PUBLIC UNDERSTANDING OF MEDICAL COUNTERMEASURES

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Medical countermeasures, including new drugs and vaccines, are necessary to protect the public's health from novel diseases and terrorist threats. Experience with the 2001 anthrax attack and the 2009 H1N1 pandemic suggest that there is limited willingness to accept such drugs and that minority groups may respond differently from others. We conducted 148 intercept interviews in the metropolitan Washington, DC, area, examining 2 hypothetical scenarios: a new respiratory virus and public exposure to high levels of radiation. Findings provide insights into key factors that affect whether diverse members of the public comply with recommended protective actions like taking emergency authorized vaccines. These insights can help improve how public health practitioners communicate during uncertain times.

Keywords: Risk communication, Countermeasures, Public health preparedness/response

SINCE THE 2001 ANTHRAX ATTACKS, federal government agencies, particularly those in the Department of Health and Human Services (HHS), have placed significant emphasis on evaluating and, as needed, producing new drugs, vaccines, and devices that can protect the US public from chemical, biological, radiological, and nuclear (CBRN) threats. Those efforts have included policy changes that enable the Food and Drug Administration (FDA) to quickly evaluate and authorize such medical countermeasures in a declared public health emergency and to communicate this approval, along with partner public health agencies like the Centers for Disease Control and Prevention (CDC). However, there is relatively little literature that explores public perceptions about such medical countermeasures and the mechanism through which they would be distributed.

BACKGROUND

The Emergency Use Authorization (EUA) authority is a legal mechanism that allows the FDA commissioner to authorize use of medical countermeasures, including unapproved medical products (eg, drug, vaccine, diagnostic device) or unapproved uses of approved medical products, to diagnose, prevent, or treat conditions associated with the emergency.^{1,2} Ongoing research is developing medical countermeasures deployable in public health emergencies, enabling the best emergency medicines and tools to be available when disaster strikes.³

According to the FDA,¹ about 26 different EUAs were in use to address public health emergencies at the time the study was conducted: Zika virus (6), enterovirus D68 (1), Ebola virus (12), H7N9 influenza (3), Middle East

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respiratory syndrome coronavirus (2), and anthrax (2). These numbers do not include the archived EUAs for Ebola virus (6), Middle East respiratory syndrome coronavirus (1), H1N1 influenza (4), and anthrax (1), in addition to past public health disasters without authorized or available EUAs such as the Fukushima nuclear disaster.^{4,5} The use of EUAs does not require informed consent by the consumer but instead relies on a fact sheet that should be highly accessible and must highlight the product's potential risks and benefits.

As a foundation for these actions, the FDA has reasonably good credibility with the US public. In a nationwide Harris Poll of 2,232 US adults surveyed between January 14 and 20, 2015, 92% understood the FDA's roles and responsibilities.⁶ Of that 92%, 57% of adults rated the FDA as doing an "excellent/pretty good" job, while the remaining 43% rated the FDA as doing an "only fair/poor" job. According to the Harris Poll, the trend in the FDA's positive ratings decreased by 5% since the first year of the study in 2000, but an overall 3% increase occurred between 2009 and 2015. This overall increase in positive FDA ratings is supported by other similar surveys.⁷ Additionally, critics disagree about whether the FDA is too risky or too risk-averse when making drug approval decisions.⁸ In a more recent poll that specifically measured public opinions on the FDA's role in the safe and timely approval of new medical treatments, nearly 6 out of 10 Americans opposed changing safety standards to allow for faster approval of new prescription drugs and medical devices, while roughly 40% favored speedier FDA action.⁹

These results provide information on how the public balances their priorities between speed and safety in the approval of new medical treatments. In the context of an emergency, it may suggest greater public concern about EUAs and medical countermeasures. Therefore, in an emergency, in which the FDA would work closely with the CDC and other agencies on decisions and communications about necessary countermeasures, communication with the public will need to clearly articulate the risks and benefits associated with proposed EUAs and medical countermeasures.

Little research has examined public reactions to the use of products available under EUAs and medical countermeasures. Focusing on the 2009 H1N1 influenza pandemic, Quinn and colleagues were the first to examine public acceptance of taking a vaccine or drug under an EUA.¹⁰ Results showed that 63.5% of 1,469 respondents would not accept a new vaccine that had not been approved through the standard process. There was greater willingness to accept Tamiflu, which was an approved drug authorized under EUA for unapproved uses, with 54% indicating willingness to take the drug. In both cases, African Americans were least likely to accept the medical countermeasure. Quinn et al also examined public acceptance of an unapproved EUA drug, Peramivir, an antiviral drug used to treat influenza, in a hypothetical medical crisis situation, finding that 48% of 2,042 respondents indicated that they

would probably or definitely take the drug.¹¹ Needing more information and the use of the term *experimental* were impediments to acceptance for all groups. An important conclusion from these 2 studies is that trust in the FDA is important for EUA acceptance and that particular care must be taken to ensure that patients and their families receive adequate and understandable information about the medical countermeasure.

The quality of communication and trust in government actions and spokespersons contributes to public acceptance. Strong communication between the FDA and the public and between providers and patients is critical to ensuring that the benefits of EUA products are realized in a time of crisis.¹¹ To do so requires effective crisis and emergency risk communication.

