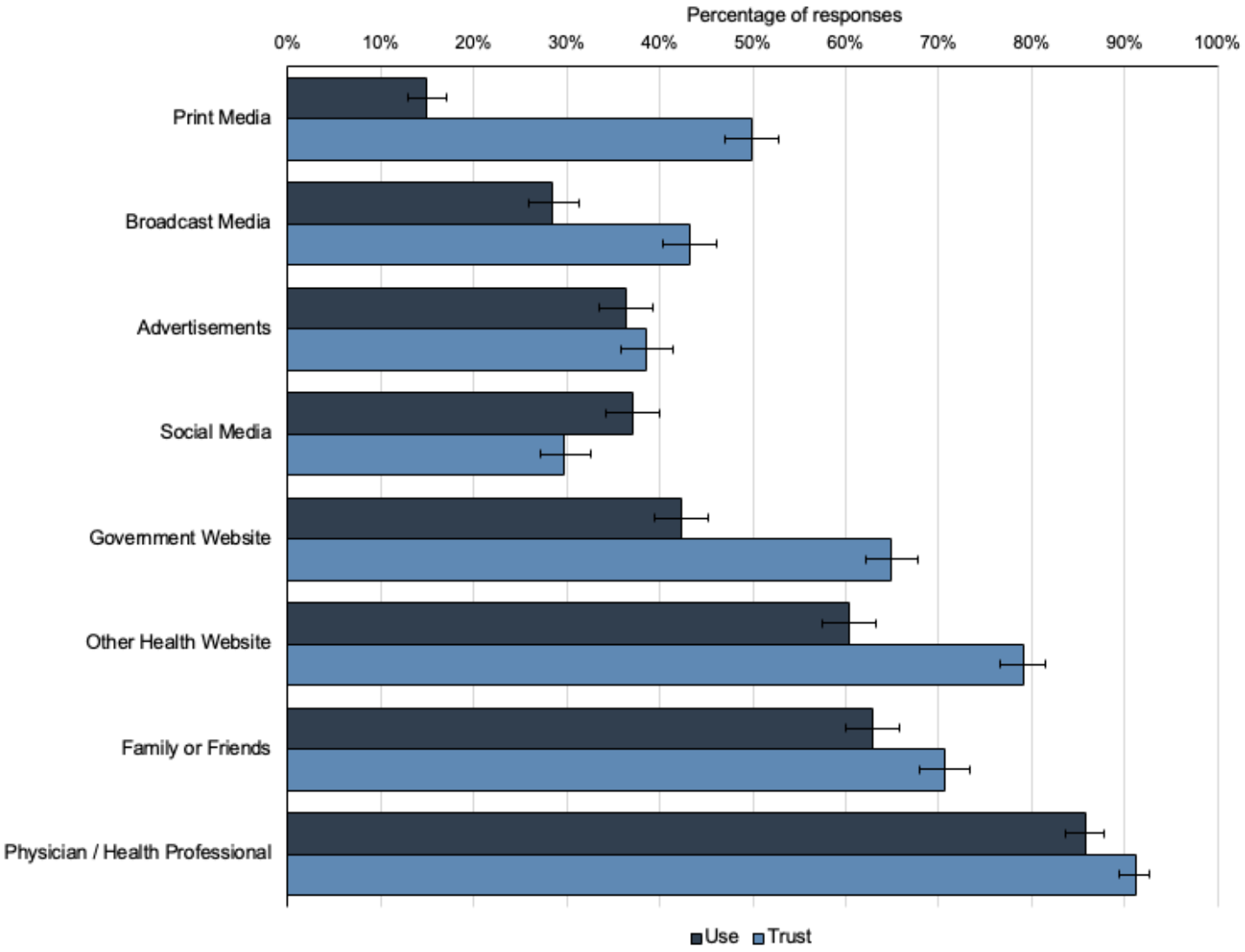
Characteristics	**Total** *(n=1,105)*	**Single arm trial** *(n=209)*	**Limited study duration** *(n=233)*	**Limited study population** *(n=219)*	**Surrogate endpoint** *(n=212)*	**Treatment effect size** *(n=232)*
Age						
18 to 24	69 (6%)	12 (6%)	14 (6%)	19 (9%)	13 (6%)	11 (5%)
25 to 44	296 (27%)	67 (32%)	62 (27%)	56 (26%)	54 (25%)	57 (25%)
45 to 64	343 (31%)	64 (31%)	77 (33%)	62 (28%)	66 (31%)	74 (32%)
65 and older	397 (36%)	66 (32%)	80 (34%)	82 (37%)	79 (37%)	90 (39%)
Sex						
Male	373 (34%)	83 (40%)	78 (33%)	63 (29%)	72 (34%)	77 (33%)
Female	724 (66%)	124 (59%)	153 (66%)	154 (70%)	139 (66%)	154 (66%)
Other	5 (0%)	1 (0%)	0 (0%)	2 (1%)	1 (0%)	1 (0%)
Prefer not to say	3 (0%)	1 (0%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)
Race or ethnicity						
White	758 (69%)	132 (63%)	156 (67%)	141 (64%)	150 (71%)	179 (77%)
Hispanic or Latino	40 (4%)	8 (4%)	5 (2%)	12 (5%)	7 (3%)	8 (3%)
African American or Black	275 (25%)	65 (31%)	64 (27%)	59 (27%)	46 (22%)	41 (18%)
American Indian or Alaska native	10 (1%)	2 (1%)	2 (1%)	3 (1%)	1 (0%)	2 (1%)
Asian	14 (1%)	2 (1%)	4 (2%)	3 (1%)	3 (1%)	2 (2%)
Other	8 (1%)	0 (0%)	2 (1%)	1 (0%)	5 (2%)	0 (0%)
Highest completed education						
Less than high school	31 (3%)	3 (1%)	7 (3%)	5 (2%)	9 (4%)	7 (3%)
High school or equivalent	485 (44%)	100 (48%)	104 (45%)	95 (43%)	86 (41%)	100 (43%)
