ABSTRACT

Title of Dissertation: DEVELOPMENT OF A CORE OUTCOME SET FOR STUDIES INVESTIGATING SAFETY, EFFICACY, AND IMPLEMENTATION OF COVID-19 VACCINES: A COLLABORATION WITH AFRICAN AMERICAN/BLACK COMMUNITIES IN BALTIMORE CITY, MARYLAND

Reva Datar, Doctor of Philosophy, 2022

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Background: Since it was declared a global pandemic in March 2020, Coronavirus Disease 2019 (COVID-19) has claimed over one million lives in the United States. Since COVID-19 vaccine rollout efforts began in Baltimore City, Maryland in December 2020, approximately 63.4% of all residents have been fully vaccinated (i.e., received their first and second doses in a two-dose series or received a single-dose vaccine). Despite efforts to implement equitable vaccine distribution in Baltimore City, prominent disparities in COVID-19 vaccine uptake persist, with poorer, predominantly Black neighborhoods frequently reporting lower levels of vaccine uptake than affluent, predominantly White neighborhoods. Guided by key principles of community-based participatory research, this dissertation explores community experiences with COVID-19 vaccines and develops a core outcome set (COS), inclusive of community-important outcomes, for use in studies evaluating the safety, efficacy, and implementation of COVID-19 vaccines.

Methods: In March 2022, semi-structured interviews were held with vaccinated and unvaccinated Black residents of a community in Baltimore City reporting 40% vaccination uptake. Data were analyzed using inductive thematic analysis with subsequent subgroup analyses and thematic network analyses. To assess the extent to which outcomes measured in COVID-19 vaccine studies published between December 2019 and March 2022 aligned with factors of vaccine hesitancy, a systematic literature review (SLR) was conducted. Results from the qualitative analyses and the SLR informed the development of a candidate list of outcomes used in the first round of a Delphi study held in June 2020. After two rounds of Delphi survey distribution, a face-to-face consensus meeting was held with community members and community health workers to prioritize outcomes of interest to all relevant stakeholders and finalize the COS.

Results: Thematic analysis yielded four emergent themes relating to COVID-19 vaccine uptake decision making: (I) Safety and efficacy of vaccines, (II) Perceived importance of COVID-19 vaccines in relation to pre-existing community needs, divided into two subthemes, a) Environmental injustice and (b) Personal health concerns, (III) Access to trustworthy, understandable information, and (IV) Physical access to vaccines. Participants acknowledged that physical access to COVID-19 vaccines was not a major barrier to uptake, however finding trustworthy and understandable information about the safety and efficacy of the vaccines were common areas of concern. Of all primary outcomes (N=20) identified in the 56 articles included in the SLR, 85% (n=17) corresponded with factors of vaccine

hesitancy. The final COS included 19 outcomes across four "domains:" "Is the vaccine safe?"; "Does the vaccine work in my body?"; "Does the vaccine work in the community?"; and "Outcomes identified during consensus meeting."

Conclusion: The findings from this dissertation suggest that although community-important outcomes related to safety and efficacy of vaccines are often addressed in clinical studies, outcomes measuring institutional trust, economic and health impacts, community acceptance of the vaccines, and trustworthiness of vaccine information are underutilized in studies of vaccine implementation. As these social factors function as barriers to vaccine uptake, particularly among underserved communities, they should be regarded as indicators of equitable access to COVID-19 vaccines. The findings from this dissertation provide a framework with which public health researchers can begin to rethink measures of equity in vaccine rollout efforts.

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by

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Dissertation submitted to the Faculty of the Graduate School of the
University of Maryland, College Park, in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
2022

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Acknowledgements

First and foremost, I want to express my sincere gratitude to the community members in East Baltimore who gave their time to participate in this study. I want to thank them for sharing their personal perspectives and experiences with me and for teaching me so much along the way. I also thank the staff members at McElderry Park Community Center and Sisters Together and Reaching, Inc. (STAR) for their support in this endeavor and for welcoming me into their community with such grace and kindness. Without their invaluable contributions, this research would not have been possible.