CRISIS AND EMERGENCY RISK COMMUNICATION

Wray and Jupka described what the public wants to know in a public health emergency: the nature of the threat; protective actions that need to be taken if not exposed, possibly exposed, or exposed; and information related to the specific attack.¹² Accordingly, communication in an emergency should include message materials that answer key questions, provide action steps, are easily understood, include credible information, and reflect disclosure from government agencies. It may be possible to encourage more people to adhere to recommended protective behaviors by ensuring that messages cover areas that members of the public wish to hear about, that the messages are communicated by trusted spokespeople through widely accessed sources, and that trust in the lead organizations is promoted and maintained.¹³

Crisis and emergency risk communication differs from standard risk communication in that a decision is made within narrow time constraints, the decision may be irreversible, the outcome may be uncertain, and the decision may be made based on incomplete information.¹⁴ The 2009 H1N1 influenza pandemic, the 2001 anthrax attacks, and other CBRN threats have illustrated the challenges of communication in emergency situations, including high uncertainty, nearly impossible time constraints, and high public anxiety.^{15,16} Indeed, evidence from the 2001 anthrax attacks suggests that inadequate crisis and emergency risk communication can reduce trust and credibility.¹⁷ Successful communication begins with accurate information delivered in a timely, empathetic, and open way. This establishes trust in a message source and the credibility of a message.¹⁴

In 2011, the office of the Associate Director for Communication at CDC convened a national panel to define and identify best practices for crisis and emergency risk communication: explain what is known at the time about an event's impact on human health; explain what is not known about the threat to human health; explain how or

why the event happened; promote action steps to reduce the threat; express empathy about the threat to human health; express accountability; and express commitment.¹⁸ Other key elements for effective crisis and emergency risk communication include enhancing trust through education efforts with community-based organizations and including targeted risk communication materials that are culturally relevant and appropriate, while paying specific attention to literacy levels.¹⁰

CONCEPTUAL MODEL

Based on previous research, trust, uncertainty, and risk perception are critical determinants of public reactions in emergencies. We describe these determinants and explore what we currently know about their impact on the public.

Trust

Although trust is known to play an important role in public adherence during a public health emergency, there is substantial interest in more nuanced studies of trust, its components, and its impact on behaviors during one specific emergency, a pandemic.^{16,19-21} Wray and colleagues determined that trust is an important factor in effectively communicating risk.²¹ Furthermore, the public's general lack of trust and confidence in the government's ability to effectively respond in an emergency may be due to the public's perception that the government has not done enough to prepare for an attack and the belief that government officials withhold important information and are sometimes dishonest.²¹

Communication during an emergency takes place in the larger context of current trust in government more generally. The Pew Research Center released a comprehensive report in 2015 stating that fewer than 3 in 10 Americans have expressed trust in the federal government in every major national poll conducted since July 2007—the longest period of low trust in government in more than 50 years.²² In a crisis, the degree to which one trusts the source of an emergency recommendation significantly affects compliance.²³ For example, trust in government agencies was found to be a powerful predictor of vaccine intention and compliance, which could be translated to the context of EUA acceptance in a crisis situation.^{16,24,25}

Additionally, uncertainty, concerns about equity, agency disagreements, and mixed messaging can diminish trust in public health agencies.²⁶ The more that people trust their government or the communicating official, the better they are able to handle fear in uncertain situations.²⁷ Most important, the willingness of a member of the public to engage in preventive or emergency behaviors depends on the risk communicator's preexisting organizational reputation, people's past and present relationship experience with the communicating organization, and the

credibility of the organization's advice.²⁵ Without trust, communicating uncertainty in a crisis situation becomes almost impossible.

Uncertainty

The best practices in risk and crisis communication acknowledge uncertainty, but empirical research on the intersection between uncertainty, crisis, and communication is limited. This may be because the uncertainty communication literature in relation to crises is sparse. Lachlan and colleagues define uncertainty as “an inherently uncomfortable state, and information seeking is a common cognitive strategy when that uncertainty is directly related to a perceived threat.”^{27(p39)} Uncertainty arises throughout public health emergencies including: who or what caused the emergency; how many lives have been lost and the extent of infrastructure damage; what members of the public can do to protect themselves; and when the emergency will be over.²⁸ Available research has identified a relationship between public trust levels in emergency information sources and the level of crisis uncertainty experienced, but with so much variation existing among crises, it is difficult to know how to effectively communicate crisis-related uncertainties to the public.^{6,27,29}

When public health agencies disagree on recommendations, as was the case in the 2001 anthrax attacks, uncertainty and conflicting opinions can create even more confusion. To mitigate this uncertainty about conflicting government guidance, having an open forum can foster trust and enhance people's abilities to make informed decisions, ultimately reducing uncertainty.¹⁷ Additionally, by directly addressing uncertainty early in a crisis, the government may be able to influence the public's acceptance of future changes in understanding and behavioral recommendations.¹⁶ These kinds of situational updates can help ensure effective communication—all while maintaining credibility in public health agencies.³⁰

Risk Perception

Psychological, social, and cultural processes often affect how the public perceives risk, including heightening or attenuating public perceptions, which can further be affected by the source of the science, media, risk management institution, social organizations, and personal networks.³¹ Covello and colleagues described outrage factors, which relate to public reactions to the risk, rather than the technical aspects of a given risk.³⁰ In addition to trust in institutions and uncertainty, they identified additional outrage factors: controllability, voluntariness, dread, effects on children, media attention, benefits, familiarity, catastrophic potential, human versus natural origin, understanding, and reversibility, among others—all of which can affect how we perceive risk.^{6,17,30} In the case of the 2001 anthrax attacks, Quinn and colleagues determined that

postal workers experienced heightened perceived risk in the beginning of the attacks due to outrage factors, including perceived inequity, lack of control, and other factors in their workplace.¹⁷

