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UNDERSTANDING AND COMMUNICATING ABOUT COVID-19 VACCINE EFFICACY, EFFECTIVENESS, AND EQUITY

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EXECUTIVE SUMMARY

Effective communication is needed to ensure shared understanding of how well COVID-19 vaccines work and whether they are being equitably distributed. Without clear, consistent, readily accessible communications, people may lose faith in the vaccines and in those providing them. State, tribal, local, and territorial officials can play a key role in conveying that information to community members or intermediaries in a timely, clear, authoritative way and in conveying community concerns to policy makers.

This rapid expert consultation summarizes social, behavioral, and decision science research relevant to communicating how well COVID-19 vaccines work are and how equitably they are being distributed. It offers practical strategies for both the process and the content of such communication, recognizing that people respond to both *how* they learn about something and *what* they learn about it. **Box 1** explains the concepts of vaccine efficacy and effectiveness. These concepts have different, but related meanings so that using them interchangeably can cause confusion. **Box 2** summarizes the science of communicating about how well COVID-19 vaccines work and its implications for practice.

Given current scientific evidence, many public health experts have concluded that the COVID-19 vaccines authorized for emergency use in the United States have similar enough health effects that the best vaccine for any individual is the one that is available to that individual. These experts see the benefits of early immunization for both individuals and their communities as outweighing any differences among the vaccines. That conclusion has, for example, led distribution programs to direct single-dose vaccines to difficult-to-reach populations (e.g., those without fixed addresses, reliable Internet, transportation, or health care). Whether such programs are welcomed or rejected will depend on a number of factors, including how well they are understood. This rapid expert consultation identifies strategies relevant to communication processes and content designed to secure fair, informed judgments.

BOX 1
Defining Vaccine Efficacy and Effectiveness

- *Efficacy* refers to the percent reduction in the probability of a designated clinical endpoint, such as infection regardless of symptoms, symptomatic disease, moderate or severe symptoms, hospitalization, or death.
- A vaccine has, for example, 95 percent efficacy for reducing symptomatic COVID-19 if a person receiving it has a 95 percent lower probability of observable symptoms relative to an otherwise identical person not receiving it. Thus if in a population in which 100 in 10,000 unvaccinated people developed disease symptoms during a given period, only 5 in 10,000 vaccinated people, on average, would develop disease symptoms in the same period. Therefore, there is a 95 percent reduction in the incidence of symptomatic disease in the vaccinated population.
- Vaccine *efficacy* is measured in clinical trials, typically randomized controlled trials, whereas vaccine *effectiveness* is measured in real-world deployment, using observational studies.

Efficacy and effectiveness refer to individual outcomes. The number of people experiencing a clinical endpoint with or without the vaccine will depend on community prevalence, which will in turn depend on how many people have been vaccinated.

BOX 2
The Science of Communicating about the Efficacy and Effectiveness of COVID-19 Vaccines

Four steps for producing communications:

1. Identify the outcomes most relevant to recipients' decisions through community partnerships.
2. Summarize the evidence regarding those outcomes.
3. Identify the most relevant subset of evidence.
4. Evaluate messages before dissemination.

Five design principles for drafting communications:

1. Define terms clearly.
2. Use numbers to describe quantities.
3. Compare options clearly.
4. Present all relevant outcomes.
5. Communicate uncertainty and anticipate changes.

INTRODUCTION

In the United States, three COVID-19 vaccines currently have emergency use authorization.[1] Their uptake will depend on a variety of factors, including whether people perceive them to work well. Those perceptions will depend on both the vaccines and the institutions involved in their production and distribution. Those institutions may include ones with a legacy of distrust, exacerbated by racial, economic, and health inequities which are magnified by the pandemic (Stanley-Becker, 2021).[2]

Effective communication is needed both to maintain trust among those eager for a COVID-19 vaccine and to build trustworthiness among those wanting to "wait and see" before receiving it.[3] Building warranted confidence means ensuring that health officials transparently share what they know and do not know about how well vaccines work and whether they are being distributed equitably distribution of vaccines, in addition to managing distribution programs so that people who wish to be vaccinated can do so with minimal friction and hassle.

This rapid expert consultation offers strategies from social, behavioral, and decision science research regarding such communication.[4] It first explains how well the COVID-19 vaccines work—the evidence that needs to be communicated, potential barriers to understanding, and ways to overcome them—focusing on the vital role of state, tribal, local, and territorial (STLT) health officials and their community partners. The discussion then turns to the question of how best to communicate about the equity of vaccine distribution. Effective communication is examined in light of evidence and experience relevant to communicating information in terms that address the decisions faced by members of a diverse public with respect to both vaccines (e.g., "Should I take the currently available vaccine or wait for a 'better' one?" "Do the differences really matter?") and vaccine distribution programs (e.g., "Is my community being treated fairly?"). A previous rapid expert consultation, *Strategies for Building Confidence in COVID-19 Vaccines,* which focuses more broadly on promoting vaccine acceptance, provides additional context for communicating about COVID-19 vaccines generally. **Box 3**, drawn from that rapid expert consultation, presents key strategies for building confidence in the COVID-19 vaccines through public engagement with targeted communications (National Academies of Sciences, Engineering, and Medicine [NASEM], 2021).

