U.S. Department of Health & Human Services
Administration for Strategic Preparedness and Response

Recommendations from the National Biodefense Science Board (NBSB):

Prioritization of Product Attribute Categories to Maximize Access for Next Generation COVID-19 Vaccines and Therapeutics

August 28, 2023

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The National Biodefense Science Board is a federal advisory committee authorized by statute (42 U.S. Code § 247d–7g) to provide independent advice to the Department of Health and Human Services (HHS). The board members welcome remarks on these recommendations, which may be sent by email to NBSB@hhs.gov. The positions and recommendations herein are not those of HHS, it's operating or staff divisions, or any employee of the federal government.

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Introduction

Vaccines and antiviral therapeutics for Coronavirus Disease 2019 (COVID-19) available in 2023 are very effective at preventing serious illness and death. In May, the U.S. Government (USG) announced *Project NextGen*—a Biomedical Advanced Research and Development Authority and the National Institute of Allergy and Infectious Diseases joint program—to accelerate and streamline the development of "next generation" COVID-19 vaccine and therapeutics to ensure improved and sustained protection against SARS-CoV-2. The goal is to have vaccines with broader protection against variants and a longer duration of protection; and therapeutics with greater efficacy and acceptability to all populations.

As with other vaccines and therapeutics for other diseases and conditions, what is learned about the first-generation products informs the development of second and future generation products. During the COVID-19 pandemic with a novel virus, emergency use authorizations enabled rapid use of new vaccines (e.g., mRNA) but there were several unknowns about the nature of the disease. Since then, much has been learned about this novel virus, disease, and the vaccines and therapeutics—including what does and does not work. For example, many people had asymptomatic or minor infections and yet could spread the virus. We now have a better understanding of the disease and the requirements of next generation vaccines and therapeutics that can improve both protection and treatment.

Project NextGen will invest in COVID-19 vaccine and therapeutic products that offer greater prevention and treatment of future SARS-CoV-2 variants. *Project NextGen* will select among and invest in development of COVID-19 vaccine and therapeutic candidates. It will consider safety and efficacy targets but also use the opportunity to consider product characteristics, or "attribute(s)," that would most contribute to increased access for the entire U.S. population.

In this context, access is defined as collective term comprising availability, accessibility, accommodation, affordability, and acceptability to better meet the needs of America's diverse populations. Access is dependent upon many partners and processes (e.g., dispensing, manufacturing, regulating); however, consideration of product attributes during the research and development process is an important contributor to the overall impact on access.

Product attributes that could increase access for diverse and broad populations will be prioritized. Although ideal vaccines and therapeutics would possess all optimal attributes, this is rarely possible. Often, this requires trading one specific attribute for another. For example, treatments with very high efficacy may cost more or possess less desirable storage conditions.

Little information is available to support prioritization of attributes that specifically improve access, and guide attribute selection when there are budget constraints for product development. Furthermore, there is no guidance related to the trade-off between the rapid availability of safe and effective but less optimal products to maximize access and the additional time required to develop products with more favorable profiles.

As the USG establishes product development goals that improve access, it requested that the National Biodefense Science Board (NBSB) advise: which product attribute categories should be prioritized to increase vaccine and therapeutics access for all populations, including the prioritized attributes' impact on specific populations and contextual factors that might change the prioritization; and what principles should be considered during trade-offs between rapid availability and additional time required to develop products with priority attributes.

Findings and Recommendations

The NBSB combined the members' expertise, information from scientific literature, and information from government experts and officials to inform its advice. Well-established principles of bioethics—autonomy (self-governance), beneficence (to provide benefit), nonmaleficence (to not cause harm), and justice (equity and distribution of scarce resources)—were used to recommend a prioritization scheme (recommendation 2), and priority attributes for vaccines and therapeutics (recommendations 3 and 4, respectively). An overarching recommendation highlights the importance of developing and adapting multiple platform technologies to quickly enable the priority attributes (recommendation 1).

Timing was critical during the development of the first generation COVID-19 vaccines and therapeutics, which were needed to quickly reduce the overall vulnerability of the U.S. population. These lifesaving products are still available. Individuals who have been vaccinated already and/or have had a natural infection may have some underlying protection against new variants. In this case, timing for new COVID-19 vaccines and therapeutics may be less important (but not unimportant). Additional time to produce the next generations of products may allow better trade-offs; it may be possible to develop vaccines and therapeutics with high priority attributes to improve access for broad and diverse populations.

