Communicating Effectively About Emergency Use Authorization and Vaccines in the COVID-19 Pandemic

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The Emergency Use Authorization (EUA) mechanism is central to the US response to coronavirus disease 2019 (COVID-19). It allows the US Food and Drug Administration (FDA) to respond quickly to novel threats by approving a new drug, device, or diagnostic procedure or expanding off-label use of an existing drug through an accelerated approval process.[1] To obtain authorization, evidence must support that a drug or product "'may be effective' to prevent, diagnose, or treat serious or life-threatening diseases or conditions," and the known or potential benefits of the product must outweigh known or potential risks.[2(p7)] The authorization also stipulates that when feasible, a fact sheet is provided to address risks and benefits and make clear that acceptance is voluntary.[2]

Since March 2020, the FDA has issued EUA for several therapeutics to treat COVID-19: chloroquine phosphate, hydroxychloroquine sulfate, remdesivir, and a monoclonal antibody drug from Eli Lilly to help the immune system fight COVID-19.[3] The FDA later revoked its approval of chloroquine phosphate and hydroxychloroquine sulfate, stating that the drugs did not meet the legal criteria for approval.[4] The FDA also revised its fact sheet for remdesivir to reflect potential drug interactions.[5] Given the rapidity of changing knowledge of COVID-19, it is not surprising that the FDA would revoke or modify EUA approvals. However, its decisions about several EUAs have called into question the extent to which the FDA can withstand political pressure as it faces all decisions.

Daily news coverage tracks progress in the accelerated COVID-19 vaccine development process.[6] On November 13, 2020, Pfizer became the first company to seek approval of its COVID-19 vaccine through the EUA mechanism, making it the first instance of EUA approval for a vaccine.[7] Therefore, it is vital to assess how the public understands the EUA mechanism and how this may influence willingness to accept COVID-19 vaccines.

LEARNING FROM PAST RESEARCH

Given the severity of the COVID-19 pandemic, it will be essential that the public willingly take a vaccine once it is available. However, multiple polls report substantial hesitancy about a potential vaccine.[8] Previous research suggests that when it comes to EUA therapeutics and vaccines, the public may have significant hesitancy. During the influenza A (H1N1) pandemic, a national survey assessing willingness to accept existing EUA therapeutics and a hypothetical EUA vaccine found that only 8% of the respondents were willing to accept an EUA vaccine, with 28% reporting uncertainty and 64% outright refusal.[9] Hispanic adults reported the highest willingness at 16.6%, followed by White adults at 7.2% and African American adults at only 4.2%. A 2010 survey examining the acceptance of peramivir, approved as an EUA, found that use of the term "experimental" on the fact sheet decreased willingness across the board, and particularly for African Americans.[10] Given the history of research abuses and ongoing racial bias in health care, this reaction is not surprising. Both studies found that greater trust in government action was associated with willingness to accept EUA products.[9,10]

In a qualitative study on public understanding of medical countermeasures, Liu et al.[11] assessed willingness to comply with protective actions during a hypothetical novel respiratory virus scenario. Respondents had poor understanding of terminology used to describe novel drugs and EUA. Free

association with terms used in EUA fact sheets like "experimental," "accelerated approval," and "off-label" prompted respondents to have strong negative emotions.[11] The phrase "Emergency Use Authorization" triggered mixed responses, ranging from "important" and "helpful" to "risky," "suspicious," "desperate," and "over-controlling."[11] Only 15% of the participants reported likely compliance with EUA recommendations in this scenario.[11] All participants reported a significant need for more information beyond what is typically included in a fact sheet. Liu et al.[11] concluded that a single fact sheet for the public will not be effective, and tailored and targeted fact sheets are necessary for different populations. They concluded that "pre-emergency education" about medical countermeasures is needed.[11]

CRAFTING AN EFFECTIVE COMMUNICATION STRATEGY

This literature suggests that unique challenges exist when communicating about drugs or vaccines offered under an EUA. The health threats they address are extraordinary, clinical experience is limited, and the development and approval processes are frequently accelerated.[12] With these challenges and an active antivaccine movement already campaigning against any COVID-19 vaccine, we recognize the significant reluctance among the American public. Public health leaders face multiple barriers to communicating effectively to ensure vaccine uptake when available. To overcome these barriers, we offer recommendations based on our previous research and the principles of effective emergency risk communication (see the box on p. 357).