Research demonstrates that effective communication requires easily understood messages, focused on recipients' concerns, delivered by trusted sources, and supported by

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[1]As of this writing, only three vaccines have been authorized for use in the United States. Other companies are expected to apply for authorization in the coming months.

[2]For an example from the seemingly discriminatory delivery of antibiotics to postal workers after anthrax was found in letters, see Schoch-Spana and colleagues (2018) and Gursky, Inglesby, and O'Toole (2003).

[3]In a March 2021 Kaiser Family Foundation survey, 17 percent of respondents said they wanted to "wait and see" before getting a COVID-19 vaccine, highlighting the need for continued efforts to build this confidence and to collect and communicate information needed to inform these decisions (Hamel, Lopes, Kearney, and Brodie, 2021).

[4]The full statement of task for this rapid expert consultation is as follows: "The National Academies of Sciences, Engineering, and Medicine will produce a rapid expert consultation that discusses COVID-19 vaccines, specifically (1) addressing vaccine efficacy for different vaccines and how to communicate this concept effectively, and (2) communicating about equitable distribution of COVID-19 vaccines and vaccine choice. Drawing on peer-reviewed literature from health and social and behavioral sciences, as well as what is being learned from current experiences, this document will be designed to be of practical use to decision makers who communicate with the public, but will not recommend specific actions or include other recommendations. It will be reviewed in accordance with institutional guidelines."

authoritative evidence (Breakwell, 2018; Fischhoff, 2013, 2019; Schwartz and Woloshin, 2013; U.S. Food and Drug Administration [FDA], 2011). Such communications will enable recipients to make the vaccination decisions that are right for them, their families, and their communities (NASEM, 2021). Enabling people to act on those decisions will require ensuring that they have been provided with access to the vaccines and addressing their economic, mobility, and other constraints (NASEM, 2020a). The public, especially members of communities subject to historical and current health inequities, must also be able to judge how equitably the vaccines are being distributed and have access to means of expressing their views on how distribution programs are designed and executed.

BOX 3
Strategies for Building Confidence in COVID-19 Vaccines

Strategies for Engaging Communities to Combat Mistrust and Build Public Confidence in COVID-19 Vaccines

1. Form partnerships with community organizations.
2. Engage with and center the voices and perspectives of trusted messengers who have roots in the community.
3. Engage across multiple, accessible channels.
4. Begin or continue working toward racial equity.
5. Allow and encourage public ownership of COVID-19 vaccination.
6. Measure and communicate inequities in vaccine distribution.

Communication Strategies for Ensuring Demand for and Promoting Acceptance of COVID-19 Vaccines

1. Meet people where they are, and do not try to persuade everyone.
2. Avoid repeating false claims.
3. Tailor messages to specific audiences.
4. Adapt messaging as circumstances change.
5. Respond to adverse events in a transparent, timely manner.
6. Identify trusted messengers to deliver messages.
7. Emphasize support for vaccination instead of focusing on naysayers.
8. Leverage trusted vaccine endorsers.
9. Pay attention to delivery details that also convey information.

SOURCE: NASEM, 2021.

UNDERSTANDING COVID-19 VACCINE EFFICACY

Vaccine *efficacy*, as quantified in randomized clinical trials, is estimated as the average response of individuals who were vaccinated relative to those who were not. Because efficacy refers to an average response, individual responses to the vaccine will vary (Lahariya, 2016). For emergency use authorization of COVID-19 vaccines, the U.S. Food and Drug Administration

(FDA) requires greater than 50 percent efficacy for a predetermined primary clinical endpoint, as demonstrated in a randomized controlled trial.[5] That is, the endpoint must be at least 50 percent less likely for a person who receives the vaccine (in the trial group) than for a person who receives a placebo or other comparator (in the control group) (Lahariya, 2016).

For example, if the clinical endpoint is observed moderate-to-severe symptoms, a vaccine is 95 percent efficacious if a person receiving it has a 95 percent lower probability of experiencing those symptoms than a person who does not receive it (Olliaro, 2021).[6] With a trial of 10,000 people, that might mean observing those symptoms in 100 people in the placebo group but only, on average, 5 in the vaccinated group.

For COVID-19 vaccine trials, the clinical endpoint is laboratory-confirmed COVID-19 with symptoms of specified severity (Hodgson et al., 2020). Thus, "efficacy" could mean the percent reduction in the risk of:

- *Infection regardless of symptoms*—individuals who have a positive diagnostic test but do not exhibit any COVID-19 symptoms.
- *Any symptoms*—individuals with mild symptoms (dry cough, tiredness, and fever), but not those who contract the disease but have no observed symptoms.
- *Moderate symptoms*—individuals with a fever above 100.4 °F, persistent cough, and shortness of breath.
- *Severe symptoms*—individuals with respiratory failure; evidence of shock; and significant acute renal, hepatic, or neurologic dysfunction.
- *Hospitalization*—admission, typically with a COVID-19 diagnosis or positive polymerase chain reaction (PCR) test.
- *Death*—with some definition of attribution to COVID-19.