Although strong emotions can create substantial barriers to effective communication during a crisis, several studies find that increased perceived risk correlates with greater public adherence to public health recommendations.³¹⁻³³ Communicating effectively with the public about specific threats is the key to successful emergency management and public health, which ultimately helps to mitigate risks, support the implementation of protective actions, and contribute to minimizing negative mental health impacts seen in public health emergencies.³⁴

RESEARCH QUESTIONS

This study provides a critical look at these foundational determinants and the public understanding of medical countermeasures in 2 hypothetical scenarios, described in detail below. Recognizing the lack of familiarity and the novelty of a threat during an emergency, and the complex terminology used by the FDA and the CDC, our first research question is: To what extent are there differences across US racial/ethnic groups and their subpopulations in their understanding of medical countermeasure messages, including FDA regulatory terms relevant to medical countermeasures used in public health emergencies (eg, IND, shelf life, EUA, adjuvants, compassionate use, animal rule, stages of drug or vaccine development)? Our second question examines to what extent did respondents understand and indicate willingness to comply with the recommended countermeasures. Finally, our third question explores what factors influence diverse audiences' informed decision making (eg, risk perception, uncertainty, trust, emotions) and to what extent are there racial and ethnic differences in such decision making?

METHODS

Data Collection and Sample

The research team conducted 148 intercept interviews from December 2015 through June 2016 across the Washington, DC, region at metro stops and in barbershops. Central intercept interviews are ideal for understanding how people immediately process and react to information and why.³⁵ The team selected metro stops that were located in diverse areas of the Washington, DC, region or that served as hubs connecting multiple metro lines.

The sample included 53 African Americans, 50 Caucasians, and 33 English-speaking Hispanic/Latino Americans. The average participant age was 32 years, ranging from 18 to

83 years old ($SD = 15.47$) and 35% self-identified as female.* Teams of trained undergraduate and graduate students, under the supervision of a postdoctoral fellow, conducted the interviews. The face-to-face interviews generally lasted 15 to 20 minutes, with interviewers transcribing all comments from subjects by hand, verbatim. Interviews were not recorded because of the sensitivity of the topic and the high level of background noise in the interview locations. Because the interview questions required short answers (ie, a few words to a few sentences), it was possible for interviewers to accurately capture participants' responses.

Interview Script

Interviewers were trained in interview techniques following guidance provided by Lindlof and Taylor.³⁵ The interview began with a brief verbal consent form explaining the study purpose and the compensation for participants' time, followed by general screening questions. Interviewers were sent to locations based on US 2010 census data indicating racial and ethnic clusters in close proximity to the businesses and metro stations used. Additionally, one location, a local barbershop, is a community partner of the Maryland Center for Health Equity. This shop primarily serves African American and Latino clients. This sampling approach helped prevent bias of interviewers attempting to use mental heuristics to identify what they thought a person from "X background" should look like. Interviews were generally conducted in the afternoons and early evenings after work hours, in the hope that participants would be more willing to engage with the research team after work than while they were commuting to work.

After consent and screening questions, participants were read a brief message that informed them about a new treatment they may be recommended to take by the FDA during a public health emergency. One of 2 scenarios was then presented to each participant. One scenario focused on a radiological threat and the other a biological threat. Both scenarios were presented as a 3-page document, mirroring existing FDA content. Page 1 showed a Facebook post from the FDA with a color graphic about the hazard; page 2 gave a brief scenario describing exposure to the hazard; and the final page was a mock-up of an FDA fact sheet about the treatment. When participants were ready, interviewers asked a series of open-ended and closed-ended questions about the documents. (See supplemental material at www.liebertpub.com/hs.)

Measures

The research team developed the interview instrument from literature and previous experience. Demographic

*The remaining 12 subjects either provided too little or suspect data for analysis, were of an ethnic or racial background of a sufficiently small group that meaningful comparisons could not be made, or had no dominant racial identity, preferring to identify only as mixed race.

information collected included self-identified gender, race and ethnicity, and age. Other questions focused on understanding what was being asked of participants; the clarity and persuasiveness of the information; the relevance of the information and its importance to self, friends, and family; the likelihood of taking the medication; trust in the government and federal agencies; and emotional response items, modified from prior research.^{6,11,15,16} All measures were administered in an oral interview in which researchers recorded responses from a scripted survey. As a result of the nature of the interaction, many measures were single-item in nature, generally measured on 10-point Likert-type scales. A sample item would read, "On a scale of 1 to 10, where 1 is not at all important and 10 is extremely important, if your family or friends were affected, how important would it be for them to read this information?" As single-item measures do not lend themselves to traditional reliability measures, the instrument was evaluated by several public health experts external to the project's data collection for face validity. Other items were assessed with open-ended responses in which interviewers recorded verbatim responses from subjects. A sample open-ended question reads, "What remaining questions do you have regarding this information?" We also included items to explore the impact of uncertainty on participants.³⁶ Participants were asked to identify other information they needed and were asked to define some common words used by the FDA, like experimental, accelerated approval, or adjuvant.