College or undergraduate	432 (39%)	71 (34%)	88 (38%)	87 (40%)	92 (43%)	94 (41%)
Graduate degree	157 (14%)	35 (17%)	34 (15%)	32 (15%)	25 (12%)	31 (13%)
Annual income (personal)						
Less than $25,000	336 (30%)	62 (30%)	63 (12%)	73 (33%)	71 (33%)	67 (29%)
$25,000 to $49,999	342 (31%)	70 (33%)	73 (31%)	67 (31%)	63 (30%)	69 (30%)
$50,000 to $74,999	203 (18%)	37 (18%)	48 (21%)	38 (17%)	32 (15%)	48 (21%)
$75,000 to $99,999	112 (10%)	16 (8%)	22 (9%)	21 (10%)	27 (13%)	26 (11%)
More than $100,000	112 (10%)	24 (11%)	27 (12%)	20 (9%)	19 (9%)	22 (9%)
Political views						
Liberal	143 (13%)	31 (15%)	21 (9%)	35 (16%)	24 (11%)	32 (14%)
Slightly liberal	122 (11%)	24 (11%)	28 (12%)	24 (11%)	26 (12%)	20 (9%)
Moderate	393 (36%)	68 (33%)	94 (40%)	77 (35%)	76 (36%)	78 (34%)
Slightly conservative	125 (11%)	27 (13%)	31 (13%)	23 (11%)	18 (8%)	26 (11%)
Conservative	236 (21%)	45 (22%)	46 (20%)	40 (18%)	49 (23%)	56 (24%)
Prefer not to say	86 (8%)	14 (7%)	13 (6%)	20 (9%)	19 (9%)	20 (9%)
Levels of optimism						
Pessimistic	46 (4%)	6 (3%)	11 (5%)	6 (3%)	12 (6%)	11 (5%)
Somewhat pessimistic	135 (12%)	25 (12%)	31 (13%)	27 (12%)	26 (12%)	26 (11%)
Neither pessimistic or optimistic	290 (26%)	60 (29%)	65 (28%)	54 (25%)	53 (25%)	58 (25%)
Somewhat optimistic	390 (35%)	67 (32%)	79 (34%)	80 (37%)	86 (41%)	78 (34%)
Optimistic	244 (22%)	51 (24%)	47 (20%)	52 (24%)	35 (17%)	59 (25%)
Limited health literacy [a]	340 (31%)	63 (30%)	77 (33%)	74 (34%)	62 (30%)	64 (28%)