Even though hospitalization and death are critical clinical endpoints for the health care system, the FDA focused its emergency use authorization decisions on laboratory-confirmed symptomatic COVID-19. Focusing on hospitalization or death would have required vastly larger population samples to provide sufficient statistical power to detect differences between the trial and control groups (Dean and Madewell, 2021; Hodgson et al., 2020). Note also that comparability of studies depends on how similarly endpoints are measured (e.g., how symptoms are evaluated, how deaths are attributed).

Another possible clinical endpoint is a vaccine's ability to prevent transmission, which can be measured through viral shedding, viral load, and tracking of close contacts. While transmission was not a determinative clinical endpoint in the FDA's emergency use authorization

[5]FDA Development and Licensure of Vaccines to Prevent COVID-19 Guidance for industry Available: https://www.fda.gov/media/139638/download.

[6]The point estimates commonly reported with respect to vaccine efficacy do not capture the precision of those estimates, which depends on the size of the sample and the prevalence of the event. Proper interpretation requires the confidence intervals around those point estimates. As mentioned in the text, hospitalization and death were not chosen as clinical endpoints in the trials, despite their public health significance, because of the much larger samples that would have been needed to determine whether the rates were statistically significant in the vaccine and control groups.

process, it is a topic of active investigation.[7] Because of current uncertainty about how many vaccinated individuals have no disease or asymptomatic disease, public health precautions (e.g., mask wearing) continue be recommended (CDC, 2021).

Efficacy of the Pfizer, Moderna, and Johnson & Johnson Vaccines

Efficacy was measured differently for the three currently authorized vaccines, making direct comparisons potentially misleading. As seen in Appendix A, measurement differed in two respects:

- **Clinical endpoints:** The Pfizer and Moderna trials measured prevention of mild, moderate, or severe disease,[8] while the Johnson & Johnson[9] trial measured prevention of moderate or severe disease.[10]
- **When the trials were conducted:**[11] The Pfizer and Moderna trials were conducted July to November 2020, while the Johnson & Johnson trial was conducted September 2020 to January 2021. During those time periods, there were have been differences in population behaviors (e.g., mask wearing) and disease variants (e.g., B.1.351 [South African]).

As mentioned, although not clinical endpoints for the trials, hospitalizations and deaths are the priority public health burdens that vaccines aim to prevent (Dean and Madewell, 2021). Although the data are based on extremely small numbers, in their trials, the Pfizer and Johnson & Johnson vaccines were both 100 percent efficacious in preventing hospitalizations, while the Moderna vaccine was 89 percent efficacious.[12] All three vaccines were 100 percent efficacious

[7]According to Dean and Madewell (2021), "Vaccine efficacy for preventing infection is harder to measure reliably. For SARS-CoV-2, it requires either frequent PCR screening, which is logistically complex for trials with tens of thousands of participants, or measuring a non-spike protein antibody response. Recently, limited antibody data from Johnson & Johnson's trial indicate a reduction in asymptomatic infection (FDA, 2021a). More detailed data on vaccine efficacy against infection is expected for the Moderna and Pfizer-BioNTech trials." Those estimates are relevant for communications meant to inform decisions about behaviors affecting disease spread (e.g., wearing a mask after being vaccinated).

[8]Pfizer defined symptomatic COVID-19 infection as having a confirmed positive COVID-19 test and at least one of the following symptoms: fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting (FDA, 2020b). Moderna defined symptomatic COVID-19 infection as having a confirmed positive COVID-19 test and at least two of the following symptoms: fever; chills; myalgia; headache; sore throat; new olfactory or taste disorder; or at least one respiratory sign or symptom, including cough, shortness of breath, or clinical or radiographic evidence of pneumonia (FDA, 2020a).

[9]Officially submitted to the FDA under the name Janssen Vaccine.

[10]Johnson & Johnson defined moderate illness as a confirmed positive COVID-19 test plus one or more of the following: evidence of pneumonia, deep vein thrombosis, shortness of breath or abnormal blood oxygen saturation above 93 percent, abnormal respiratory rate (≥20), or two or more systemic symptoms suggestive of COVID-19. Severe illness was defined as a confirmed positive COVID-19 test plus one or more of the following: signs consistent with severe systemic illness, admission to an intensive care unit, respiratory failure, shock, organ failure, or death (FDA, 2021a),

[11]The trials referred to here are the Phase 3 clinical trials.

[12]For the Johnson & Johnson vaccine, five people in the placebo group were hospitalized and none in the vaccinated group within 28 days; for the Pfizer vaccine, two people in the placebo group were hospitalized and none in the vaccinated group; and for the Moderna vaccine, nine people in the placebo group were hospitalized and one in the vaccinated group (FDA, 2020a; 2020b; 2021a).

in preventing deaths.[13] Thus, among vaccinated individuals, few experienced symptoms, with rare hospitalizations and no deaths (Piper, 2021).

The Pfizer and Johnson & Johnson vaccines had similar efficacy across the demographic factors of age, race, and ethnicity. The Moderna vaccine had slightly lower efficacy for preventing symptomatic COVID-19 in individuals older than 65, with no difference related to race or ethnicity. Statistical power for detecting differences in these subgroups is necessarily smaller than in the overall trial. Table 1 (Appendix A) summarizes the evidence to date as reported in the FDA's emergency use authorizations for the three vaccines (FDA, 2020a, 2020b, 2021a).