Analysis Procedure

A mixed methods approach was used to evaluate the data collected. Qualitative analysis methods were employed in line with Corbin and Strauss's recommendations for data analysis.³⁷ Additionally, a computer-assisted semantic analysis assessed the tone of participants' open-ended responses, which interviewers transcribed verbatim during the interviews. Quantitative methodologies like ANOVA, linear regression, and multivariate GLM were used to analyze the closed-ended responses. Where relevant, Variable Inflation Indexes (VIF) were calculated and assessed to ensure multicollinearity was not present. No values above 1.262 or below 1.108 were noted.

RESULTS

Understanding Medical Countermeasure Messages

The majority of participants reported that they understand that the FDA was asking them to immediately take the recommended vaccine or medication (111 of the 145 completed responses for this question). Comparing those who would take the medication to those who would not (used as an indicator for inadequate comprehension) independent samples *t*-test indicated that those who would not take the drug ($M=5.13$, $SD=3.30$) were significantly less confident in their ability to identify the causes of the ailment than those

who would take the medication ($M=6.88$, $SD=2.54$; $t(\text{unequal variance})=-2.885$, $DF=44.44$, $p<.006$). There were no significant differences between Hispanics and African Americans in certainty, prevention, emotional responses, or likelihood to take the countermeasure. On aggregate, the radiation-based scenario was reported as being significantly easier to understand as to the causes of the illness than the biological threat ($F(134,1)=5.009$, $p=0.027$, $\eta^2=.11$). There were no significant differences between groups on understanding of the scenarios (see Table 1).

Understanding Regulatory Terms

To explore to what extent participants understand language commonly used to communicate about medical countermeasures, we asked participants to listen to a series of words and then tell us immediately what comes to mind. Table 2 displays exemplar responses. Overall, the language seemed challenging to participants. On average, respondents did not know the meaning of a word[†] more than a tenth of the time ($M=13.63$, $SD=12.19$). Removal of the word *adjuvant*, which was an outlier, did not reverse the trend. Respondents still were unable to respond with any definition of a word more than one-tenth of the time ($M=10.56$, $SD=6.30$). Participants predominantly responded negatively to the words (see Table 2). Some participants also expressed confusion about the meaning of the words.

Given the findings about the overall challenging language, we further probed understanding of regulatory terms through affective responses. While participants may not be able to define terms, whether they respond positively or negatively provides insights into their risk information processing.

Linguistic Inquiry and Word Count (LIWC) reads a text-based dataset and compares the individual modules of that text to established categories of words, punctuation, and other components of the documents. The sum of these categories is the LIWC dictionary, which has a tone composite category constructed from subcategories focused on the emotionality of words. This category drills into the positivity and negativity of expression. To understand the positivity or negativity of people's responses to medical countermeasures, the following procedure was undertaken. LIWC reports various standards for different types of text to give a rubric that can be used to compare evaluated data to different types of information.³⁸ These categories are things like blogs (tone $M=54.50$), expressive writing (tone $M=38.60$), natural speech (tone $M=79.29$), the *New York Times* (tone $M=43.61$), and Twitter (tone $M=72.24$). The standard deviation of all these categories when pooled is 23.27. For this study, if a significant difference existed between medical countermeasure responses collected here as compared to the LIWC text standards, the positivity or negativity of the expressions in our set were unique. This

[†]"Did not know" for this analysis was defined as respondents who said "nothing," "huh?," "I don't know," or something similar.

Table 1. Group Differences in Understanding Medical Countermeasure Messages

<i>Variable</i>	<i>Group</i>	<i>N</i>	<i>Mean (SD)</i>	<i>DF</i>	<i>F</i>	<i>P</i>	η^2
Recognition	Caucasians*	50	4.64(2.75)	133,2	7.635	.001	.10
	Hispanics	33	7.12(2.34)				
	African Americans	53	6.08(3.33)				
Prevent	Caucasians*	49	5.14(2.67)	132,2	4.113	.019	.06
	Hispanics	33	6.76(3.04)				
	African Americans	53	6.47(2.86)				
Pleased	Caucasians*	49	3.16(2.52)	132,2	14.836	.001	.18
	Hispanics	33	6.67(3.29)				
	African Americans	53	5.74(3.45)				
Relieved	Caucasians*	49	3.92(2.41)	132,2	6.427	.002	.09
	Hispanics	33	6.33(3.40)				
	African Americans	53	5.23(3.31)				
Confident	Caucasians*	49	4.10(2.79)	131,2	7.722	.001	.11
	Hispanics	33	6.15(3.04)				
	African Americans	52	6.27(3.19)				
Trust Govt	Caucasians*	49	6.47(2.53)	132,2	3.127	.047	.05
	Hispanics	33	5.85(3.00)				
	African Americans	53	5.06(3.05)				
Trust CDC	Caucasians*	48	7.65(2.48)	130,2	4.232	.017	.06
	Hispanics	33	6.18(3.13)				
	African Americans	52	6.17(2.85)				
Compliance	Caucasians	48	5.46(3.03)	133,2	.251	.778	<.01
	Hispanics	33	5.36(3.23)				
	African Americans	52	5.81(3.31)				
Comprehension	Radiation*	69	7.00(2.47)	134,1	5.009	.027	.11
	Biological	66	5.94(3.00)				

*Significant difference from other groups.

uniqueness is outside what is normally found in a variety of common information exchange formats—including emotionally charged writings.

