Assessing How Consumers Interpret and Act on Results From At-Home COVID-19 Self-test Kits
A Randomized Clinical Trial

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➕ **Multimedia**

➕ **Supplemental content**

IMPORTANCE The US Food and Drug Administration (FDA) authorized SARS-CoV-2 rapid at-home self-test kits for individuals with and without symptoms. How appropriately users interpret and act on the results of at-home COVID-19 self-tests is unknown.

OBJECTIVE To assess how users of at-home COVID-19 self-test kits interpret and act on results when given instructions authorized by the FDA, instructions based on decision science principles, or no instructions.

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial was conducted of 360 adults in the US who were recruited in April 2021 to complete an online survey on their interpretation of at-home COVID-19 self-test results. Participants were given 1 of 3 instruction types and were presented with 1 of 4 risk scenarios. Participants were paid $5 and had a median survey completion time of 8.7 minutes. Data analyses were performed from June to July 2021.

INTERVENTION Participants were randomized to receiving either the FDA-authorized instructions (authorized), the intervention instructions (intervention), or no instructions (control), and to 1 of 4 scenarios: 3 with a high pretest probability of infection (COVID-19 symptoms and/or a close contact with COVID-19) and 1 with low pretest probability (no symptoms and no contact). The intervention instructions were designed using decision science principles.

MAIN OUTCOMES AND MEASURES Proportion of participants in the high pretest probability scenarios choosing to quarantine per federal recommendations and perceived probabilities of infection given a negative or positive COVID-19 test result. A Bonferroni correction accounted for multiple comparisons (3 instruction types × 4 scenarios; α = 0.004).

RESULTS After excluding 22 individuals who completed the survey too quickly, the responses of 338 participants (median [IQR] age, 38 [31 to 48] years; 154 (46%) women; 215 (64%) with a college degree or higher) were included in the study analysis. Given a positive test result, 95% (322 of 338; 95% CI, 0.92 to 0.97) of the total participants appropriately chose to quarantine regardless of which instructions they had received. Given a negative test result, participants in the high pretest probability scenarios were more likely to fail to quarantine appropriately with the authorized instructions (33%) than with the intervention (14%; 95% CI for the 19% difference, 6% to 31%; *P* = .004) or control (24%; 95% CI for the 9% difference, −4% to 23%; *P* = .02). In the low pretest probability scenario, the proportion choosing unnecessary quarantine was higher with the authorized instructions (31%) than with the intervention (22%; 95% CI for the 9% difference, −14% to 31%) or control (10%; 95% CI for the 21% difference, 0.5% to 41%)—neither comparison was statistically significant (*P* = .05 and *P* = .20 respectively).

CONCLUSIONS AND RELEVANCE The findings of this randomized clinical trial indicate that at-home COVID-19 self-test kit users relying on the authorized instructions may not follow the Centers for Disease Control and Prevention's quarantine recommendations, producing unintended risks and unnecessary disruptions. Redesigned instructions that follow decision science principles may improve compliance.

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Early in the COVID-19 pandemic, the US National Institutes of Health identified SARS-CoV-2 testing as "the key to getting back to normal" because testing could identify infected individuals and interrupt viral transmission through quarantine, as well as gauge local prevalence and inform public health efforts.[1] Even where COVID-19 vaccine rates are high, testing remains important to uncovering new case clusters and breakthrough infections, assessing vaccination effectiveness, and protecting individuals at high risk for serious complications.

The US Food and Drug Administration (FDA) has prioritized home testing for SARS-CoV-2 to help people "take immediate action, based on their results, to protect themselves and those around them."[2] In November and December 2020, the FDA issued emergency use authorizations (EUA) for 3 rapid at-home self-testing kits, including the Ellume COVID-19 home test, available over-the-counter for individuals with or without symptoms;[3] as of December 23, 2021, there are 11 such FDA-authorized kits.

Although COVID-19 at-home test kits provide results within 30 minutes, they test for viral antigens, ie, they are less sensitive (ie, have more false negatives) than PCR (polymerase chain reaction) tests,[4] which have an estimated clinical sensitivity of approximately 70%.[5,6] Therefore, users with a high pretest probability of disease should still quarantine even after receiving a negative test result. If users ignore that probability, a negative test result may encourage behavior that is risky to them and others.

In this study, we asked people how they would respond to the results of a home test kit in scenarios with high or low pretest probabilities of COVID-19. Participants chose from 5 response options ranging from "take no precautions" to "stay at home all the time, without exceptions, and avoid contact with others, including others in the household." We treated this last option as the response most closely aligned with the recommendation of the US Centers for Disease Control and Prevention (CDC) for individuals with a positive test result or a negative test result with a high pretest probability of disease.[7] We called this state "quarantine," a simple word representing the formal CDC definition.[8]

We communicated pretest probabilities by asking participants to imagine having COVID-like symptoms and/or having been in close contact with actively infected patients. We asked what actions they would take, in terms that could be compared with CDC recommendations. We randomized the participants to receive either no instructions, the FDA-authorized instructions accompanying the test kits, or instructions designed following decision science principles.