Efficacy versus Effectiveness

As noted above, vaccine *efficacy* is measured in clinical trials, typically randomized controlled trials (Lahariya, 2016). Effectiveness, on the other hand, refers to the average response to the vaccine when it is administered under real-world conditions using observational studies, and is typically lower than efficacy observed in controlled conditions. When a vaccine is deployed to the general population, factors such as medications people may take, their general health status, the conditions under which the vaccines were stored and administered, and many others can decrease the vaccine's effect and increase the variability in responses among those who are vaccinated. This is expected with every vaccine, and it is therefore important to monitor additional data that arise as vaccination programs continue.

Collecting, analyzing, and communicating these experiences is essential for having authoritative knowledge of effectiveness including potential rare or delayed side effects (NASEM, 2020b). For example, real-world data from Israel matching 596,618 people who received the Pfizer COVID-19 vaccine with unvaccinated people, showed that receiving two doses reduced symptomatic cases by 94 percent, severe cases by 92 percent, and hospitalizations by 87 percent, similar to the efficacy reported in clinical trials (Dagan et al., 2021). In the United States, a recent study released by the Centers for Disease Control and Prevention (CDC) followed a cohort of essential and front-line workers who had received the Pfizer and Moderna COVID-19 vaccines for 13 weeks. In this study, the vaccines were found to be 90 percent effective against COVID-19 in real-world conditions, consistent with the efficacy reported in clinical trials (Thompson et al., 2021). The effectiveness of COVID-19 vaccines also informs assessments of the overall community immunity needed to protect the population.

COMMUNICATING ABOUT COVID-19 VACCINE EFFICACY AND EFFECTIVENESS

The effectiveness of communications depends on both their process and their content: people respond to both *how* they learn about something and *what* they learn about it. The communication process includes timing (how soon people are told), channel (e.g., mail, social media, broadcast media), source (e.g., experts, health professionals, officials, family members, celebrities, trusted advisers), tone (e.g., sympathetic, authoritative, condescending), and

[13]For the Johnson & Johnson vaccine, there were no deaths in the vaccinated group and five deaths in the placebo group; for the Pfizer vaccine, there were no deaths in either group; and for the Moderna vaccine, there were no deaths in the vaccinated group and one death in the placebo group (FDA, 2020a; 2020b; 2021a).

responsibility (e.g., liability, accountability, incentives) (National Research Council [NRC], 2008; Taylor and Lurie, 2004). The communication content includes its relevance, accuracy, authority, uncertainty, usability, and comprehensibility, as well as cultural competence and linguistic appropriateness (Breakwell, 2018; FDA, 2011; NASEM, 2017b).[14]

Risk communication is the common term for communications intended to inform choices that involve risks, as well as accompanying costs and benefits. It is distinct from *health promotion*, involving communications intended to secure desired behaviors. The two activities are mutually supportive. People may accept recommendations more readily (health promotion) if they understand the science supporting them and have been trusted with information (risk communication). Conversely, people may understand the science more readily (risk communication) if they see how it is translated into recommendations (health promotion) (NASEM, 2017a, 2020). However, presenting the science on COVID-19 vaccines does not guarantee that people will accept recommendations or modify their behavior accordingly. People can see the same evidence and reach different conclusions if they have different priorities.

The next two sections summarize, in turn, strategies related to the process and content of communication. They emphasize the roles of public engagement, building community trust, and formative message testing, and of supporting the relationships that emerge from those efforts by avoiding misinterpretation.

The Communication Process

The recent report *Framework for Equitable Allocation of COVID-19 Vaccine* (NASEM, 2020b) describes the multiple sources and channels available and needed for communicating about how well the vaccine provides protection and is distributed. The report recommends two-way communication, proactively engaging community members, representatives, and professional organizations to enhance their trust and address their needs; imparting empathy; and responding to concerns and questions. The report also recommends testing all messages to ensure that they are understood as intended, as well as monitoring changes in community trust and needs as the pandemic, the vaccine program, and the social environment evolve.[15]

The previous rapid expert consultation on *Strategies for Building Confidence in COVID-19 Vaccines* also provides strategies for public engagement that can also inform about how well the vaccine works (NASEM, 2021). It notes that the communication process requires

[14]National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care. Available: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

[15]The full recommendation in that report is as follows: "Recommendation 4: Create and appropriately fund a COVID-19 vaccine risk communication and community engagement program (NASEM, 2020). The U.S. Department of Health and Human Services should create and appropriately fund a COVID-19 vaccination risk communication and community engagement program to support state, tribal, local, and territorial (STLT) authorities as an integral part of an effective and equitable national COVID-19 vaccination program. The program should ensure public understanding of the foundational principles, procedures, expected outcomes, and performance of vaccination efforts, including changes in response to research, experience, and public input; be informed by the concerns and beliefs, as revealed by surveys, news media, public discourse, and social media channels, with special attention to information gaps and misinformation; support STLT authorities in their engagement and partnership with community-based organizations, local stakeholders, and others to provide two-way communication with their constituencies and most effectively reach diverse populations; be grounded on scientific foundations, incorporating the expertise of individuals with the cultural competency to hear and speak to diverse communities that have a stake in successful vaccination efforts; rely on transparent, trustworthy assessments of vaccine safety and efficacy, as reviewed by the federal government and independent external scientists; begin immediately; and sustain proactive two-way communication" (NASEM, 2020b, p. 184).