I am extremely grateful to have benefitted from the mentorship, support, and insights of my esteemed Committee members. With the deepest gratitude, I thank my Committee Chair, Dr. Donna Howard, for the unconditional support and positivity she showed me throughout my doctoral journey. In the face of every challenge, she inspired resilience, grit, and optimism. I am blessed to have had her as an advisor and will always be grateful for her patience, mentorship and, of course, her meticulous edits of my dissertation. I thank Dr. Kirsten Stoebenau for the genuine support she has shown me throughout this process and for pushing me to think about my research in new and challenging ways. I greatly appreciate Dr. James Butler's mentorship and willingness to share his experiences and knowledge with me throughout the dissertation process. I thank Dr. Devlon Jackson for introducing me to core tenets of health communication and encouraging me to include them in this work and Dr. Jennifer Roberts for sharing with me her passion for and knowledge of environmental justice.

With deepest gratitude, I thank Reverend Debra Hickman, President and CEO of STAR and all the community health workers with whom I was lucky enough to get to know. I appreciate the faith that Reverend Hickman and Ms. Randi Woods put into this study and their belief in the power of

community advocacy and research. The effort they put in to ensure the continuation of this study is not lost on me and I am forever grateful. I am blessed to have had the opportunity to work with community health workers Mr. James Wilson, Mrs. Brandi Coles, Mrs. Tracy Barnes-Malone, Mrs. Angela Lowrey, Mr. Terry Lindsey, Mrs. Karen English, and, of course, the late Mrs. Gail Jones-Childs throughout the implementation of this study. Their knowledge, compassion, authenticity, humor, and unparalleled dedication to the community reflect the essential role that STAR fills within the community. I thank them from the bottom of my heart for their partnership. It is an indelible reminder of the importance of community health workers in achieving health equity.

Finally, I want to thank my dear friends and family for their support during all the highs and lows (and everything in between!) of the dissertation process. Although the pandemic gave me a dissertation, it also altered everyone's life, in one way or another. I am grateful to have had strong, supportive relationships that remained the same through it all. To Sara, Julia, Israel, Munjireen and other members of our "graduate school support system," I am thankful for all the times we laughed, cried, and commiserated about the trials of grad school together. I don't know what I would have done without you and our much-needed gym sessions and coffee runs. Eric, thank you for your love, support, and encouragement at every stage of the dissertation process. I am forever grateful. Finally, thank you to Mom, Dad, and TJ for always loving me and encouraging me to aim high in life and persist when things get hard. I cannot express how critical your support is and has always been to my growth, both personally and professionally.

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List of Abbreviations

3C's. Convenience, Complacency, Confidence

AIDS. Acquired Immune Deficiency Syndrome.

CDC. Centers for Disease Control and Prevention

CHW. Community Health Worker

COMET. Core Outcome Measures in Effectiveness Trials

COS. Core Outcome Set

COVID-19. Coronavirus Disease 2019

DNA. Deoxyribonucleic Acid

EUA. Emergency Use Authorization

FDA. Food and Drug Administration

FGD. Focus Group Discussion

GRADE. Grading of Recommendation Assessment, Development, and Evaluation

HABC. Housing Authority of Baltimore City

HHS. US Department of Health and Human Services

HIV. Human Immunodeficiency Virus

HPV. Human Papillomavirus

J&J. Johnson and Johnson.

JHU CHE. Johns Hopkins University Center for Health Equity

MMR. Measles Mumps and Rubella

mRNA. Messenger Ribonucleic Acid

NGT. Nominal Group Technique

OMERACT. Outcome Measures in Rheumatoid Arthritis Clinical Trials

PIO. Patient-important Outcome

RNA. Ribonucleic Acid

SAGE. Strategic Advisory Group of Experts

SARS. Severe Acute Respiratory Syndrome

SARS-CoV-2. Severe Acute Respiratory Syndrome Coronavirus 2

SES. Socioeconomic Status

STAR. Sisters Together and Rising, Inc.