Public messaging, itself, is not a product attribute and yet messages that inform the public about steps taken to improve access may establish trust and increase acceptability, particularly among cultural and age subgroups that may be hesitant to use products. Messages about how products are being developed could contribute to general and subgroup-specific dialogue that counterbalances misinformation and misperceptions, which ultimately increases use of products and comparative efficacy (e.g., products offer different degrees of immunity at different times and for different durations) through inclusion of diverse populations during development (e.g., researchers, institutions, test subjects). Communicating what is being done but not yet complete, particularly if it is testing in children, is also valuable.

Recommendation 1 – Platform technologies

Develop and adapt multiple platform technologies to generate different types of vaccines and therapeutics. Having multiple platforms with multiple approaches (e.g., adenovirus, isolated protein, mRNA and other types of vaccines) and multiple therapeutic targets (i.e., spike protein, other viral proteins) are important for improving efficacy and access. In the case of therapeutics targets, such as viral protease, viral RNA polymerase, and other virus specific enzymes could be targets. At this time, host-specific immunologic response targets are beyond the scope of these recommendations as those are not being considered for COVID-19. Flexible and adaptable platforms provide options for unknown and unpredictable variants of a known virus. Parallel platform efforts increase the chance of a successful product in an uncertain or evolving disease landscape.

Access could be improved in several ways. First, the ability to rapidly pivot allows products to be more quickly available to the public. Second, different platforms improve access by offering a variety of products that might work better for or appeal to different population subgroups. Each product will work differently (e.g., duration of protection, mechanism) and have different potential interactions and side effects. This may increase access by making more options available for subjects who are immunocompromised, have chronic diseases, elderly individuals, and neonates who might choose or be medically advised to use one product over another. Monoclonal antibodies with a broad spectrum of activity to address new variants are needed for those who are immunocompromised, including the elderly and neonates who may not have the ability to mount an immune response after vaccination, especial as intravenous treatment or prophylaxis for those who are infected or exposed, respectively. Properties to increase access include rapid production, minimal serious side effects, strong and lasting effects to prevent infection and spread, and low cost with ease of distribution. These would help fill gaps among outpatient and elderly populations.

Recommendation 2 – Prioritization criteria

Use an ethics-based prioritization scheme of considerations, in this ranked order, to prioritize attribute categories: 1) reduction of risk and side effects, 2) improved efficacy over existing products, 3) broader accessibility/availability, 4) easier to use, and 5) inclusion of diverse populations. This prioritization scheme may guide trade-offs between product attributes as the context and urgency shifts. Application of the prioritization scheme would begin with:

(1) Reduced risk and side effects – People should not be harmed by the product (e.g., no deaths from the product and minimal morbidity). Comparative safety data would help people to make informed decisions. Risk reduction is particularly important if robust comparative efficacy data are unavailable for subgroups that were not included in or have not yet been tested.

(2) Improved efficacy over existing products – The vaccine or therapeutic should achieve its aim. Given the succession of SARS-CoV-2 mutations—and current vaccines are effective at reducing

hospitalizations and deaths—*NextGen* vaccines should be broad spectrum for SARS-CoV2 variants or even more aspirational, for all SARS viruses in a single vaccine or boosters to prevent infection and decrease resistance. Escape infections and repeated unpredictable events could affect public acceptability, accommodation—and potentially impact availability and affordability. Mucosal vaccines could offer greater respiratory protection. Therapeutics should be virucidal and fast acting, using a long-acting, simplified dosing regimen, with minimal side effects to decrease relapses and resistance. Ideally, by preventing infection, these products could prevent "long COVID" (post-COVID-19).

(3) Broader accessibility/availability – Vaccines and therapeutics should be adequate and require fewer resources (e.g., cost, storage requirements). Goals would be lower cost, longer shelf-life, and closer to room temperature, with fewer resources and conditions needed to support accessibility and availability may reduce risk in the supply chain and logistical coordination among governments and other entities, increasing both speed and breadth of access.

(4) Easier to use – Vaccines and therapeutics should be easy for health care professionals to administer or patient groups to use. Minimal special administration needs (e.g., bifurcated needles, specialized syringes) and less complicated products and processes would increase access. For health care professionals, color-coding or another indicator to quickly identify dosages would increase speed, safety, enabling wider access. Nasal and oral vaccines (mucosal) are needed to block infections and to prevent spread. In children the availability of an oral vaccine would be accepted. For example, one of the most effective polio vaccine delivery methods was a sugar cube. More therapeutics that are available for oral outpatient use, with or without a prescription with easy-to-understand self-administration instructions would be easier to use, increasing comfort of the public to access the products. There is a trade-off with safety because individuals would not be clinically monitored.