Methods

This study was given expedited review and approval by the institutional review board of the Carnegie Mellon University (STUDY2020_00000501) and was designated exempt by the Committee for the Protection of Human Services at Dartmouth College (STUDY00032249). Informed consent was obtained from each participant before beginning the online survey, which did not collect any identifying information. The

Key Points

Question How do people interpret results of at-home COVID-19 self-test kits when they use instructions authorized by the US Food and Drug Administration or instructions developed with decision science principles, or no instructions, and do they choose to self-quarantine per federal recommendations or quarantine unnecessarily?

Findings randomized clinical trial of 360 adults in the US found that a substantial proportion misinterpreted the negative results of at-home self-tests by failing to consider the implications of a high pretest probability of infection and ignoring the federal self-quarantine recommendations. Decision science–based instructions may increase the contribution of at-home self-test kits to public health.

Meaning The findings of this randomized clinical trial indicate that people who use at-home COVID-19 self-test kits may fail to self-quarantine or may quarantine unnecessarily because they misinterpret the implications of test results. Redesigned instructions may increase the benefits and reduce the harms from at-home self-test kits.

study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

The study protocol was registered with ClinicalTrials.gov and posted to the Open Science Framework prior to data analysis (https://dx.doi.org/10.17605/OSF.IO/A2E4F). The protocol is also available in Supplement 1. The complete survey is available in eAppendix 1 of Supplement 2.

Trial Design

We conducted a parallel group individually randomized clinical trial to assess the differences in how people interpret results of COVID-19 home test kits given the FDA-authorized instructions, instructions based on decision science principles, or no instructions.

Randomization to Authorized, Intervention, or Control

Participants were randomized (1:1:1) using the embedded randomization function in the survey software (Qualtrics) to receive either the actual FDA-authorized instructions from the over-the-counter Ellume COVID-19 Home Test (authorized); instructions of similar length but designed along decision science principles (intervention); or no instructions (control). The texts of the authorized and intervention instructions are available in eAppendix 1 of Supplement 2.

In the authorized and intervention groups, participants were shown the group's instructions directly on the screen of their electronic device. The instructions were repeated on each relevant survey page. The FDA-authorized instructions were the section of the full instructional pamphlet that described what to do for a positive or negative test result; the remainder of the pamphlet provided only general information about COVID and about the test kit, step-by-step instructions for performing the test, frequently asked questions (eg, "I have a nosebleed after swabbing my nose, what should I do?"), and clinical test performance (expressed as percent agreement with known positive and negative samples).

Figure 1. Instructions Authorized by the FDA Compared With Intervention Instructions Designed With Science Decision Principles
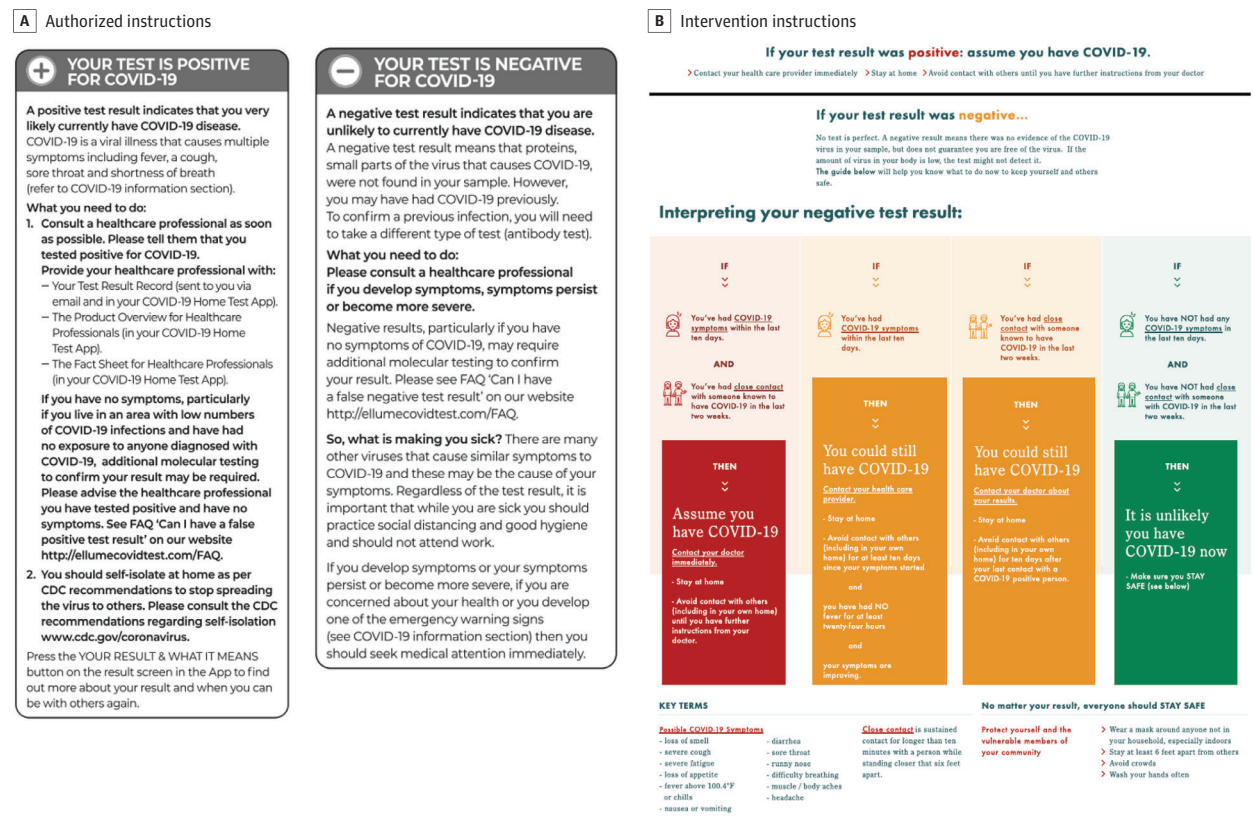
Abbreviation: FDA, US Food and Drug Administration.