WHO. World Health Organization

Chapter 1: Introduction

1.1 Background

COVID-19 Disease

Coronaviruses belong to the *Coronaviridae* family of viruses and make up a class of single-stranded RNA viruses (Dhama et al., 2020). Several species of coronaviruses are zoonotic pathogens that have caused fatal diseases in humans such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (Bhagat et al., 2020). On December 31, 2019, a SARS-like disorder was identified in Wuhan, China by the World Health Organization (WHO) country office of China (Cascella et al., 2020). Subsequently, the Chinese Center for Disease Control and Prevention identified the viral agent as a novel coronavirus which was named SARS-CoV-2 and the disease caused by the virus was called Coronavirus Disease 2019 (COVID-19) by WHO Director-General Dr. Tedros Adhanom Ghebreyesus on February 11, 2020 (Sahin et al., 2020). On March 11, 2020, WHO declared COVID-19 a global pandemic (WHO 2021). As of September 2022, COVID-19 has been responsible for over 6,500,000 deaths globally with the United States recording more than 94,780,000 confirmed cases and over 1,000,000 deaths (WHO, 2022).

COVID-19 Vaccines

During 2020, over 200 COVID-19 vaccines were in development worldwide (Burgess et al., 2020). Two pharmaceutical companies, Pfizer (along with its partner BioNTech) and Moderna, each produced their own messenger RNA (mRNA) vaccines (Walsh et al., 2020). These vaccines use a novel technology that delivers genetic code (mRNA) to cells, providing them with instructions to produce the spike surface protein found on the surface of SARS-CoV-2 (Walsh et al., 2020). The production of this spike protein activates the immune system, developing

antibodies in the body (Walsh et al., 2020). On December 11, 2020, the US Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for the mRNA vaccine produced by Pfizer-BioNTech (FDA 2020). On December 19, 2020, Moderna's mRNA vaccine was also issued an EUA by the FDA (FDA 2020). In Phase III clinical trials, Pfizer-BioNTech and Moderna's vaccines were found to be 95% and 94.5% effective in protecting against COVID-19, respectively (FDA, 2020). To achieve optimal efficacy, both vaccines require two separate doses approximately one month apart (FDA, 2020). Johnson & Johnson (J&J) produced a viral vector vaccine which inserts genetic code for the SARS-CoV-2 spike protein into a live adenovirus, a non-enveloped, double stranded DNA virus; (Belete, 2020). On February 27, 2021, the FDA issued an EUA for J&J's one-dose COVID-19 vaccine, which was shown to be 85% effective in preventing severe disease, but only 72% effective among participants in the United States (FDA 2020). On November 19, 2021, both the Moderna and Pfizer-BioNTech COVID-19 vaccines were authorized by the FDA for use of a single booster dose for all individuals 18 years and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine (FDA 2021).

Vaccine-based protection at the community level provides a pathway for achieving "herd immunity," or a threshold of immunity that should protect a population from invasion of a new infection (Fine et al., 2011). However, this is dependent on sufficient population uptake of the vaccine and requires effective implementation strategies including behavioral countermeasures (i.e., social distancing, mask wearing), even for those individuals who receive the vaccine (Schoch-Spana et al., 2020). As evidenced by prior infectious disease outbreaks, even if vaccine coverage at the national level is high, geographic clustering of unvaccinated people can lead to severe disease outbreaks (Phadke, 2017). Sufficient vaccine coverage will only be achieved by ensuring effective community-level acceptance and adherence through efforts to better understand and

address community needs. In doing so, implementers must identify and address cultural, socioeconomic, and political concerns as well as socio-structural and environmental barriers to access that may hinder uptake of vaccines (Dodd et al. 2020).

COVID-19 Vaccine Rollout in the United States

On April 29, 2020, The US Department of Health and Human Services (HHS) organized a public-private partnership between the federal government and the biomedical industry called "Operation Warp Speed". The objective was to "ensure that every American who wants to receive a COVID-19 vaccine can receive one, by delivering safe and effective vaccine doses to the American people beginning January 2021" (USDOD, 2021). To achieve herd immunity and effectively control the disease, researchers estimate that approximately 70% or more of the population must be fully immunized to COVID-19 (Fontanet & Cauchemez, 2021). However, these estimates assume that the vaccine will be equally effective in every individual, a scenario that is not playing out in the real world (Fontanet & Cauchemez, 2021).