(5) Inclusion of diverse populations – The broadest range of possible populations should be included in development activities, particularly vaccine and therapeutic clinical testing. Testing should include the various subgroups in which the product is intended to be used. Subgroup-specific efficacy data may uncover accommodation considerations, and could increase trust, contributing to population-level access. Currently, some products produce a better immune response in certain populations than others. Inclusion of diverse researchers may also help ensure that cultural, geographic, and other considerations are not missed opportunities. Unique recruitment approaches and decentralized clinical trials may increase inclusion. The USG could bring in trusted community spokespersons during development to gain their support prior to vaccine or therapeutic roll-out and provide messaging throughout the process. Inclusion of diverse populations should be highlighted in public messaging; as knowledge may improve public acceptability, particularly of hesitant populations.

Recommendation 3 - Vaccines

Prioritize the following product attributes to maximize broad and equitable access to next generation COVID-19 vaccines: efficacy to prevent infection and spread, rapid onset and long protection duration, fewer doses, alternate routes of administration, fewer special storage and shelf-life requirements and low cost, as well as monoclonal antibodies for those less responsive to vaccines.

- Efficacy – Broad spectrum (SARS or SARS-CoV2) mucosal vaccines would prevent infection and spread. This could gain support of broad and diverse populations.
- Monoclonal antibodies – Vaccines could be supplemented by use of monoclonals to increase immunity among subgroups that are unable to naturally make antibodies from a vaccine alone. This would impact access for a large portion of the population because it would include those with other chronic immune conditions, dialysis, transplants, the elderly, children under six months old, and pregnant women. [Note: the same monoclonals could also be used for therapeutic purpose so access is maximized in more than one way. See recommendation 4.]
- Rapid onset and long protection duration – The duration of vaccines should be at least one year. This impacts access for most of the population because it addresses accessibility, acceptability, and accommodation. Rapid onset is needed for large subgroups who are at risk of serious disease. Long protection duration would decrease the number of vaccinations (thus, product to individuals or individuals to products). Long protection duration might particularly help those who have limited income and healthy adults who view their risk of serious illness lower than the inconvenience and cost of obtaining multiple vaccines.
- Fewer doses – Fewer doses increase the speed of access (i.e., more individuals can be fully vaccinated or boosted more quickly) and most of the population is likely to be vaccinated because they are accommodated. Fewer doses impacts working families with children, rural and transportation-limited populations, hard-to-reach populations (e.g., unhoused, traveling).
    - Primary vaccine: Single dose is preferred but at most two doses, one to three months apart
    - A booster vaccine every five years is preferred; one every year is acceptable
- Multiple routes of administration - Mucosal vaccines (including oral ones for children) will be needed to prevent infection and spread. This could enhance public acceptance. Orally administered vaccines (such as sugar cubes) could be used to develop mucosal immunity in children. However, intramuscular injections could be an alternate product since it is a time-tested standard method that is familiar to the public. Pediatric versions should be available. Skin patches could be an alternative to injections.
- Multiple platform technologies – See recommendation 1. New and old technologies could encourage acceptance.
- Fewer special storage and shelf-life requirements – Room temperature or basic refrigeration are preferred; but -20°C is acceptable. This would impact rural, frontier, and

transportation-limited populations that may need to travel to access the requirement-heavy products. It would limit the supply chain and unique distribution models to reach targeted populations.

- Low cost –This impacts access for young adults who have lower incomes and are less likely to be insured, the self-employed (e.g., farmers) with less disposable income and may be less likely to be insured, children, and individuals who have lost Medicaid coverage. This attribute is less important for vaccines than for therapeutics.

Additional, but lower priority, attributes include:

- Coadministration with other vaccines – Able to be administered with other vaccines (e.g., influenza). This increases access by improving convenience of vaccination (accessibility and accommodation) and not interfering with developing immunity from other vaccines. This could impact many populations but not in a predictable way due to the unique timing of vaccination schedules, conditions, and ages.
- Improved adjuvants – A good adjuvant(s) that aids in eliciting an effective immune response in both older adults and children. The first-generation vaccines have limited efficacy for these populations.

Recommendation 4 - Therapeutics

Develop next generation COVID-19 therapeutics prioritizing the following attributes to increase population access: few drug-drug interactions, efficacy, low cost, low potential for adverse events, and multiple routes of administration.