The tone value for open-ended responses in this study was a 36.50 mean with a standard deviation of 40. However, when we removed single-word responses, the new value had a mean of 25.20 and a standard deviation of 33.70. LIWC reports that values under 50 are “generally negative,”³⁸ making the discussion of medical countermeasures here strongly negative. To determine just how negative the data collected here are, a series of *t*-tests were conducted. When one considers that the category for comparison most appropriate for this data is natural speech, as the surveys here were collected in face-to-face interviews, it becomes evident that even with the higher value including single-word responses (2-tailed *t*-test, $t=11.32$, $DF=6327$, $p<.001$), or without the single-word responses (2-tailed *t*-test, $t=16.18$, $DF=6327$, $p<.001$), there is a

significant difference between the data here and other forms of expression and a strong negative skew such that people are generally quite negative about emergency medical countermeasures. In other words, people in general are quite negative about the idea of emergency medical countermeasures, significantly beyond what people normally encounter in their daily, nonemergency activities, such as conversations with friends and family and news consumption.

Compliance Likelihood

Participants were asked how likely they were to take the medication or vaccine after reading the provided information. On a scale of 1 to 10, where 1 is “will not take the medication” and 10 is “will absolutely take the medication,” participants on average reported being slightly likely to take the medication or vaccine ($M=5.57$; $SD=3.17$). Compliance was distributed

Table 2. Participants' Understanding of Common Medical Countermeasures Language

<i>Word</i>	<i>Responses</i>
Experimental	animals, cautious, deceptive, guinea pigs, high risk, iffy, lab rat, medicine, new, prevention, risky, sabotage, scam, scared, science, still in verification, testing, trial, Tuskegee experiment, unproven, watch out, working
Unapproved	approved, bad, big red X, cancer, dangerous, do not take it, early, fake, FDA, lied to, not regulated, no-go, preliminary, risky, scary, sketchy, terrifying, test, unsecure
Clinical trial	AIDS, cancer, distrust, doctor, experiment, fake, gold standard, guinea pig, helpful, medicine, money, NIH, patent pending, pleased, progressive, promising, rats, risky, secret, test, test dummy study, testing, war, worried
Accelerated approval	acceptance, anxious, crisis, dangerous, Donald Trump, emergency, extra scared, fast track, FDA, good, green light, last resort, lying, more deceiving, nervous, not acceptable, not a good thing, not tested, pushed, rush through, safe, sketchy, the law, uncertainty, underhanded, worry
Off-label	black market, cheap, cutting corners, damaging, herbs, generic, illegal knock-off, just as good, lobby, medicine, mediocre, nervous, nonstandard, normal, questionable, risky, snake oil, sketchy, suspicious, thrifty, uncertain, unapproved, warning needed, weird
Extended shelf life	bad, beneficial, chemical enhancers, confused, durable, error, expired harmful, good, grocery store, iffy, ingredients, longevity, okay, old, perishable, preservative, protection, questionable, skeptical, unneeded, unsafe
Investigational new drug	bad, CDC, concerned, crazy, crucial, dangerous, desperate, experiment, extreme caution, FDA, good, government, guinea pig, H1N1, hospital, important, lab rat, last resort, necessary, panic, problematic, professional, risky, rushed, scary, soothing, surprised, test, trauma, use only in an emergency, wouldn't trust it
Emergency use authorization	ambulance, a must, civil rights, concerned, emergency, extreme caution, desperate, fast-track approval, fear, FEMA, good, helpful, important, interesting, last resort, major health emergency, mandatory, need, over-controlling, pandemic, panic, police, prioritize, risky, rushing, scary, SOS, sneaky, soothing, suspicious, unapproved, unsure, urgent
Federal stockpile	abundant, bad, conspiracy, civil liberty, disaster prevention, drugs, enormous, emergency, federal, food, for certain people only, gasoline, gold, good, government, market, nuclear weapons, plan, prevention, research chemicals, reserve, rice, sketchy, supplies, surplus, unfavorable, Wall Street, weapon, worry
Adjuvant	clouds, confusion, dictionary, don't know, doubtful, health restriction, lies, medication, most likely, new word, no clue, no idea, not really sure, nothing, paper piles, prison, scary, something you put into drugs, so-so, sports, upper, youth
Investigational device exemption	bad, court system, band – could be bribed, criminal, concerned, confusion, delay, desperate, emergency, favorable, harmful, huh, iffy, law abuse, legal, lobbying, no idea, not okay, not sure, not yet approved by FDA, paranoid, phone tap, police, policies, procedural, research, science, secret lab, screwed, spy, technology, uncomfortable, weird
Medical countermeasure	alternative, concerned, cure maybe, defense, disease, doctor, doing their job?, drug, FDA, flu shot, free, good – life saving, happy, inconvenient, informant, lies – all lies, medicine, mental health, pharmacy, precaution, procedure, reassuring, reserve, safety, scared of side effects, treatment, vaccine, worry

multi-modally, with the 2 largest clusters of individuals grouping at noncompliance (1 on a 1-to-10 scale, 16.4% of the sample) and complete compliance (10 on a 1-to-10 scale, 15.1% of the sample). No clear racial/ethnic differences were apparent when comparing groups to the whole sample.

Of those who indicated that the FDA was asking them to do something else (participants were asked, "What is the FDA asking you to do?"; responses were categorized as "take the medication" or "other"), most responses reflected comprehension of the FDA's message. For example, par-

ticipants stated that the FDA was asking them to "watch out for the disease," "tell you about a vaccine," "decide whether to take it," and "research more." However, a few respondents completely misinterpreted the message. Reasons for complying focused on avoiding negative health outcomes (eg, "don't want radiation poison," "high cost of not taking it," and "because I don't want to die").