Experience with cancer [b]	745 (67%)	146 (70%)	151 (65%)	141 (64%)	149 (70%)	158 (68%)

[a] Response to “how often do you need someone to help you understand instructions or other written material from your doctor or pharmacy about prescription drugs”. Based on a systematic review from Powers *et al.* (2010) which found that a single item question asking about a patient's use of a surrogate reader, confidence filling out medical forms, and self-rated reading ability performed moderately well at identifying individuals with limited health literacy, compared to validated scales.[23] Participants who responded “always”, “often”, or “sometimes” were considered to have limited health literacy, consistent with previous studies.

[b] Participants that have been personally diagnosed with cancer, or participants that had a family member or close friend that has been diagnosed with cancer.

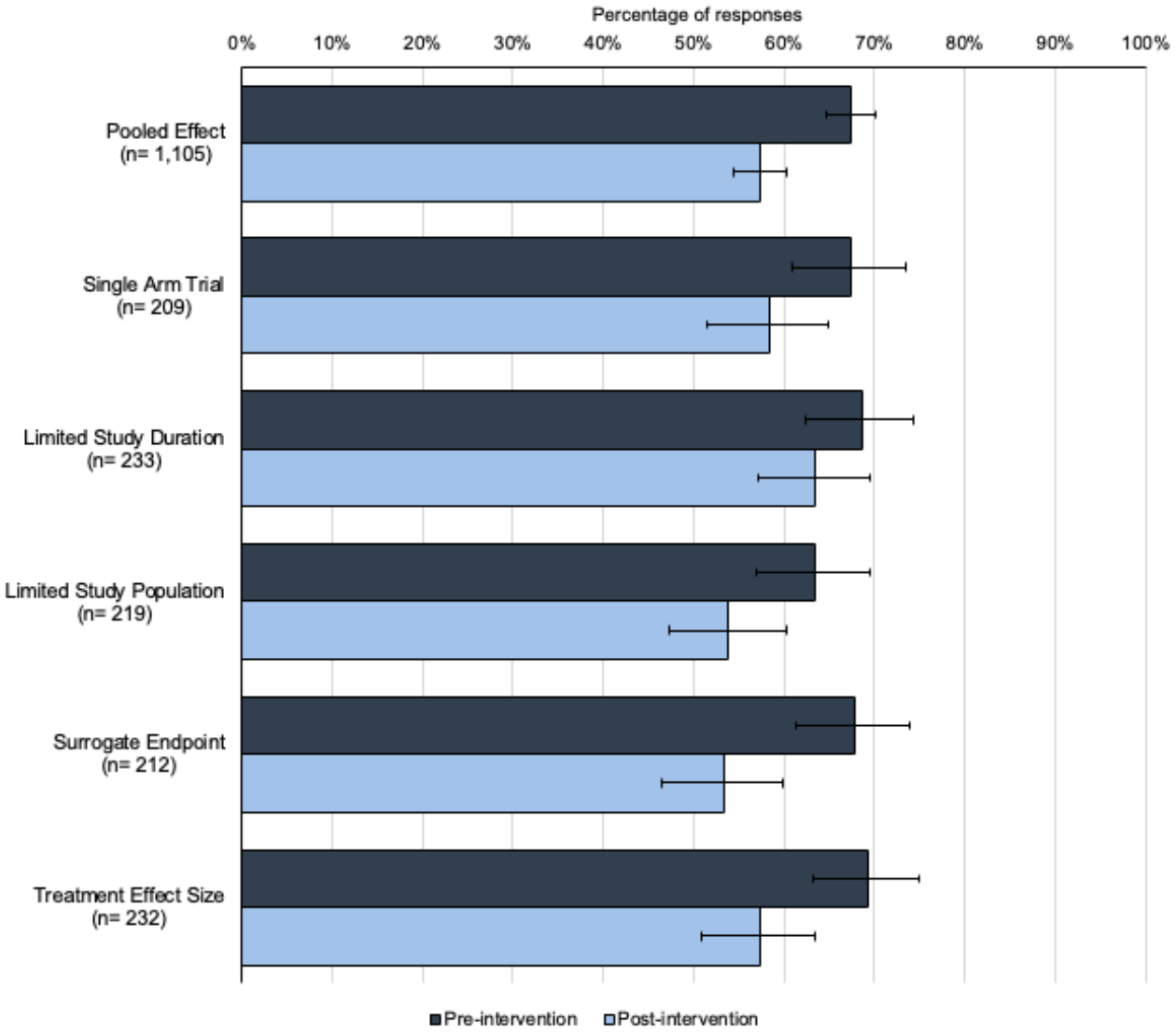
Figure 2: Use and trust in sources of information about prescription drugs



Note: Sources were based on the National Cancer Institute's Health Information National Trends Survey, from Hesse *et al.* (2005).[24] Physician / health professional corresponds to "physician, nurse, or other health professional".