When vaccine distribution first began in December 2020, the United States prioritized healthcare workers and individuals aged 65 and older to receive the vaccine first, as these populations accounted for over 80% of COVID-19 related deaths (PRB, 2019). Subsequent groups eligible for immunization included individuals with underlying medical conditions and other essential workers; each state set their ranking of priority groups independently (PRB, 2019). By March 1, 2021, over 78 million doses of vaccine had already been administered and 15.3% of the total US population had received at least one dose of the Pfizer or Moderna vaccine and eight percent of the total US population had been fully vaccinated (CDC, 2021).

COVID-19 Vaccine Rollout in Baltimore City, Maryland

Baltimore City is Maryland's second poorest city, with 21.1% of its residents - and 25.6% of its Black residents - living below the poverty line (U. S. C. Bureau, 2020). Non-

Hispanic Black individuals account for a majority of the population (62.8%) and non-Hispanic White individuals account for 27.7% (U. S. C. Bureau, 2020). In 2021, the Baltimore City Health Department revealed a comprehensive strategy for equitable vaccine distribution prior to the start of COVID-19 vaccine distribution (Department, 2021b; Dzirasa, 2021; Health, 2021). The strategy, titled "COVID-19 Vaccination Strategy and Equity Plan" acknowledges "historic and ongoing medical abuse and racism within the health care system that Baltimore City residents and their families have experienced" and the need to "focus special attention to populations that are most vulnerable to COVID-19 or that require specialized outreach and education" (Dzirasa, 2021). The proposed evaluation of this plan identifies three primary outcomes of interest: vaccinations procured (i.e., supply of vaccines available to the public), vaccinations provided (i.e., number of individuals receiving a COVID-19 vaccine), and vaccine coverage (i.e., geographic distribution of vaccine sites throughout the city) (Dzirasa, 2021).

Despite these efforts to ensure equity in vaccine distribution, disparities in vaccine uptake have been observed across neighborhoods in Baltimore City. By December 2021, some neighborhoods in Baltimore experienced vaccination rates of over 90% while other neighborhoods, primarily in East and West Baltimore, experienced vaccination rates as low as 20% (Figure 1) (Department, 2022b). COVID-19 cases, hospitalizations and deaths surged in early January 2022 (Department, 2022a), suggesting that although the City had achieved high vaccination status overall, much of the disease burden may have fallen onto communities with low vaccine uptake. Notably, many of the neighborhoods reporting greater than 95% coverage, such as Inner Harbor/Federal Hill, Mt. Washington, and Fells Point were located in central Baltimore and composed of primarily high-income, White populations (Department, 2022c). In contrast, many neighborhoods reporting less than 40% coverage, such as Sandtown/Winchester,

Midway/Coldstream, and Franklintown, were located in East and West Baltimore and were composed of predominantly low-income, Black populations (Department, 2022c).