authentic engagement and messages tailored to recipients' concerns and perspectives. Individuals respond to different motivating factors for getting vaccinated—some may choose to get vaccinated to mitigate personal risks and others may desire contributing to the protection of their friends, family, or community (Motta, et al., 2021). Earning community trust and building relationships "encompasses organizing for policy change, providing accessible COVID-19 testing and treatment, listening to the needs of communities, addressing the structural factors that create greater exposure to and poorer treatment for COVID-19, and ensuring the equitable allocation of vaccines" (NASEM, 2021, p. 7). Moreover, responding to adverse events in a transparent, timely manner is also critical to building trust. It is important to "help people understand what is known, what is unknown, and what should be done. In addition, post vaccination surveillance is essential to identify rare adverse outcomes that may be vaccine related. Taking this approach will help mitigate concerns about safety, side effects, and adverse events moving forward (Salmon, 2020)." (NASEM, 2021, p. 12).

Producing Communication Content about COVID-19 Vaccine Efficacy and Effectiveness

This section outlines four steps for producing communication content about COVID-19 vaccine efficacy that is responsive to recipients' needs. The following section offers design principles for conveying that content (Chou et al., 2020; Fischhoff, 2013; Fischhoff and Davis, 2014; NASEM, 2017b; Schwartz and Woloshin, 2013).

1. *Identify outcomes most relevant to recipients' decisions through community partnerships*. For personal decisions regarding COVID-19 vaccines, those outcomes might include efficacy, effectiveness, safety, discomfort, convenience, social acceptance, and effects on the economy, education, family, and friends, and social and cultural life. Community partnerships can enlist local informants in identifying target audiences' concerns (NASEM, 2021).

2. *Summarize the evidence regarding those outcomes*. Addressing concerns about vaccine outcomes requires having the relevant evidence. The above-referenced National Academies report *Framework for Equitable Allocation of COVID-19 Vaccine* (NASEM, 2020b) emphasizes the need to collect, analyze, and share real-world evidence on vaccine effectiveness, safety, and distribution. It also emphasizes the importance of knowing the quality of that evidence, such as the size of clinical trial samples, the quality of measurements, and the relevance of changes in the world (e.g., new variants) or in the vaccines (e.g., quality control problems). Information of interest to communication recipients may also include the institutions involved in the vaccine program, particularly for people who interpret their actions in the context of current and historical inequities.

3. *Identify the most relevant subset of evidence*. People have limited attention spans for processing new information. Any communication will need to use that capacity wisely by focusing on the evidence most material to recipients' decisions. That evidence will vary; for example, people in different groups may want to know, "Has this been tested on people like me?" Explaining the evidence can help people create mental models of the issues, making it easier to understand and trust changes in the evidence (Bruine de Bruin and Bostrom, 2013; Morgan et al., 2002). It is important to note that communications can convey more information if they use consistent terms and formats. People also can absorb more when messages use familiar frames of reference and culturally appropriate terms (Substance Abuse and Mental Health Services Administration [SAMHSA], 2019). For example, drug facts boxes, patterned after nutrition facts boxes, have proven to be an effective way of communicating clinical trial results

(Schwartz and Woloshin, 2013).

4. *Evaluate messages before dissemination*. A vast body of research documents the tendency for people to overestimate how well they understand one another. That gap is larger when communicators draw inferences about people whom they see as less powerful or having less social status (Talaifar et al., 2021). As a result, experts' communications may not be interpreted as intended. Formative evaluation—evaluation conducted prior to dissemination—addresses this risk with *think-aloud interviews*, in which individuals from the target audience read a draft and state how they interpret each line, including what is unclear. These interviews cost little in time or resources. They can also help build relationships with target communities by fostering engagement in vaccine promotion if community partners help with recruiting draft readers and interpreting their messages.

Designing Communication Content about COVID-19 Vaccine Efficacy and Effectiveness

Extensive research has documented how best to communicate the information on which to base risk-based decision making. It has found that people can usually understand what they need to know about how well medical treatments work if provided that information in a clear, timely, trustworthy way that builds on their current knowledge (Schwartz and Woloshin, 2013; Trevena et al., 2013). People differ in their numeracy, science and health literacy, and decision-making competence. Some of those differences are large enough to suggest tailoring messages to specific audiences (with attention to the primary language of those audiences), and where needed relying on social networks to reach people who struggle with standard communication (Peters, 2020). The following five design principles, drawn from that research, are particularly relevant to communicating about how well the COVID-19 vaccine works.