Figure shows the percentage of participants who responded, "often" or "very often", for use of each of each sources, and "somewhat trust" or "extremely trust", that the information from each of these sources is correct. Confidence intervals for single group proportions were estimated using the Wilson score method.

Figure 3: Participants' decisions before and after learning about a source of uncertainty with a new cancer drug's evidence



Note: Percentage of participants who responded, "somewhat likely" or "very likely" for whether they would take a new cancer drug before and after learning about a source of uncertainty with the drug's evidence.

Table 3: Change in participants' decisions and perception of uncertainty after learning about a source of uncertainty with a new cancer drug's evidence

Source of uncertainty	Pre-intervention	Post-intervention	Absolute difference	Odds ratio
Primary outcome: Change in participants' decisions				
Pooled effect	67.4% (64.6-70.1)	57.3% (54.4-60.2)	10.0% (7.3-12.7)	2.98 (2.2-4.11)
Single arm trial	67.4% (60.8-73.4)	58.3% (51.5-64.8)	9.1% (2.7-15.4)	2.72 (1.3-6.0)
Limited study duration	63.4% (56.9-69.5)	53.8% (47.2-60.3)	5.1% (-0.2-10.5)	2.00 (0.96-4.3)
Limited study population	68.6% (62.4-74.2)	63.5% (57.1-69.4)	9.5% (2.9-16.1)	2.50 (1.3-5.0)
Surrogate endpoint	67.9% (61.3-73.8)	53.3% (46.5-59.8)	14.6% (7.9-21.1)	4.44 (2.1-10.4)
Treatment effect size	69.3% (63.1-74.9)	57.3% (50.8-63.5)	12% (5.9-18.1)	3.80 (1.8-8.5)
Secondary outcome: Change in participants' perception of uncertainty				
Pooled effect	37.1% (34.3-39.9)	34.5% (31.8-37.4)	2.5% (-0.1-5.2)	1.29 (0.9-1.7)
Single arm trial	37.7% (31.5-44.5)	34.4% (28.3-41.1)	3.3% (-3.2-9.9)	1.38 (0.7-2.7)
Limited study duration	40.4% (34.2-46.7)	39.0% (33.0-45.4)	1.2% (-4.5-7.1)	1.15 (0.6-2.2)
Limited study population	35.6% (29.5-42.1)	31.0% (25.2-37.4)	4.5% (-1.7-10.9)	1.58 (0.8-3.1)
Surrogate endpoint	37.2% (31.0-43.9)	32.0% (26.1-38.6)	5.1% (-0.8-11.2)	1.84 (0.9-3.9)
Treatment effect size	34.4% (28.6-40.8)	35.7% (29.8-42.1)	-1.2% (-7.8-5.2)	0.89 (0.4-1.6)

Note: Percentage of participants who responded, "somewhat likely" or "very likely" or "somewhat certain" or "very certain". Table shows 95% confidence intervals alongside each estimate. Confidence intervals for single group proportions were estimated using the Wilson score method. The absolute difference between groups and odds ratios were estimated using the McNemar's X^2 test for paired data.

Appendix

Scenario

Please read the following scenario about Alex.

Alex is 38 years old. A year ago, Alex was diagnosed with non-small cell lung cancer that had spread to other parts of her body. Since her diagnosis, Alex has tried 2 different treatments, but none have worked. Alex's doctor says that less than 10% of people in her situation live for more than 5 years.

Alex's doctor tells her that the US Food and Drug Administration (FDA) recently approved a new drug for patients like her who did not respond to other treatments. Her doctor wants to know if she would be interested in taking the drug. It would be covered by Alex's health insurance with no additional costs.

Here is the information Alex's doctor gave her to help her decide about the new drug. The source of this information was the US Food and Drug Administration (FDA).

Information about ZENOVA for non-small cell lung cancer	
ZENOVA is a prescription medicine used to treat adult patients with non-small cell lung cancer (NSCLC) that has an abnormal KRAS G12C gene mutation, is locally advanced or has spread to other parts of the body (metastatic) and has progressed on or after one prior treatment. The FDA approved ZENOVA based on evidence from 1 clinical trial in 112 patients.	
Benefits	**% of patients in trial**
Partial or complete shrinkage of tumors	**43%**
Complete shrinkage of tumors	1%
Partial shrinkage of tumors	42%
Harms	**% of patients in trial**
Serious harms (life threatening or requiring hospitalization)	**45%**
Pneumonia	17%
Hepatoxicity (liver damage)	10%
Common side effects	**98%**
Diarrhea	70%
Nausea	69%