First, we need to begin communication immediately. Most people form judgments about new ideas based on mental models they have developed from past experiences. Few people have a clear mental model of the vaccine development process, making it difficult to understand what it means for the process to be accelerated. The White House's adoption of Operation Warp Speed and promises of a vaccine by fall 2020 have undermined trust in any vaccine, whether as an approved EUA or not.[13] Graphic representations of the vaccine process, such as the *New York Times* "Coronavirus Vaccine Tracker," may be helpful to demystify the complex process and reassure individuals about the multiple levels of quality control and the independence of various entities along the production chain.[14] Greater transparency about the process may potentially address underlying fears about the pharmaceutical industry's motives or concerns about the politicization of the process.

We also need to be sensitive to the language we use when communicating about new vaccines. Messages should be jargon-free, accurate, confident, and consistent. Formative research should start now while vaccines are in development to understand socioeconomic, cultural, and other issues that can inform message development and appropriate personal and media sources when communicating to different segments of the public, recognizing that Black, Latinx, and Native communities will require specific attention. EUA fact sheets present their own communication challenges, because they are required to balance legal mandates while still communicating effectively to both medical and public audiences.[9]

Transparency is key, particularly as new data become available. The release of trial protocols by Moderna and Pfizer, and now other trial sponsors, is a step in the direction of transparency but will require further translation for public audiences.[15] Any vaccine will likely have risks associated with its use, and these must be clearly communicated. Two vaccine candidates now in clinical trials are using technologies not previously approved for vaccines, and given the speed of the research process, it would not be surprising to learn more about potential side effects after any EUA.[14] It would behoove the FDA to be forthright and clear in communicating with the public and to avoid overpromising on results, balancing optimism with realistic assessments of existing research. We already have evidence that some elected officials and individuals do not recognize that change is a given in this fast-moving pandemic and may interpret any new findings about a vaccine given EUA as problematic. We must inform the public that even after a vaccine is approved as an EUA, the FDA and the Centers for Disease Control and Prevention will continue to monitor for safety and adverse events and will adjust its guidance as needed.[2] Clarifying this process and identifying how the FDA will communicate any revised guidance will be critical.

We know that public health and government officials are not the only ones who will be communicating about these new vaccines. With the antivaccine movement already fully engaged in spreading misinformation and elected officials sharing inconsistent and contradictory information, the United States has a competitive communication environment. All this communication should be monitored and judgments used to determine when misinformation should be addressed and when it should be