1. *Define terms clearly*. Clinical trials for the three currently authorized vaccines defined their clinical endpoints for efficacy differently. Unless the vaccines are described in the same terms, the public may be legitimately confused. Decision makers can reduce that confusion by consistently focusing messages on the same clinical endpoints, such as severe illness, hospitalization, and death.[16]

2. *Use numbers to describe quantities.* Many studies have found that verbal quantifiers (e.g., "rare" side effect, "likely" success, "probable" cause) communicate poorly (Morgan, 2014). The same word can mean different things to different people and to the same person in different settings. Although experts often prefer to use words, people typically prefer to hear numbers (Mandel and Irwin, 2021). Communications can satisfy that preference.[17]

3. *Compare options clearly*. To reduce their cognitive load, people sometimes focus on one option, leading them to favor it over others. Well-designed tables can facilitate comparing options in terms of their respective advantages and disadvantages. For example, they can encourage looking at the various effects of both choosing and declining vaccination, and not just focusing on one effect (e.g., reported vaccine side effects). Providing confidence intervals around point estimates of clinical endpoints can help people decide whether differences are meaningful (Schwartz and Woloshin, 2013).

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[16]National public health officials can aid that work by commissioning statistical analyses that translate into common terms the results from the different trials and ensuing real-world experience, including the associated uncertainties.

[17]In a classic study, Sherman Kent (1964), a founder of U.S. intelligence analysis, found that analysts had very different probabilities in mind when they signed a consensual National Intelligence Estimate forecasting a "serious possibility of Stalin intervening militarily in Yugoslavia."

4. *Present all relevant outcomes*. Individuals may weigh the importance of clinical outcomes differently. Unless one option is better than all others in all respects, communications need to present evidence regarding all outcomes (e.g., severe symptoms vs. hospitalization). Including community effects of vaccines (e.g., whether they decrease spread to other people, permit people to go to work, or send their children to school), not just personal ones, will acknowledge those effects, which may be important to some people (Motta et al., 2021).

5. *Communicate uncertainty and anticipate changes*. Public trust can be undermined when officials suddenly change course. Those changes may reflect new evidence that was always within the range of possibility. However, unless officials acknowledge that possibility and existing uncertainty, they implicitly overpromise. As a result, they may appear to have been surprised by the new evidence or to have been hiding something—reducing trust in their competence or honesty. Decision makers can reduce threats to their credibility by communicating how much they know, what they do not know, and when they expect to know more (SAMHSA, 2019).

For example public health and other officials may do well to acknowledge that current efficacy results from clinical trials of the 3 vaccines currently available under emergency authorization show that some cases of mild disease are to be expected, even among those fully vaccinated. Moreover, the absolute number of those fully vaccinated experiencing mild disease is expected to increase as more people become vaccinated. Expecting such cases will help keep public officials from inadvertently eroding faith in the vaccine as such cases arise (Slovic, 1987; Tversky and Kahneman, 1974). It may also encourage people to take precautions, to avoid being among the unfortunate few.

COMMUNICATING ABOUT EFFICACY AND EFFECTIVENESS IN THE CONTEXT OF EQUITY IN COVID-19 VACCINE DISTRIBUTION

The *Framework for Equitable Allocation of COVID-19 Vaccine* (NASEM, 2020, Box 1) defines equity as "Being fair and impartial. According to the World Health Organization, health equity 'implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential."

Transparent, clear communication about vaccine distribution is needed for observers to judge how well equity has been achieved and to guide needed changes. The lack of such communication, to date, has eroded trustworthiness of the process in some Black, Indigenous, and People of Color (BIPOC) communities—who already face health inequities including greater exposure to infection and lack of access to quality health care. Such lack of trustworthiness may encourage individuals to "shop" for a seemingly better vaccine and decision makers to reject vaccines believing that their community has been assigned inferior ones.[18] These reports are especially troubling since this pandemic has disproportionately affected Black, American Indian/Alaska Native, Pacific Islander, and Hispanic communities, who have suffered higher rates of disease, hospitalization, and death compared with White communities (Centers for Disease Control and Prevention [CDC], 2021). These disparities and lack of trustworthiness can undermine efforts to protect these vulnerable populations.

The three currently authorized vaccines are sufficiently similar in preventing severe symptoms, hospitalization, and death that many people may be indifferent to which of the

[18]See: https://www.cnn.com/2021/03/04/health/detroit-mayor-johnson-and-johnson-vaccine/index.html.

vaccines they receive once they understand their minor differences.

One issue that can be misunderstood, however, unless proactively explained, considerations that may make one vaccine more appropriate for distribution to particular areas or groups. For example, one-dose vaccines may address allocation challenges in populations that are most difficult to reach, face barriers to access, or have difficulty completing a two-dose vaccine regimen.[19] Utah, for example, is using the Johnson & Johnson single-dose vaccine for residents without reliable contact with the health care system, such as people experiencing homelessness, those without insurance, and those employed in migrant agricultural labor (Utah Department of Health, 2021). Evidence on the response to this program and its effectiveness could inform other vaccination programs. Similarly, in one survey, 26 percent of those who responded "wait and see" with respect to getting vaccinated said they were more likely to do so if only one dose were required (Hamel et al., 2021).