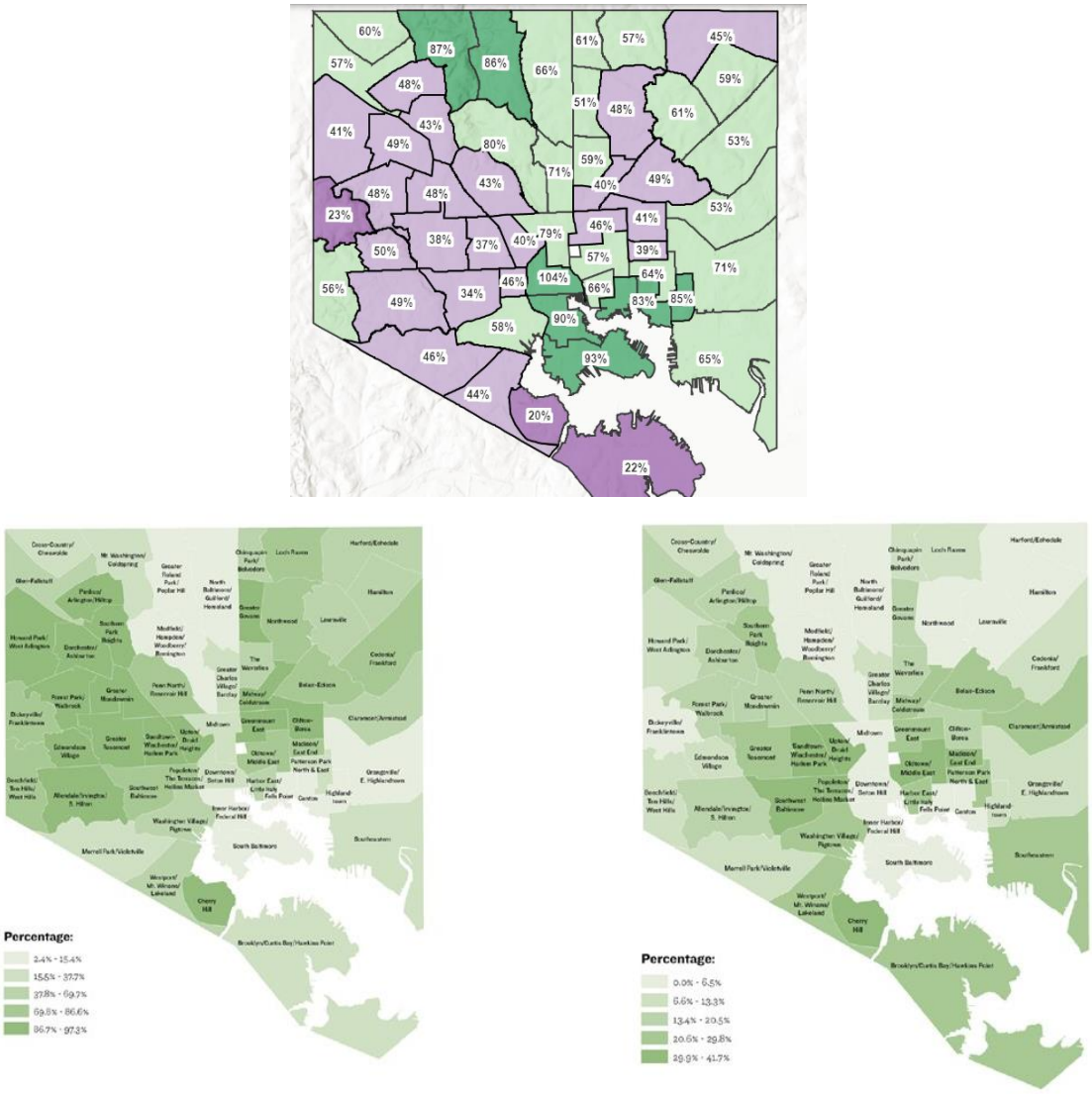


Figure 1.1 Population Density Maps of Baltimore City (Top): Baltimore City COVID-19 Vaccination Coverage Map as of December 3, 2021 (Baltimore City Health Department 2021) *Dark purple = <30% coverage, light purple = 31-50% coverage; light green = 51-80% coverage; dark green = >81% coverage; **(Bottom Left):** Population Distribution of Black/African American Residents in Baltimore City, 2015-2019; **(Bottom Right):** Percent of Family Households Living Below the Poverty Line in Baltimore City, 2015-2019. *Adapted from (Ibe, 2021)*

Challenges to Equitable Vaccine in the United States

Despite the astounding progress of vaccine development, approval, and distribution, Operation Warp Speed has not sufficiently addressed a key social gap. The program is built upon the assumption that if a vaccine is supplied, all people will accept and be able to access it (Schoch-Spana et al., 2020). Evidence from previous infectious disease outbreaks suggest that, for a variety of reasons, not all segments of the population will equally accept vaccines nor will the supply itself be provided through avenues of equitable access (Reinhart 2020; Kim et al., 2020). Thus, it is important to note that factors relating to vaccination accessibility as well as those pertaining to equity, perceptions, attitudes, and beliefs should be evaluated when evaluating the implementation of vaccine rollout efforts.

Demographic statistics for vaccine distribution and uptake in the United States are severely lacking. According to Dr. Marcella Nunuez-Smith, Chair of the COVID-19 Health Equity Taskforce at HHS, "people of color are getting vaccinated at rates that are lower than their representation in the population." (Academy Health National Health Policy Conference, 2021). As Dr. Nunez-Smith noted during the 2021 Academy Health National Health Policy conference on February 16, 2021: "While we have filled in some of the data gaps related to race and ethnicity, those data are inconsistent and incomplete." She went on to note that additional marginalized populations "are still largely unrepresented in our data and in our research." (Academy Health National Health Policy Conference, 2021).