Full-size versions of both instruction types are available in eAppendix 1 of Supplement 2. The intervention instructions were designed using the best

available evidence at the time of the study; for updated guidance, visit cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html

Participants could opt to download a PDF of their group's instructions, an option used by 19 participants (16%) in the authorized group and 11 (10%) in the intervention group. They could also download a PDF of the full FDA-authorized instructional pamphlet, an option used by 16 (14.3%), 4 (3.5%), and 5 (4.6%) in the control, authorized and intervention groups, respectively. This option allowed all participants to view all of the FDA-required information, although this study addressed only the interpretation of the at-home test results. In reality, tests always come with instructions, even though users may ignore them; therefore, we gave participants with no instructions the opportunity to download the instructional pamphlet. The authorized and intervention instructions are shown in **Figure 1**.

Randomization to Clinical Scenario

Participants were further randomized (1:1:1:1) to 1 of 4 possible scenarios. Each scenario asked participants to imagine themselves as Jamie, "a healthy 45-year-old who lives with two other people, works from home, has not been vaccinated against COVID-19," and has decided to take a home test. Three scenarios described conditions with a high pretest probability of infection: (1) COVID-19–typical symptoms and recent

close contact with an individual infected with COVID-19, (2) no COVID-19–typical symptoms and recent close contact, and (3) COVID-19–typical symptoms and no close contact; and the last scenario (4) described a low pretest probability of infection: no symptoms and no recent contact (see the CONSORT diagram [eFigure 1] in Supplement 2). Participants were asked to answer all of the survey questions based on Jamie's test results, symptoms, and exposure-level, after reviewing the instructions provided (authorized, intervention, or control).

Intervention

The intervention instructions followed decision science principles, emphasizing clear, structured comparison of alternatives.[9-11] The instructions about the need to quarantine after a negative antigen test came directly from the CDC website[4] (eAppendix 2 in Supplement 2 has the exact source text). The intervention instructions were iteratively pretested with potential users and reviewed for accuracy by colleagues.

Survey Pretest

We conducted pretests of the survey with colleagues, friends, and family, eliciting informal feedback on the survey design,

especially the clarity of the instructions. After making revisions based on that feedback, we conducted a pilot study with 60 participants recruited from the CloudResearch platform front end to Amazon's Mechanical Turk (MTurk),[12] after which we revised the survey to its final form. None of the preliminary data were used in the trial's statistical analyses. Individuals who participated in the study pretest or pilot could not participate in the final trial.

Trial Participants

We recruited an online sample of 360 individuals from the CloudResearch Platform[12] on April 2 to 3, 2021. The study was limited to participants identified by MTurk as having completed at least 100 MTurk tasks successfully[13] with a "human intelligence task approval rating" of 98%, reflecting satisfactory performance. CloudResearch also disqualified MTurk participants identified as providing low-quality responses on previous studies (eg, failing attention checks).[10] Individuals were eligible to participate if they resided in the US (confirmed by MTurk), were 18 years of age or older, were literate in English, agreed to the online consent form, and had not participated in the pilot study.

Exclusion criteria were specified prior to the data analysis. Participants who failed a reCAPTCHA screening (a service that protects websites from spam/abuse), a 7-question screening to identify bots and/or scripts, using 7-questions) or who completed the survey too quickly were excluded. The last criterion was defined as faster than the tenth percentile in the distribution of pilot survey completion times (control group, 3.9 minutes; authorized and intervention groups, 5.0 minutes). Median completion times for the remaining (included) participants were 7.7, 9.6, and 9.9 minutes, respectively (participants in the control group completed the tasks more quickly because they did not have test instructions to read). Participants were paid US $5 for completing the survey.