Recommendations for Effective Emergency Risk Communication to Ensure Vaccine Uptake
Transparency
FDA must communicate to the public about the monitoring process during vaccine trials and after any EUA.
FDA must confirm that they will release full data on adverse events and modify EUA approvals and fact sheets accordingly.
FDA needs to develop guidelines for the timing of reporting adverse events.
Pharmaceutical companies must release protocols for review by independent scientists.
Pharmaceutical companies must continue to update the public on enrollment.
Pharmaceutical companies should release findings on safety and efficacy from their Data Safety and Monitoring Boards, including data and recommendations.
Partnerships
Local, state, and federal public health agencies must engage with partners, both public agencies and other organizations, including health professional associations; national public health partners such as Association of State and Territorial Health Officials and National Association of County and City Health Officials; national organizations that represent diverse members including civil rights groups, faith communities, civic groups, and media and communication firms that specialize in reaching Black, Latinx, and Native Americans and Alaska Natives.
Public health agencies must work with these partners before release of a vaccine to understand community concerns and begin to tailor communication messages and channels.
Public health agencies must share key messages with these partners to increase FDA and CDC reach.
Agencies need to sustain this engagement to help monitor community reactions, clarify misconceptions, and amplify messages.
Training for health care providers
Public health agencies should distribute tested talking points for providers and community leaders to help them answer questions about the EUA mechanism and the new vaccine, such as: How do we know these products are safe? How does this new vaccine work? How is an EUA different from a "normal" vaccine?
Public health leaders must recognize that the initial vaccines will have been tested only on adults, which therefore will require that health care providers who treat adults, and may have less experience with vaccination, will need extra assistance in preparing for patients' questions and concerns.
Fact sheets
Public health leaders should start testing terminology before vaccine availability.
Public health leaders should examine understanding of terminology and affective responses.
The sponsor submits fact sheets in the EUA application, and then FDA should engage their communication staff and legal staff in reviewing fact sheets and, ideally, work with the sponsor to test them with audiences before using them.
FDA and the sponsor must ensure that the messages in the fact sheets are consistent with information disseminated before vaccine administration.
FDA and the sponsor must test for readability and clarity and avoid language that stimulates negative responses (i.e., experimental).
FDA and the sponsor should consider formats that may facilitate understanding, including questions and answers and inclusion of a glossary.
Local, state, and federal public health agencies must widely circulate fact sheets through multiple channels and in advance—under ideal circumstances.
Uncertainty and changing guidance
FDA, CDC, and others must continue to acknowledge uncertainty and prepare the public for change.
FDA should share with the public the difficulties faced while making decisions about an EUA vaccine, particularly with continually evolving information.
FDA should inform the public that they will share new information even after approval of an EUA vaccine.
FDA, CDC, and others must remind the public that changes in fact sheets or even approvals occur because ongoing monitoring identifies new data.
Monitoring media communication
FDA, CDC, and other public health leaders should monitor communication in traditional and social media and make sound judgments about when to ignore and when to respond to misinformation.
FDA and public health agencies should monitor social media to identify emerging issues with FDA communication about an EUA vaccine.
FDA needs to work with agency and external partners to use social media to amplify key messages.
Effective use of role models for taking the EUA vaccine
Public health agencies can use photographs and quotes from role models, such as community leaders, celebrities, elected officials, and health care providers, as they take the EUA vaccine.
Public health agencies must be cognizant of tailoring these messages to specific audiences.
Clear communication
Public health communicators should use the CDC Clear Communication Index to assist in ensuring readability of all fact sheets and printed materials and understandability of online materials (https://www.cdc.gov/ccindex/index.html).

Note. CDC = US Centers for Disease Control and Prevention; EUA = Emergency Use Authorization; FDA = US Food and Drug Administration.

ignored, weighing the risks of inadvertently amplifying a fringe conspiracy theory against the need to publicly debunk a widespread and dangerous falsehood.

This task of communicating effectively must be a shared one. In a crisis when the public has an intense need for information, one organization cannot do it alone. Local, state, and federal public health agencies must form partnerships with community organizations, health care providers, faith communities, the media, the private sector, unions, and civic associations. These organizations are closer to their audiences; know how to effectively tailor information; and, most importantly, have trusted leaders who can be effective spokespersons for any upcoming vaccine receiving EUA. Ideally, this communication is a bidirectional process, with feedback that enables public health leaders to adapt and tailor their communication strategies.

LOOKING AHEAD

Today, we face a unique constellation of factors that will affect the public's acceptance of any vaccine given EUA. With the steadily rising death toll, the public's perception of risk may remain high, but with clear communication about the vaccine, acceptance may be higher than history and today's polls would tell us to expect. However, accelerated timelines and active antivaccine misinformation, coupled with distrust of expert opinion and declining trust in governmental agencies, present an unprecedented challenge. Public health agencies and their partners must start communicating effectively now. AJPH

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The authors have no conflicts of interest to disclose.