Another common theme related to complying was trust in the CDC and/or the countermeasure (eg, "FDA approved," "because I trust vaccines"). Reasons for hesitating to comply

Table 3. Between-Subjects Effects

Source	DV	SS	F	P	P*
Likelihood to take medication	Trust in FDA	28.44	4.854	.030	
	Trust in Govt	55.76	9.559	.003	*
	Trust in CDC	54.83	11.084	.001	*
Certainty in prevention	Trust in FDA	80.722	13.777	.000	*
	Trust in Govt	67.742	11.614	.001	*
	Trust in CDC	66.762	13.497	.000	*
Racial identity	Trust in FDA	45.918	3.918	.023	
	Trust in Govt	84.081	7.208	.001	*
	Trust in CDC	98.263	9.933	.000	*

P* = Bonferroni adjusted significance level determined by a/n , where N is the number of planned comparisons.³ The critical value becomes .017.

*indicates a still significant value.

included negative health outcomes from taking the medical countermeasure (eg, “lots of side effects,” “uneasy about safety of vaccine”) along with frequently expressed uncertainty (eg, “hasn’t been approved,” “don’t have much research,” “the symptoms are a little mysterious”). Reasons for not complying included calls for more research (eg, “more research needed”), dislike of medical interventions in general (eg, “don’t like needles,” “don’t need no vaccine”), and distrust in the government (eg, “not convincing,” “use you as a lab rat”).

When asked what remaining questions participants had about the information provided, answers emphasized a need for more information about the countermeasure. For example, participants asked: “Why hasn’t a definitive list of side effects been found?” “How is the medicine tested? Sample size of the trial?” “How do they know the medicine works?” “Why hasn’t it been approved by the FDA?” Participants also wanted to know more about the emergency. For example, participants asked: “Where did they first find out someone had radiation poisoning?” “Is this a real thing?” “What was the cause of the radiation outbreak?” “When did this happen?” Furthermore, some participants had questions about disease transmission, such as “How do you get a virus?” and “Is radiation poisoning contagious?” Finally, some participants had questions about how the emergency information was disseminated: “Why didn’t they send information over the TV screens or metro?”

A multivariate general linear model was conducted to predict trust in government, the CDC, and the FDA based on racial identity, gender, and type of hazard presented[#] while allowing for the following covariates: information clarity,

likelihood of taking the emergency medication, certainty of disease recognition, disease prevention, self-reported fear, sense of relief, sense of being pleased, and sense of confidence. The analysis indicated significant differences for willingness to take the medication ($F(3,109) = 4.391$, $p = .006$, Wilks $\lambda = .892$), disease prevention ($F(3,109) = 5.567$, $p = .001$, Wilks $\lambda = .867$), and racial identity ($F(6, 218) = 3.682$, $p = .002$, Wilks $\lambda = .824$). Between-subjects testing confirmed the above relationships (see Table 3) and demonstrated good explanatory power for trust in the government (adj. $R^2 = .300$) and the CDC (adj. $R^2 = .371$). However, after applying the Bonferroni adjustment, trust in the FDA was not significant. What is interesting is that when treating trust as a dependent variable, we see that racial/ethnic identity is critical for predicting trust in the government overall as well as trust at the organizational level, such as for the CDC (Table 3). Later, we treat trust as an independent variable to better explore the nature of its role in decision making. When viewing Table 3, attention should be paid to larger F values and smaller p values, especially the p^* .

Diverse Audiences’ Informed Decision Making

One-way ANOVAs and Bonferroni tests were conducted to evaluate what, if any, differences existed between racial and ethnic groups. Hispanics and African Americans self-reported higher levels of certainty and prevention, more positive emotional responses for a sense of being pleased, relieved, and confidence about the information, but they were no more likely to take the medication or vaccine than were their Caucasian counterparts ($F(133,2) = .251$, $p = 0.778$, $\eta^2 < .01$). In general, results indicated that Caucasians differed from African Americans and Hispanics. Specifically, Caucasians were the least certain about their ability to recognize an illness and their ability to prevent the illness, and were less pleased, relieved, and confident after being presented with the information. Caucasians had higher trust in the government and the CDC compared to African Americans

[#]Socioeconomic status was not assessed because of the high proportion of participants who declared they were, or who appeared to be, homeless. Researchers were concerned about negative impacts on response rates regarding questions of household income to participants who were homeless. As such, household income was not included in the instrument or subsequent analyses. Education was measured, but was not included in the final models as the focus of the article was on race/ethnicity. Finally and notably, education was a negative predictor that lowered the explanatory capacity of all models when tested per reviewer suggestion.