Measures

Primary Outcome

The prespecified primary outcome was the proportion of individuals who failed to state that Jamie should quarantine when appropriate, per the CDC recommendations for initial actions (ie, before any confirmatory testing; precise language is available in eAppendix 2 of Supplement 2) in each scenario.[14] Quarantine is the correct first action for a positive test result or for a negative result in 3 scenarios with high pretest probability, but no quarantine is needed for the 1 low pretest probability scenario. That is, for a negative test result with no symptoms or known recent contact, no quarantine is recommended; however, for a negative result and (1) symptoms and a known recent contact, (2) no symptoms and a known recent contact, or (3) symptoms and no known contact, quarantine is recommended.

Secondary Outcomes

The prespecified secondary outcomes were participants' estimates of the probability of being infected by COVID-19 after receiving a negative or positive test result, elicited with both verbal (ie, definitely yes, very likely, likely,

unlikely, definitely not) and numeric (ie, from 0 [no chance] to 100 [definitely infected]) scales. Other secondary outcomes were valuations of the authorized or intervention materials as easy or difficult to read, useful, and helpful for interpreting a positive test and a negative test result (5-point scales). The complete survey is available in eAppendix 1 of Supplement 2.

Statistical Analysis

We used response variance in the pilot study to estimate the sample size needed for approximately 80% power to detect a difference of 10 percentage points in the elicited probability of infection, given a negative test, between the authorized and intervention groups, with an α level of 0.05.[15] That analysis indicated a sample size of 360 individuals (120 per group) for 80% power to detect a small to medium effect size difference in the proportion choosing to quarantine (assuming α = .05, the normal approximation to the binomial distribution and the standard formula for comparing proportions in independent equal-sized groups).[16]

We hypothesized that participants in the high pretest probability scenarios who saw the intervention materials would (1) be more likely to choose quarantine given a negative test and (2) provide higher probability estimates for a false negative, compared with participants who saw the authorized instructions or no instructions. We hypothesized no difference given a positive test, as the intervention instructions were not designed to increase caution in any scenario.

Sensitivity Analyses

We conducted 3 sensitivity analyses to examine how the primary outcome changed when we (1) used a definition of *appropriate* response that did not require avoiding contact with people in one's own home; (2) included data from the 22 individuals who were excluded because they had completed the survey too quickly; and (3) excluded data from individuals who had downloaded the complete version of the Ellume instructions. For statistical comparisons, we used tests for medians (Kruskal-Wallis) for continuous variables, and χ^2 tests for proportions. Tests were 2-sided except for 1-sided Kruskal-Wallis tests. Bonferroni correction accounted for multiple comparisons (α = 0.004 for comparisons across the 12 instructions × scenario groups). Data analyses were performed from June to July 2021, using STATA, version 15.1 (StataCorp).

Results

Of the 360 adults enrolled, 338 participants (mean age [IQR], 38 [31-48] years; 154 [46%] women) were included in the study; 22 were excluded because they finished too quickly (5, 8, and 9 individuals in the authorized, intervention, and control groups, respectively). No participants were excluded for failing the reCAPTCHA or bot and/or script screening. The CONSORT diagram is available as eFigure 1 in Supplement 2. Among the 338 participants, 215 (64%) had a college degree

or higher education; race and ethnicity information were not collected (**Table**).

Decision to Quarantine

Given a positive test result, overall, 95% (95% CI, 0.92-0.97) of participants chose quarantine. The proportion choosing to quarantine was similar regardless of instructions group (94%-97%) or scenario (93%-98%).

Given a negative test result and high pretest probability scenarios, many participants did not choose quarantine as recommended by the CDC.[14] Participants in the high pretest probability scenarios were more likely to fail to say they would quarantine appropriately with the authorized instructions (33%) than with the intervention (14%; 95% CI for the 19% difference, 6% to 31%) or, nominally, with no instructions (24%; 95% CI for the 9% difference, −4% to 23%). **Figure 2** shows the proportions choosing quarantine, by instruction group and scenario. In all groups in all scenarios, the proportion of incorrect responses was highest with the authorized instructions, even higher than with no instructions. In the highest pretest probability scenario (symptoms and close contact), the proportion inappropriately choosing not to quarantine was higher with the authorized instructions (36%) than with the intervention (4%; 95% CI for the 32% difference, 13% to 51%) or nominally with no instructions (21%; 95% CI for the 14% difference, −9% to 38%; Figure 2). The same pattern was seen with the 2 other high pretest probability scenarios, although the differences were smaller and not statistically significant.

Given a negative test result in the low pretest probability scenario, more participants inappropriately chose quarantine with the authorized instructions (31%) than with the intervention (22%; 95% CI for the 9% difference, −14% to 32%) or the control instructions (10%; 95% CI for the 21% difference, 0.5% to 41%)—neither comparison was statistically significant.

Sensitivity Analyses

The first sensitivity analysis used a less strict definition of quarantine, one that required staying at home but did not require avoiding others in the home. The patterns were similar, although the differences between instruction groups were smaller (eFigure 2 in Supplement 2). The other 2 sensitivity analyses used the strict definition of quarantine. One analysis included the 22 individuals who had been excluded for a quick completion; the second excluded the 25 individuals who downloaded the full authorized test instructions. The patterns were similar (eFigures 3 and 4 in Supplement 2).