- Few drug-drug interactions – Toxicity from interactions between the new therapeutic and multiple medicines taken for a variety of indications, such as hypertension, diabetes, chronic immunologic diseases etc. should be minimized. This impacts the elderly and populations with chronic health conditions which is also a population that needs increased access.
- Low potential for adverse events - The risk and severity of the therapeutic's side effects should not be perceived to be greater than the side effects of the disease itself to be acceptable by many populations.
- Efficacy – Virucidal therapeutics would improve efficacy. Broad spectrum monoclonal antibodies as a treatment will further help individuals who are immunosuppressed, elderly and neonates and who do not respond to vaccination.
- Different mechanisms of action (new targets) – avoiding or reducing cross-resistance with new drugs and ensuring potential for lower frequency for development of resistance.
- Multiple routes of administration – Oral and intravenous formulations to accommodate outpatient and hospitalized patient treatment
    - Oral antivirals are highest priority to improve access

    - Tablets and capsules with good oral bioavailability; and taste-masked liquids (suspension) for individuals who cannot swallow tablets (e.g., children, elderly, ill).
    - Intravenous (IV) formulation that is compatible with IV fluids routinely used in intensive care units and has no or little pain during injection; with oral tablets or capsules of the same product to enable step-down therapy upon hospital discharge.
- More flexible timing for administration of an effective dose, expanding the window of opportunity for therapeutic administration, including post exposure prophylaxis.
- Mechanisms that enable quick access (e.g., over the counter, telemedicine, home order) with or without a prescription, increasing access for geographically unique, elderly, immune compromised, and other populations. This might have tradeoffs with safety-related attributes (ease of use, fewer drug-drug interactions, etc.). More time may be needed to ensure safety to ensure that products are used by the correct individual with the correct circumstances.
- Low cost – Enable out of pocket cost since therapeutics are less likely than preventive vaccines to be covered by insurance. This attribute increases in importance when the therapeutic is experimental because it is less likely to be covered by insurance. This impacts access for young adults who have lower incomes and are less likely to be insured, the self-employed (e.g., farmers) with less disposable income and may be less likely to be insured, children, and individuals who have lost Medicaid coverage.
- Ability to target multiple RNA viruses – broad spectrum of therapeutic efficacy would improve preparedness for future public health emergencies caused by RNA viruses

Additional, but lower priority, attributes include:

- Fewer special storage requirements and longer shelf-life - Stable at room temperature or refrigeration. Liquid formulation for intravenous administration should be lyophilized. Special injection doses or oral formations may be needed for children.
- Few and long-acting courses – While current products do not have long courses, prioritize five or fewer days; once a day (twice per day at most).
- Ease of use – Simple to confidently use without high health literacy and in diverse settings. For example, an autoinjector is familiar to the public and may be useful for antibodies as therapeutics. This impacts children, the elderly, and individuals with complex medication regimens. Self-administration might require a safety level that might exceed emergency use authorization.

Implementation of these priority attributes for next generation therapeutics would support safe and effective oral therapeutics that are compatible with other medications. This would benefit the entire population. However, the subgroup for which the protection would be most useful is

individuals who have other health conditions (e.g., immunocompromised, obesity, chronic diseases) that increase the severity of COVID-19 infection.

Contextual factors

There are contextual policy, communication, and environmental factors that can positively or negatively impact broad population access to vaccines and therapeutics. Some factors might necessitate a reprioritization of product attributes to guide investment decisions in next generation COVID-19 vaccines and therapeutics. Others are not directly tied to product attributes but might be considered, from a risk perspective, by partners that are responsible for capabilities outside the scope of product development but still ultimately impact access.