Table 4. Regressions Predicting Countermeasure Compliance

<i>Model</i>	<i>Variable</i>	<i>B</i>	<i>SE(B)</i>	β	<i>T</i>	<i>P</i>
African American $F(48,4) = 12.195, p < .001$ $R^2 = .463$	Info Clarity	.264	.217	.140	1.214	.231
	Persuasiveness	.562	.177	.398	3.177	.003
	Fear	.352	.113	.336	3.107	.003
	Trust in Govt.	.165	.128	.152	1.288	.204
Hispanic $F(27,4) = 7.750, p < .001$ $R^2 = .466$	Info Clarity	.176	.258	.094	.682	.501
	Persuasiveness	.775	.187	.619	4.152	<.001
	Fear	-.217	.161	-.187	-1.344	.190
	Trust in Govt.	.213	.164	.195	1.300	.204
Caucasian $F(43,4) = 11.963, p < .001$ $R^2 = .483^*$	Info Clarity	.108	.180	.066	.602	.550
	Persuasiveness	.669	.159	.497	4.197	<.001
	Fear	.222	.125	.208	1.773	.083
	Trust in Govt.	.238	.142	.196	1.681	.100

*Significant difference from other regression values based on *F*-Ratio Test.

[($F(132,2) = 3.127, p = .047$), Bonferroni ($p = 0.042$), $\eta^2 = .05$]. Caucasians also had the highest trust in the CDC [($F(130,2) = 4.232, p = .017$), Bonferroni ($p = 0.029$, $p = 0.067$), $\eta^2 = .06$]. (When viewing Table 1, focus on *p* values, means, and η values describe the relative relationship across groups and variables.)

A series of linear regressions indicated differences between racial/ethnic groups in vaccine and medicine compliance (DV) as predicted by information clarity (IV), persuasiveness (IV), fear from reading the information (IV), and trust in government (IV). Specifically, decisions made by Caucasians were better explained than for other groups.[¶] To test the difference between regression models, a series of *F*-ratio tests were conducted (Test *F* statistic = 2.44, $3.09 > 2.44$; therefore, difference is significant).[‡] Findings indicated significant differences between Caucasians and African Americans (Test *F* statistic = 2.44, $3.09 > 2.44$; therefore, difference is significant). The difference between Caucasians and Hispanics was not significant (Test *F* statistic = 1.83, $1.37 < 1.83$; therefore, difference is not significant) (Table 4).

When viewing Table 4, focus on *p* values and *standardized b* values is important for understanding the relationship between variables for decision making across groups. Importantly, persuasiveness was the only consistent motivating factor across groups, with the second most common factor, fear, having inconsistent directional implications on different demographics.

[¶]Three linear regressions were conducted that were significant ([African American] ($F(48,4) = 12.195, p = 0.000$) adj $R^2 = .463$, ([Hispanic] ($F(27,4) = 7.750, p = 0.000$) adj $R^2 = .466$ ([Caucasian] ($F(43,4) = 11.963, p = 0.000$) adj $R^2 = .483$).

[‡] $F_{df_1, df_2} = ((RSS_1 - RSS_2) / (DF_1 - DF_2)) / (RSS_2 / DF_2)$. Note: residuals were normally distributed.

DISCUSSION

Understanding Medical Countermeasure Messages

Our first research question focused on public understanding of medical countermeasure messages. The majority of participants reported that they understood that the government was asking them to immediately take the recommended vaccine or medication. Results further indicated that those who would not take the drug were significantly less confident in their ability to identify the causes of the ailment than those who would take the medication. On aggregate, the causes of the illness in the radiation-based scenario were reported as being significantly easier to understand than the biological threat. There were no significant differences in self-reported understanding of the scenarios, despite Caucasians' self-reported higher levels of certainty and prevention, more positive emotional responses for a sense of being pleased, relieved, and confident about the information received (see Table 1).

Understanding Regulatory Terms

While respondents reported they understood the FDA messages, they demonstrated poor understanding of the terminology in the messages. This suggests that future research will need to attend more carefully to examining the contribution of message components to any desired behavioral or attitudinal outcomes rather than a more standard approach of examining the effect of the overall message. It also suggests that the FDA should anticipate that any messages aimed at the general population—and specifically at lower income, immigrant, or minority groups—will require careful attention to literacy levels and English as a second language. Finally, these

findings suggest that relying on self-reported measures of understanding of medical countermeasure messages may be misleading, and research needs to include tests of understanding.

Compliance Likelihood

Our second question focused on the extent to which respondents understood and were willing to comply with the recommended countermeasures. Participants on average reported being slightly likely to take the medication or vaccine, but compliance was distributed multi-modally, with the 2 largest clusters of individuals grouping at noncompliance and complete compliance. Prior research also found that participants were somewhat likely to accept a vaccine or drug under EUA.⁶ However, findings here about a multi-modal distribution indicate that additional persuasive communication likely is needed during an emergency beyond the initial factsheet to those who are completely noncompliant. Future research is needed to determine what factors may motivate people from noncompliance to compliance. It may be possible to encourage compliance through ensuring that messages cover topics of most interest to members of the public.¹³ This study found that those topics include more information about the countermeasures (eg, side effects, medicine testing, approval process) and the emergency itself (eg, cause of the outbreak, when did the emergency begin, is the emergency real). Some participants also wanted more information about disease transmission. Others wanted more information about how emergency information is transmitted.

We were surprised that we found no significant difference in perceived risk of the 2 hazards—an infectious disease and a radiation exposure. Typically, risk perception literature might point to a higher perceived risk for the radiation scenario.³⁹ However, these were hypothetical scenarios, which could differ from real world reactions.