Effect of Instructions on Perceived Likeliness of Infection

We elicited participants' perceived chance of COVID-19 infection with numeric (0%-100%) and verbal (5-point rating scale) response modes. Responses to the 2 scales were highly correlated within individual (Spearman ρ = 0.89; *P* = .0001; eFigure 5 in Supplement 2). We have reported each separately.

Numeric Probabilities

Given a negative test, participants' judgments of the probability of a COVID-19 infection varied by clinical scenario (Kruskal-Wallis test of medians; *P* < .001; **Figure 3**A). The medians (pooled across instruction groups) followed the implicit probabilities: contact and symptom group (70%), contact and no symptoms (32%), no contact and symptoms (37%), and no contact and no symptoms (9%). For each of the 3 high pretest probability scenarios, the median probability was lowest for the authorized instructions group. These judgments differed statistically for the highest-risk group (contact and symptoms): authorized, 20%; intervention, 85%; control, 60% (Kruskal-Wallis test of medians, *P* < .001; Figure 3A). For the low-risk scenario (no contact and no symptoms), the median probability was similar for all groups (approximately 10%).

With a positive COVID-19 test result, the median probability was similar for all 3 high pretest probability scenarios and instructions combinations (87%-95%). It was somewhat lower for the low-risk scenario for each instruction condition (approximately 80%; Figure 3B).

Verbal Quantifier

Figure 4 shows the proportion of participants who reported the likelihood of COVID-19 infection as "unlikely" or "definitely not" given a negative test result. Given the association between verbal and numeric ratings (eFigure 5 in Supplement 2), both responses are implicitly lower than the actual likelihood in the high-risk scenarios. For all 3 of these scenarios, the proportion giving these low estimates was significantly higher with the authorized instructions than with the intervention instructions: symptoms and close contact (0% vs 61%; *P* < .001); contact and no symptoms (36% vs 80%; *P* = .001); no contact and symptoms (41% vs 79%; *P* = .003). For the low-risk scenario, almost all participants in all 3 instructions groups, rated the likelihood of infection given a negative test result as "unlikely" or "definitely not."

For a positive COVID-19 home test result, participants responded similarly in the 3 instruction groups. Pooling their responses, the proportion judging COVID-19 infection as "likely," "very likely," or "definitely infected" was 100% (contact and symptoms), 89% (contact and no symptoms), and 91% (no contact and symptoms); it was lower (79%) for the no contact and no-symptoms scenario (eFigure 6 in Supplement 2).

Valuation of Materials

Most respondents rated the authorized and intervention instructions as easy or very easy to read (82% and 81%, respectively) and useful" or extremely useful for interpretation of at-home test kit results (93% and 86%, respectively). Similar proportions agreed or strongly agreed that both the authorized and intervention instructions "helped me know what to do" if the test result was positive (96% vs 86%; *P* = .07) and if it was negative (90% vs 91%; *P* = .2).

Discussion

In this randomized clinical trial, a substantial proportion of US adult respondents indicated that they would not follow the CDC recommendations for self-quarantine after receiving a nega-

Table. Characteristics of Study Participants According to Randomized Groups

| Characteristic	Contact and symptoms (n = 84)			Contact and no symptoms (n = 85)			No contact and symptoms (n = 84)			No contact and no symptoms (n = 85)			Total
	Authorized	Intervention	Control	Authorized	Intervention	Control	Authorized	Intervention	Control	Authorized	Intervention	Control	
No.	28	28	28	30	28	27	29	27	28	29	27	29	338
Age, median, (IQR), y	38 (32-56)	38 (31-48)	40 (32-48)	37 (28-48)	40 (35-52)	38 (32-41)	36 (29-44)	43 (34-51)	38 (31-42)	42 (32-49)	34 (29-41)	39 (33-49)	38 (31-48)
Sex, %													
Female	54	46	68	37	43	52	28	52	39	48	33	48	46
Male	46	54	32	60	57	41	72	48	61	52	63	52	53
Nonbinary	0	0	0	3	0	0	0	0	0	0	0	0	0
Self-described	0	0	0	0	0	7	0	0	0	0	4	0	1
Education, %													
Some high school	0	0	0	0	0	0	0	0	0	0	0	3	0
High school degree	11	14	4	17	4	19	31	19	14	4	0	14	12
Some college	25	29	25	37	21	26	21	26	18	17	15	24	24
College degree	46	46	57	37	61	33	38	48	39	59	59	48	48
Graduate school	18	11	14	10	14	22	10	7	29	21	26	10	16
Health status, %													
Excellent	18	11	11	13	18	26	3	4	18	17	19	7	14
Very good	39	54	14	27	39	22	34	48	29	38	37	55	36
Good	29	21	46	47	29	41	45	19	39	34	33	17	33
Fair	14	11	21	10	14	11	17	26	7	7	11	17	14
Poor	0	4	7	3	0	0	0	4	7	3	0	0	2
Any comorbidity, %[a]	25	29	50	27	18	26	28	33	32	29	22	38	30
Comorbidity, median (IQR)	0.5 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-0)	0 (0-2)	0 (0-1)
Prior COVID-19 tests, %													
None	71	89	75	70	57	74	86	56	64	55	67	69	70
1-3	29	7	25	23	29	22	14	41	29	45	19	31	26
>3	0	4	0	7	14	4	0	4	7	0	15	0	4
Any positive COVID-19 result, %	7	7	11	17	7	7	0	7	4	3	11	9	8
Friend is COVID-19 positive, %	29	32	36	37	39	30	34	37	29	41	41	31	35
Received vaccine dose, %	29	29	36	20	46	19	21	30	21	41	37	21	29
Asymptomatic spread possible, %													
Yes	100	100	96	100	93	93	97	96	89	100	93	97	96
No	0	0	4	0	4	7	3	4	4	0	4	0	2
Unsure	0	0	0	0	4	0	0	0	7	0	4	3	1