- Variety of platforms – See recommendation 1. These could shorten time to availability, increase products with different efficacy, safety, and access attributes for diverse populations, and increase public acceptability by providing choice (informed by published comparative efficacy and safety).
- Limited population data - Low participation of diverse populations in studies and low quality (thus unusable) foreign clinical data might impact the tradeoff of time (to obtain more data) for vaccine acceptability. Structures to rapidly and accurately evaluate a new product should be established to capture data from all broad elements of society – age, pediatric, pregnancy, broad ethnic representation – whether there are among the initial or later populations (e.g., pregnant women) to use the product.
- Insurance coverage – Additional changes in insurance coverage (e.g., Medicaid policy, private medical insurance) might increase the importance of cost to lessen impact on people with limited incomes and children.
- Packaging – The packaging can add real or perceived complexity of product use. The instructions, guidelines, markings, and grouping (or not) of multiple unique pieces, all may increase safety risk or decrease speed of administration, thus access. Color coding for dosages, use of commonly available or reusable supplemental supplies, and other approaches might mitigate access risk due to packaging.
- Supply chain - Supply chain disruption might necessitate reprioritization of the therapeutic attributes, particularly if it impacts some, but not other attributes.
- Ease of manufacturing – This could impact access by slowing product availability and accessibility, thus access. Some risk might be reduced by, for example, requiring fewer synthetic steps, using starting materials that are available in the western hemisphere, or stockpiling key starting materials are ways that could potentially lower the risk of supply chain problems.
- Public messaging – Establishing trust increases acceptability among the public. How well or not well general COVID-19 public messaging occurs may impact accommodation and acceptability despite the products having the optimal attributes to increase access. For example, a stable and effective product might be available through mail order but if the

public doesn't clearly understand who may (or how to) obtain it, then they might not use it. However, better conveying product development successes (especially with broad and diverse populations). On December 16, 2021, the NBSB recommended that the U.S. Department of Health and Human Services (HHS) "*build a public communications system that allows HHS to understand how the public perceives and receives information about public health emergencies and develop protocols that diminish the occurrence and impacts of health-related mis-, dis-, and mal-information*."

Trade-offs

There often are limitations to what products that can be developed quickly (time) with financial resources available (cost) and ideal attributes—in this case to increase the access to next generation COVID-19 vaccines and therapeutics (quality). The following priorities could potentially be accommodated without trade-offs for the next generation vaccines and therapeutics if substantial research and development that have already been committed in these priority areas area leveraged. Cost could be considered in each trade-off.

Priorities for vaccine access

The priority for vaccines should be prevention of infection and spread. The ability of COVID-19 to cause subclinical and mild infection which then spreads and could cause more serious disease or additional subclinical infections should be prevented by raising local mucosal immunity. Subclinical infections also encourage the selection of variants. Children could be immunized using technology such as the vaccine in sugar cubes as was used in poliovirus vaccine. This could have wider acceptability in populations with an aversion to needles. The technologies could be useful for preventing other respiratory viruses (i.e., an added value).

The second priority is to develop technologies that can provide long-lasting protection (ideally, a booster every five years and, in the worst case, every year).

The third priority is to develop a vaccine that can provide broad protection—perhaps using more than one antigen (spike protein) to minimize the selection of variants.

The fourth priority is to develop vaccines (and adjuvants) that are effective in elderly patients, neonates and the immunocompromised. For those who are unresponsive to vaccination, the focus may need to pivot to monoclonal antibodies that address a large number of variants.

The fifth priority should be vaccine stability and the ability to store the vaccines for at least two years in refrigerated or 0^0C conditions.

The cost, ease of administration, fast manufacturing, can be addressed once the technologies and particular vaccines have been identified. Safety and efficacy will be required for FDA approval.

Priorities for therapeutics access:

The highest priority would be to have an orally bioavailable capsule or tablet (and suspension for pediatrics and for those who cannot swallow capsules and tablets) that can be taken at any stage of the disease to: shorten the disease's duration, decrease population spread, and, while outside the scope of Project NextGen, decrease "long COVID" (post-COVID-19) cases. It should have minimal drug-drug interaction (polypharmacy acceptable) and a high safety profile to be made available to outpatients who can quickly transition from testing to treatment. Having an intravenous formulation of the same product is important.

The second priority is to develop a therapeutic that is virucidal to prevent relapses and decrease virus resistance selection.

The third priority is to develop a therapeutic that should be dosed no more than twice per day; and require no more than five days of administration. Having broad spectrum SARS-CoV and RNA virus activity would add value.

When the COVID-19 pandemic occurred, government and industry scientists worked together with the resources (e.g., technologies, products, data, science) they had "in hand" to meet the urgent need for vaccines and therapeutics. These products have effectively stopped the pandemic but now we have the time to design and innovate new vaccines and therapeutics against COVID-19 and its variants to be ready for future pandemics. Beyond product attributes, to allow innovation, the commitment to fund research against these priority characteristics should include a small percentage (for example 10%) to unstructured new vaccines and therapeutics development as "blue sky" research could yield completely new approaches that are not currently imagined—to keep the United States in the forefront of vaccine technology in the case of future pandemics.

Appendix 1: National Biodefense Science Board Roster

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