The design of communications regarding vaccine equity follows the same principles as the design of communications regarding vaccine efficacy effectiveness. Here, too, process and content matter.

In terms of process, proactively explaining a program's rationale acknowledges the public's right to know what official distribution priorities are, what efforts are being made to achieve them, how successful they are, and how problems are being addressed. That process necessarily entails engagement with the community.

Engaging with communities is also necessary to achieve equitable access. As described in the National Academies report referenced earlier (NASEM, 2020b, Chapters 4–6), health officials and decision makers need to implement distribution strategies developed with input and feedback from community leaders and members. Such engagement and transparency can help secure warranted confidence that public health considerations, not political pull, social status, and economic power, drive access (NASEM, 2020b; NRC, 2008).

In terms of content, the quality of communications about vaccine distribution will depend on the quality of the information collected, analyzed, and shared. Without clearly described evidence from population-based trials and observations, members of the public (and even professionals) may rely on anecdotal reports, which can be unwittingly or deliberately misleading. As with efficacy and effectiveness, these communications need to focus on audience concerns, use well-defined terms, present evidence clearly, acknowledge social and historical context, and engage trusted intermediaries. These communications, too, require formative testing to avoid unnecessary confusion and distrust regarding these sensitive issues.

Transparent decision making, accountability, and effective messages together can garner public trust.

CONCLUSION

Many health experts interpret current scientific evidence as indicating that the best vaccine is the one a person can get. In this view, the benefits of early immunization outweigh any differences among the authorized vaccines, for both individuals and their communities. Some members of the public will trust these experts' conclusions. Some will respect the

[19]For example, one-dose vaccines may be more appropriate for populations without reliable access to transportation or child care, or those that have difficulty making and keeping a second appointment. One-dose vaccines can also reduce the amount of time people have to take off work, and may be particularly less burdensome for hourly wage-earners.

conclusions, but will still want to see the supporting evidence. And some will want to see the evidence and decide for themselves. That evidence will include the efficacy and safety of the vaccines, as observed in clinical trials, and effectiveness based on real-world experience. It will also include the rationale and performance of the vaccine distribution program, especially with respect to communities subject to historical and current health inequities.

Communicating clearly about vaccine efficacy, effectiveness, and distribution is a critical responsibility for health officials. Social, behavioral, and decision science research can provide practical guidance on fulfilling that responsibility. It requires a disciplined approach, characterizing vaccines in common terms; clearly comparing their risks and benefits; creating and disseminating records of vaccine distribution; eliciting community feedback; and developing effective messages, with the formative testing needed to ensure that they are understood as intended. Applying these research-based principles can help COVID-19 vaccine and distribution programs achieve their fullest contribution to public health and well-being.

APPENDIX A

As mentioned above, although not clinical endpoints for the trials, hospitalizations and deaths are the priority public health burdens that vaccines aim to prevent (Dean and Madewell, 2021). Though the data are based on extremely small numbers, in their trials, the Pfizer and Johnson & Johnson vaccines were both 100 percent efficacious in preventing hospitalizations, while the Moderna vaccine was 89 percent efficacious.[20] All three vaccines were 100 percent efficacious in preventing deaths.[21] For preventing symptomatic COVID-19, the Pfizer and Moderna vaccines showed 95 percent and 94.1 percent efficacy, respectively. The Johnson and Johnson vaccine trial reported 66.3 percent efficacy for preventing moderate to severe COVID-19, 76.7 percent efficacy for preventing severe/critical COVID-19 (beginning 14 days after dose), and 85.4 percent efficacy for preventing severe/critical COVID-19 (beginning 28 days after dose). Thus, among vaccinated individuals, few experienced symptoms of COVID-19, with rare hospitalizations and no deaths (Piper, 2021). Mild disease is, however, common enough that some cases are to be expected.

The Pfizer and Johnson and Johnson vaccines had similar efficacy across the demographic factors of age, race, and ethnicity. The Moderna vaccine had slightly lower efficacy for preventing symptomatic COVID-19 in individuals older than 65 with no difference related to race or ethnicity. Statistical power for detecting differences in these subgroups is necessarily smaller than in the overall trial. Tables 1 and 2 summarize the evidence to date, as reported in the FDA's emergency use approval authorizations for the three vaccines (FDA, 2020a; 2020b; 2021a). Table 1 summarizes results for the three approved vaccines, showing how well each vaccine worked in clinical trials. Table 2 describes the characteristics of the three COVID-19 vaccine currently available under emergency authorization. Together, they show the value of the vaccine and the need for continued precautions.

TABLE 1 Summary of Clinical Trial Results as of March 26, 2021

Pfizer BioNTech Vaccine	**Moderna Vaccine**	**Johnson & Johnson (Janssen) Vaccine**
Clinical Endpoints for Defining Vaccine Efficacy		
Preventing Death[a]		
• 100%	• 100%	• 100%
Preventing Hospitalizations[b]		
• 100%	• 89%	• 100%
Preventing Symptomatic COVID-19[c]		
• *Preventing symptomatic COVID-19:* 95% (beginning 7	• *Preventing symptomatic COVID-19:* 94.1%	• *Preventing moderate to severe COVID-19:* 66.3%

[20]For the Johnson & Johnson vaccine, five people in the placebo group were hospitalized and none in the vaccinated group within 28 days; for the Pfizer vaccine, two people in the placebo group were hospitalized and none in the vaccinated group; and for the Moderna vaccine, nine people in the placebo group were hospitalized and one in the vaccinated group (FDA, 2020a; 2020b; 2021a).