Proportions may not sum to 100% owing to rounding; health status missing for 1 person in no contact and no symptoms (control). All P values >.05 within scenarios except for prior COVID-19 test in the no contact and no symptoms group.

[a] Asthma, cancer, chronic obstructive pulmonary disease, diabetes, heart disease, obesity, or weakened immune system.

Figure 2. Respondents in Each Randomized Group Choosing Not to Quarantine After a Negative At-Home COVID-19 Self-test Result
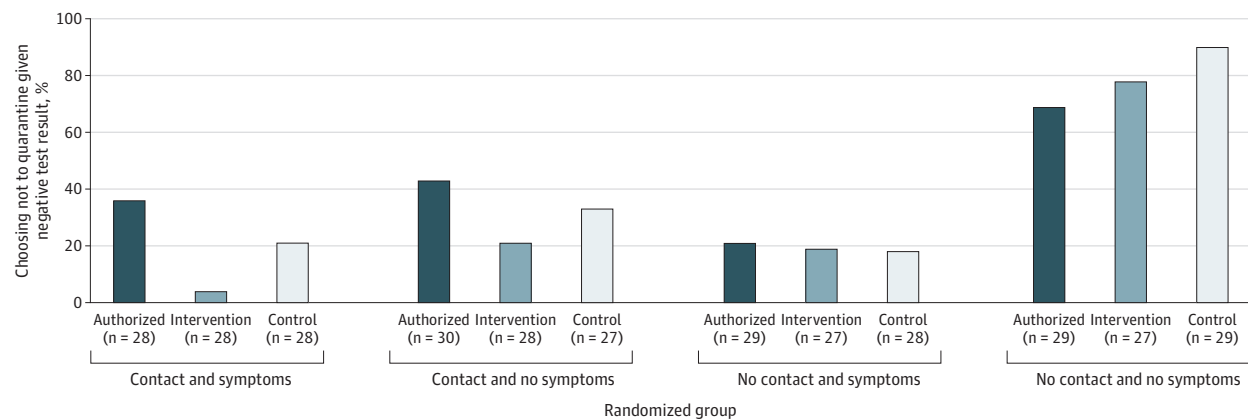
At the time of the study, the US Centers for Disease Control and Prevention recommended quarantine for scenarios 1-3 (high pretest probability) but not scenario 4 (low pretest probability); for updated guidance, visit cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html