Although the LIWC is less commonly used in public health research, it is a valuable tool for understanding emotional reaction to a medical countermeasure. Our results identified strong negativity toward medical countermeasures, even more than expressive writing about tragic personal events, and a substantial undertone of concern about the use of medical countermeasures. Prior research linked high public anxiety to crisis and emergency risk communication.^{15,16} This study emphasizes just how strong the public's negative emotions are when it comes to risk communication about medical countermeasures. However, it is unclear whether the negativity found in this study is about the countermeasure itself, the public health emergency, the underlying risks the countermeasure seeks to address, or the government itself. This high negativity presents significant challenges for FDA communication about medical countermeasures, suggesting that any campaign will need to be more extensive and require more exposures in order to foster positive attitudes toward the medical counter-

measure and its adoption. Although negativity is not unexpected nor necessarily problematic in crisis situations, future research will need to explore where counterproductive negativity resides and the most effective strategies for increasing compliance.

Diverse Audiences' Informed Decision Making

The final research question explored the factors that influence diverse audiences' informed decision making and whether there are racial and ethnic differences in such decision making. In an analysis on compliance as predicted by information clarity, persuasiveness, fear from reading the information, and trust in government, there were significant differences between Caucasians and African Americans. Indeed, decisions made by Caucasians were better explained than for the other groups.

Importantly, persuasiveness was the only consistent motivating factor across groups, with the second most common factor, fear, having inconsistent directional implications on different racial/ethnic groups. From this finding several conclusions can be drawn. First, if a single untailored message is used to communicate about medical countermeasures, messages likely should avoid fear appeals. Second, future research could identify what makes medical countermeasure messages persuasive to different target audiences. Here we found that the 2 least persuasive factors, and thus the worst predictors of compliance, were government trust and information clarity. Recall that trust, when treated as a dependent variable, was predicted by racial/ethnic identity. However, when trust is an independent predictor of positive behavioral outcomes, the relationship becomes even more complex. From this finding we can deduce that medical countermeasure messages cannot rely on government agencies' credibility or public trust, as extensively argued in prior research.^{13,14,16,17,24,25} These messages also are unlikely to be persuasive if they rely on a clear argument that the medical countermeasure is necessary for public health to motivate compliance. Additional research is needed to identify what discrete message characteristics are most persuasive for motivating public compliance for medical countermeasures. Here we only tested persuasiveness as a global construct and found it was the strongest predictor of compliance.

Furthermore, important racial/ethnic group differences emerged in participants' informed decision making. First, compared to other groups, Caucasians were least certain about their ability to recognize an illness and their ability to prevent an illness. They also were less pleased, relieved, and confident. Second, compared to African Americans, Caucasians had higher trust in the government in general and higher trust in the CDC in particular. It is possible that these findings are related to a socially desirable response effect. People in relatively powerless positions, like

minorities or economically repressed individuals, learn and use an adaptive strategy of agreeing with statements in order to maintain a “good face” and avoid psychological distress.⁴⁰ Socially desirable responses have been long investigated,⁴¹ with recent work noting the common nature of the effect in various powerless groups.⁴² Further research is needed to explore whether the differences found here are real differences or differences caused by a socially desirable response effect. Furthermore, future research should explore what other factors might affect how diverse audiences respond to medical countermeasure communication, including economic status and employment.

These findings once again support the limited prior research on racial and ethnic group differences in responding to medical countermeasures^{6,11} and call for additional research and consideration as to how best to tailor communication for different groups while maintaining consistency in government communications about medical countermeasures. This may also suggest that the FDA, CDC, and their partners should continue to work with other national partners whose credibility with diverse communities may help the agencies disseminate messages that can be more trusted.²⁶ Finally, the findings suggest that a single factsheet for all groups may not be effective and that agencies communicating about medical countermeasures may wish to develop tailored factsheets for different groups.

LIMITATIONS AND CONCLUSION

Like all research, this study has limitations. First, participants were recruited from select metro stops and barbershops in the Washington, DC, metropolitan area, and thus the findings are not generalizable to other areas within or outside of the United States. The high proportion of homeless people who participated in this study further limits the study’s transferability to dissimilar contexts. Second, the study examined 2 public health emergencies, and the findings are not generalizable to other public health emergencies. Third, the interviews were conducted only in English. Future research should examine how non-English-speaking members of racial/ethnic groups respond to medical countermeasures, along with other potential within-group differences such as acculturation level and immigration status. Finally, the study examined 2 hypothetical public health emergencies, and the findings may not apply to real public health emergencies.

In sum, this study adds to the extremely limited body of knowledge on how diverse members of the public respond to medical countermeasures issued during public health emergencies. Key and novel findings include: (1) participants demonstrated poor understanding of terminology commonly used by the FDA and other government agencies to communicate about medical countermeasures;

(2) participants generally were likely to take the recommended drug or vaccine, but compliance was distributed multi-modally, indicating a wide divide among likely compliant and noncompliant publics; (3) source credibility and government trust are less persuasive in motivating public compliance with medical countermeasures than has been found in previous research; (4) message persuasiveness is the strongest motivator for message compliance; (5) racial/ethnic differences emerged in certainty about abilities to recognize an illness, abilities to prevent an illness, and feeling pleased, relieved, and confident; and (6) members of the public have a lot of unanswered questions not typically covered in government factsheets about medical countermeasures.

In terms of risk communication policy, these findings point to a need for more pre-emergency education about medical countermeasures, disease transmission, how to best obtain information during a public health emergency, and the government’s role in public health emergencies. The findings also point to a need for more research testing discrete message components to design medical countermeasure messages that are even more persuasive. While much is known about effective emergency risk and crisis communication, we cannot continue to assume that this knowledge base transfers to the specific context of medical countermeasures without additional research.

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