REFERENCES

1. US Food and Drug Administration. Emergency use authorization. June 15, 2020. Available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. Accessed June 16, 2020.
2. US Food and Drug Administration. *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*. Silver Spring, MD: Office of Counterterrorism and Emerging Threats; January 2017. Available at: https://www.fda.gov/media/97321/download. Accessed June 12, 2020.
3. Ison MG, Wolfe C, Boucher HW. Emergency use authorization of remdesivir: the need for a transparent distribution process. *JAMA*. 2020;323(23):2365–2366. https://doi.org/10.1001/jama.2020.8863
4. US Food and Drug Administration. Coronavirus (COVID-19) update: FDA revokes emergency use authorization for chloroquine and hydroxychloroquine [press release]. Silver Spring, MD: US Food and Drug Administration; June 15, 2020. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and. Accessed June 16, 2020.
5. US Food and Drug Administration. Coronavirus (COVID-19) update: FDA warns of newly discovered potential drug interaction that may reduce effectiveness of a COVID-19 treatment authorized for emergency use [press release]. Silver Spring, MD: US Food and Drug Administration; June 15, 2020. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-newly-discovered-potential-drug-interaction-may-reduce. Accessed June 16, 2020.
6. US Department of Health and Human Services. Trump Administration announces framework and leadership for 'Operation Warp Speed' [press release]. Washington, DC: US Department of Health and Human Services; May 15, 2020. Available at: https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html. Accessed June 15, 2020.
7. Schoch-Spana M, Brunson EK, Long R, Ravi S, Trotochaud M, Working Group on Readying Populations for COVID-19 Vaccine. *Enhancing Public Trust and Health With COVID-19 Vaccination: Planning Recommendations Informed by Design Thinking and the Social, Behavioral, and Communication Sciences*. Baltimore, MD: Johns Hopkins Center for Health Security; 2020.
8. NORC. Expectations for a COVID-19 vaccine. Chicago, IL: Associated Press–NORC Center for Public Affairs Research; 2020. Available at: https://apnorc.org/projects/expectations-for-a-covid-19-vaccine. Accessed June 3, 2020.
9. Quinn SC, Kumar S, Freimuth VS, Kidwell K, Musa D. Public willingness to take a vaccine or drug under Emergency Use Authorization during the 2009 H1N1 pandemic. *Biosecur Bioterror*. 2009;7(3):275–290. https://doi.org/10.1089/bsp.2009.0041
10. Quinn SC, Hilyard K, Castaneda-Angarita N, Freimuth VS. Public acceptance of peramivir during the 2009 H1N1 influenza pandemic: implications for other drugs or vaccines under emergency use authorizations. *Disaster Med Public Health Prep*. 2015;9(2):166–174. https://doi.org/10.1017/dmp.2014.156
11. Liu BF, Quinn SC, Egnoto M, Freimuth V, Boonchaisri N. Public understanding of medical countermeasures. *Health Secur*. 2017;15(2):194–206. https://doi.org/10.1089/hs.2016.0074
12. Schoch-Spana M, Gronvall GK, Brunson E, et al. *How to Steward Medical Countermeasures and Public Trust in an Emergency—A Communication Casebook for FDA and Its Public Health Partners*. Baltimore, MD: UPMC Center for Health Security; 2016. Available at: http://www.centerforhealthsecurity.org/ourwork/events/2016%20FDA%20MCM/FDA_Casebook.pdf. Accessed April 15, 2018.
13. Trogen B, Oshinsky D, Caplan A. Adverse consequences of rushing a SARS-CoV-2 vaccine: implications for public trust. *JAMA*. 2020;323(24):2460–2461. https://doi.org/10.1001/jama.2020.8917
14. Corum J, Wee S-L, Zimmer C. Coronavirus vaccine tracker. *New York Times*. November 10, 2020. Available at: https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html. Accessed November 10, 2020.
15. Grady D, Thomas K. Moderna and Pfizer reveal secret blueprints for coronavirus vaccine trials. *New York Times*. September 17, 2020. Available at: https://www.nytimes.com/2020/09/17/health/covid-moderna-vaccine.html. Accessed September 17, 2020.