Figure 3. Median Estimated Probability of COVID-19 Infection

A After negative test

B After positive test
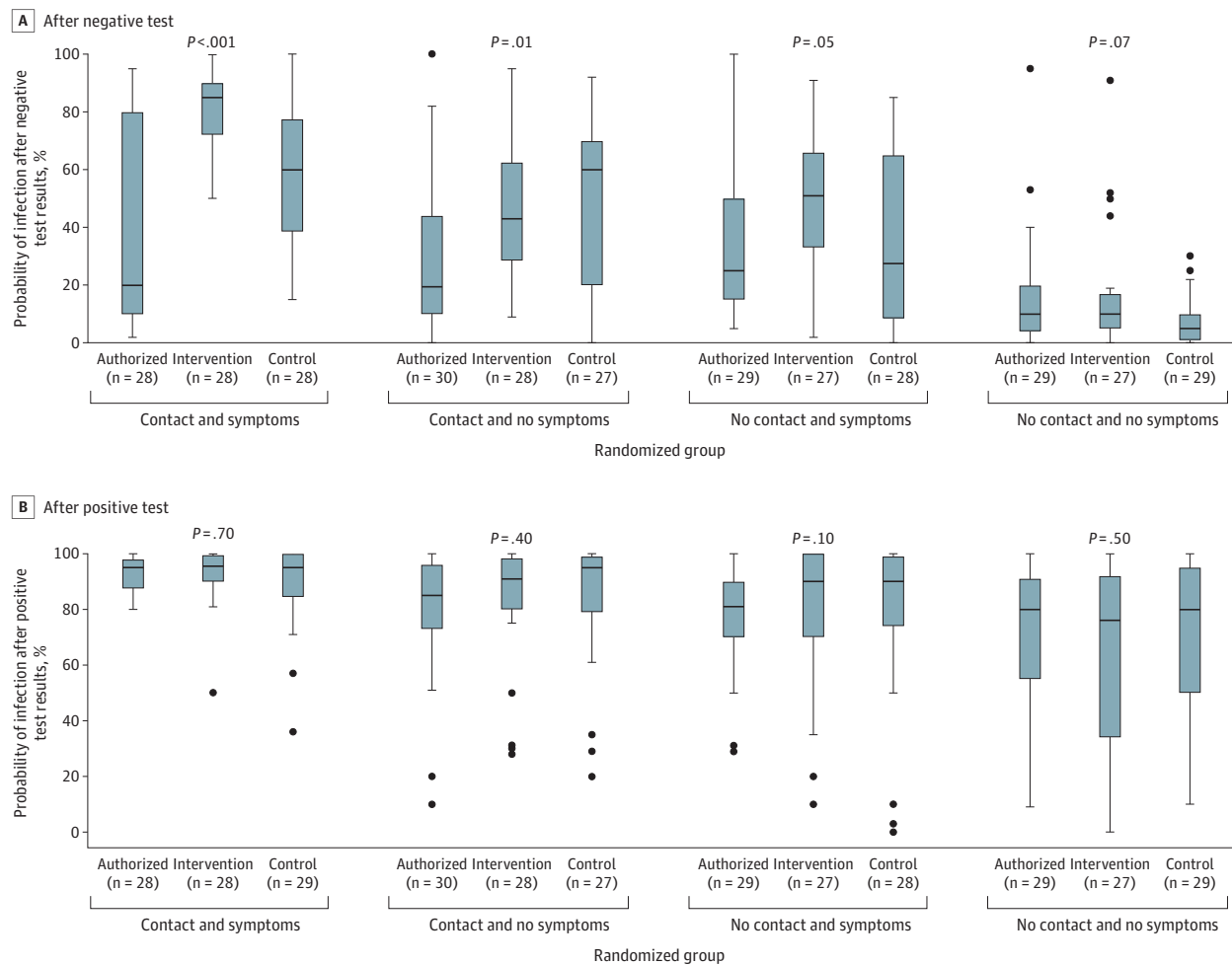
tive result from an at-home COVID-19 self-test in the context of a high pretest probability of infection. Fewer respondents chose to quarantine if they had received the FDA-authorized instruc-tions instead of the intervention instructions (based on decision-science principles) or no instructions. Judgments elicited with both numeric and verbal scales indicated that participants who

Figure 4. Respondents in Each Randomized Group Who Believed That After a Negative COVID-19 Test Result a Person is "Unlikely" to Be or "Definitely Not" Infected With COVID-19
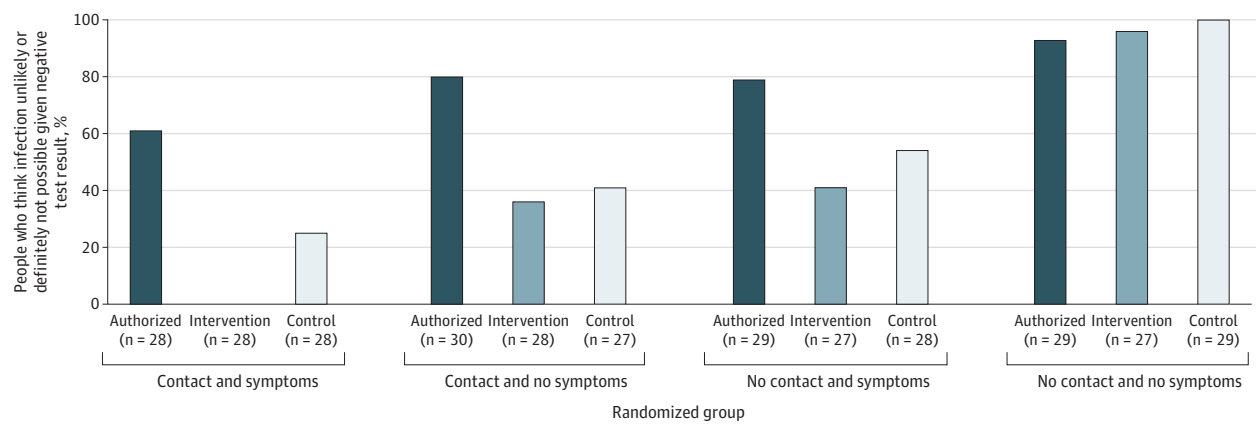
received the intervention instructions best understood the risks in the high pretest probability scenarios.

These findings suggest that many at-home COVID-19 self-test users will draw false reassurance from a negative result, ignoring conditions that pose a high pretest probability of infection—and were perhaps the reason for testing. This misinterpretation was highest among those who received the authorized instructions, suggesting that they confused recipients or gave them false reassurance. Indeed, the authorized instructions may override intuitive common sense—performance was poorer among this group than in the group with no instructions. Performance improved with the intervention instructions aligned with decision science principles. However, even with these instructions some people made the inappropriate choice despite being focused on the instructions, which may not happen in everyday use.