[21]For the Johnson & Johnson vaccine, there were no deaths in the vaccinated group and five deaths in the placebo group; for the Pfizer vaccine, there were no deaths in either groups; and for the Moderna vaccine, there were no deaths in the vaccinated group and one death in the placebo group (FDA, 2020a; 2020b; 2021a).

days after second dose)	(beginning 14 days after second dose)	(beginning 14 days after dose) • *Preventing severe/critical COVID-19 :* 76.7% (beginning 14 days after dose) • *Preventing severe/critical COVID-19:* 85.4% (beginning 28 days after dose)

NOTES: [a] The trials did not sample a large enough population to measure mortality, although it was included as a secondary endpoint. Across all the three vaccine trials, no deaths occurred in the vaccinated groups (FDA, 2020a; 2020b; 2021a).
[b] Confidence intervals (CIs) for preventing hospitalization: Pfizer—95% CI [–9.9, 100]; Moderna—95% CI [13, 99]; Johnson and Johnson—95% CI [74.3, 100].
[c] Confidence intervals (CIs) for efficacy: Pfizer—95% CI [90.3, 97.6]; Moderna—95% CI [89.3, 96.8]; Johnson & Johnson preventing moderate to severe COVID-19 beginning 14 days after dose—95% CI [59.9, 71.8]; preventing severe/critical COVID-19 beginning 14 days after dose—95 % CI [54.56, 89.09]; preventing severe/critical COVID-19 beginning 28 days after dose—95% CI [54.15, 96.90].
SOURCE: FDA, 2020a; 2020b; 2021a; 2021b.[22]

TABLE 2 Characteristics of Authorized COVID-19 Vaccines in the United States as of March 26, 2021

Pfizer BioNTech Vaccine	**Moderna Vaccine**	**Johnson & Johnson (Janssen) Vaccine**
Target Population		
• Authorized for 16+	• Authorized for 18+	• Authorized for 18+
Vaccine Type		
• mRNA[a]	• mRNA[a]	• Virus-vector[b]
Vaccine Administration[c]		
• 2 shots • 21 days apart	• 2 shots • 28 days apart	• 1 shot
Common Side Effects[d]		
• Pain at injection site, fatigue, headache, muscle pain, joint pain, fever (more common after 2nd dose)	• Pain at injection site, fatigue, headache, muscle pain, joint pain, fever (more common after 2nd dose, more so in younger adults)	• Pain at injection site, fatigue, headache, muscle pain, joint pain, fever
Storage Requirements		
• Frozen vials are shipped in thermal containers with dry ice. Undiluted frozen vials can be stored at temperatures –25°C to	• Vials arrive frozen at –25°C to –15°C (–13°F to 5°F) and should be stored in the original carton to protect from light.	• Must be transported at refrigerated temperatures of 2°C to 8°C (36°F to 46°F). • Can be stored for up to 3 months at refrigerated

[22]Available: https://www.astho.org/COVID-19/Vaccine-Comparison.

–15°C (–13°F to 5°F) for up to 2 weeks. • Vials must be kept frozen and protected from light until ready to use.	• Vials can be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.	temperatures of 2°C to 8°C (36°F to 46°F).

NOTES: [a] "mRNA vaccine delivers a tiny piece of genetic code from the SARS CoV-2 virus to host cells in the body, essentially giving those cells instructions, or blueprints, for making copies of spike proteins (the spikes you see sticking out of the coronavirus in pictures online and on TV). The spikes do the work of penetrating and infecting host cells. These proteins stimulate an immune response, producing antibodies and developing memory cells that will recognize and respond if the body is infected with the actual virus" (https://www.yalemedicine.org/news/covid-19-vaccine-comparison#:~:text=The%20researchers%20report%20that%20the,effective%20at%20preventing%20severe%20disease).
[b] Virus vector vaccine: "Instead of using mRNA, the Johnson & Johnson vaccine uses a disabled adenovirus to deliver the instructions. This adenovirus is in no way related to the coronavirus. It is a completely different virus. Although it can deliver the instructions on how to defeat the coronavirus, it cannot replicate in an individual's body and will not result in a viral infection. (See: https://www.vcuhealth.org/news/covid-19/johnson-and-johnson-vaccine-how-is-it-different#:~:text=The%20Moderna%20and%20Pfizer%20vaccines,vaccine%20delivers%20to%20your%20cells).
[c] These symptoms are expected transient reactions to the vaccine. The term "side effects" can confuse them with the adverse reactions central to decisions regarding safety and efficacy.
[d] The interval between the Pfizer and Moderna vaccines can be up to 42 days between doses when a delay is unavoidable.
SOURCE: FDA, 2020a; 2020b; 2021a; 2021b.[23]

[23] Available: https://www.astho.org/COVID-19/Vaccine-Comparison.

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