The results of this study show how important it is to design and pilot-test instructions to ensure that they can be understood by as many users as possible. These findings also indicate that public health policies need to reflect both the limited sensitivity of rapid antigen tests and the possibility and probability of improper use. The latter problem can be addressed easily and cheaply with better instructions. Furthermore, as rapid antigen testing norms change (eg, frequent repeated vs intermittent testing) and new quarantining policies emerge, instructions will need to be updated to clearly communicate the goals of use and to guide the appropriate interpretation of results.

At-home test kits might play an important role in managing the COVID-19 pandemic, but only if users interpret their results appropriately when deciding whether to quarantine. When the FDA authorizes a test kit, it authorizes both the device and the accompanying instructions; currently however, vendors must provide evidence on the device but not its instructions.

We propose a methodology for evaluating instructions. Demonstrated with the first over-the-counter COVID-19 test kit with EUA from the FDA, this methodology was used to evaluate the responses of a diverse sample of US adults re-

cruited online and asked to choose an action given a test result and 1 of 4 scenarios. Three scenarios had a high pretest probability of disease—COVID-like symptoms and/or close contact with someone with the disease. For these scenarios, many participants interpreted the negative test result as indicating that they did not need to quarantine, treating the test as sufficiently diagnostic to ignore the a priori risk. Roughly twice as many participants made that mistake when using the authorized instructions than when using the intervention instructions. In the highest-risk scenario (disease symptoms and close contact), the proportion dropped from 36% with the authorized instructions to 4% with the intervention instructions; 21% with no instructions at all. The intervention instructions did not increase the proportion of participants who would quarantine with the low-risk scenario (no symptoms, no close contact), indicating that the instructions did not just increase caution across the board. Participants in all three groups interpreted a positive result similarly.

Ignoring the pretest probability of infection is a special case of the natural tendency that Tversky and Kahneman[17] called base-rate neglect. Addressing that tendency requires clearly communicating that at-home test kits have imperfect diagnostic capability and that this carries implications for decision-making. The intervention instructions applied decision science principles to that end. As noted, these instructions did not achieve greater caution with high-risk scenarios at the price of greater caution in the low-risk scenario.

The decision science design principles applied to the intervention instructions included using simple and familiar wording; enhancing users' intuitive mental models of the disease and test; providing an easily navigable visual design; spelling out the implications of different scenarios in comparable terms; and explicitly recognizing uncertainty without suggesting ignorance. These instructions went through multiple rounds of user testing, as required for all communications; we found no such evidence of testing for the authorized instructions.

The intervention instructions were based on CDC recommendations for quarantine after a negative antigen test in vari-

ous clinical scenarios. In the process of designing the intervention instructions, we found that the CDC information was hard to follow, distributed across multiple webpages, poorly summarized, and not entirely consistent. Clearer communication should help clinicians and consumers make better decisions and might help test kit manufacturers write better instructions.

At-home COVID-19 self-test kits have generated substantial enthusiasm for helping people protect themselves and others. The US Departments of Defense and Health and Human Services have invested more than $230 million in Ellume—manufacturer of the first over-the-counter home self-test kit with EUA—to increase the company's production and to procure 8.5 million tests for national distribution. In the fall of 2021, the Biden Administration announced that it will use the Defense Production Act "to increase production of rapid tests, including those you can use at home," and that it has "worked with top retailers like Walmart, Amazon, and Kroger's…to sell at-home rapid test kits at cost."[18] More recently, the federal government announced its decision to distribute at least 500 million free at-home COVID-19 self-test kits to the public.[19] To maximize their public health benefit, self-test kits must be accompanied by scientifically sound instructions that reflect the best available evidence and that have been empirically evaluated with users to ensure that the public understands when to use them and how to apply the results.

Limitations

This study had several limitations. First, we tested hypothetical decisions made in an online setting rather than actual decisions. People using actual tests may read instructions more closely, less closely, or just differently. Second, we used a self-selected sample of study participants enrolled through MTurk—younger and better educated than the general public. Other individuals may have interpreted the test results and read the instructions differently. We expect that the evaluation protocol would have similar internal validity (eg, comparing decisions and risk judgments). We hope that the FDA and other communicators carefully develop and review test kit instructions in the relevant target populations, with appropriately diverse language, literacy, numeracy, culture, and resources. Third, the size of our study sample was chosen to compare performance on alternative instructions. A larger sample may be required for estimating rates of appropriate and inappropriate test kit decisions for use in epidemiologic models.

Conclusions

The findings of this randomized clinical trial indicate that at-home COVID-19 self-test kit users relying on the authorized instructions may not follow the CDC quarantine recommendations. The study also illustrates how to design and test clear instructions efficiently and how poor at-home self-test instructions can create a public health risk and unnecessary disruptions.

The virus, the tests, the evidence, and CDC guidance[20] continue to change. However, the message of the present study remains. The potential benefits of at-home self-test kits will only be realized if users know how to interpret their results. Whether they do is an empirical question requiring evidence such as that collected here. These findings show that the intervention instructions are a better place to start when adapting to new conditions, better than the originally approved and apparently untested instructions.

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