Since January 2020, the US population has not uniformly experienced the effects of the pandemic, with some communities disproportionately affected through increased exposure or severity of outcomes (Yancy 2020; JHU 2021). In the first year of the pandemic, racial disparities were stark; Black individuals comprise just 13.4% of the US population yet accounted for more

than 24% of COVID-19 deaths in 2020 (Burgess et al., 2020). Black Americans were more likely to be diagnosed, hospitalized, and to die from COVID-19 (Kim et al., 2020). In 2020, the death rate from COVID-19 was reported to be 2–3 times higher among Black versus White individuals (Kim et al., 2020). Marginalized populations characterized by low socioeconomic status, high housing density, and poor access to healthy foods (i.e., adverse social determinants of health) faced an increased risk of exposure and infection (Kim et al., 2020). While these inequities have narrowed over time, disparities in COVID-19 related morbidity and mortality rates persist, particularly in times of viral surge (KFF, 2022).

Racist historical experiences with medical research among some communities may further contribute to the disproportionate risks for COVID-19- associated illness, hospitalization, and death, as these communities may be less likely to seek treatment or assistance from healthcare workers and place less trust in the healthcare system (Yancy 2020; Scharff et al., 2010). The Tuskegee syphilis study, for instance, in which 600 Black Americans were enrolled in a syphilis study without providing informed consent and not offered treatment for their condition, stands as a stark reminder of the potential for exploitation of Black Americans in medical research (Scharff et al., 2010). Even after Tuskegee, several instances of unethical medical research involving Black participants have been conducted at highly esteemed academic institutions (Farfel and Chisolm, 1990). A recent study examining racial bias in pain assessment found an association between clinicians exhibiting false beliefs about biological differences between Blacks and Whites and racial bias in pain treatment recommendations (K. M. Hoffman, Trawalter, Axt, & Oliver, 2016). Behavioral studies suggest that mistrust of medical research is strongly influenced by sustained racial disparities in health, limited access to health care, and negative encounters with health care providers (Scharff et al., 2010). Previous research indicates that a lack of ethnic diversity and

cultural competence among physicians and medical researchers is a major contributor to distrust of medicine among minorities, and likely influences the lack of representation among Black and Latinx populations in clinical trials (Gray et al., 2021; Scharff et al., 2010; Clark et al., 2019). Given the clear disparities in mortality rates, hospitalization rates, and case rates, between Black Americans and White Americans, it is likely that the COVID-19 pandemic has amplified these concerns.

As evidenced by other disparities in COVID-19 vaccine uptake observed throughout the country, different communities face different challenges and/or harbor different beliefs regarding COVID-19 vaccines (Ritu Agarwal et al., 2021; B. P. Murthy et al., 2021). Studies have shown these disparities to be associated with region of residence (urban/rural), socioeconomic status, political ideology, and race/ethnicity, among other demographic characteristics (Ritu Agarwal et al., 2021; Hughes et al., 2021; B. P. Murthy et al., 2021; Reitsma, Goldhaber-Fiebert, & Salomon, 2021). Importantly, structural racism, defined as inequitable access to goods, services and opportunities among racial groups, has played a critical role in generating disparities associated with these demographic characteristics (Zeng, Pelzer, Gibbons, Peek, & Parker, 2022). Evidence indicating clear instances of racial biases in medical treatment allocation (K. M. Hoffman et al., 2016) adds to recent instances of Black individuals allegedly being treated with insufficient care for COVID-19, as was the case with Dr. Susan Moore, who died of COVID-19 in 2020 (Hutchinson, 2020).

In the many months preceding the approval of COVID-19 vaccines, the prolonged implementation of behavioral countermeasures, including lockdown and social distancing, have had profound adverse effects on the economic, social, psychological, and physical wellbeing of individuals nationwide (Kim et al., 2020), impacting Black/African American populations hardest

(National Collaborating Centre for Determinants of Health, 2021). By distributing vaccines without simultaneously monitoring and addressing issues relating to equity and cultural experience, officials are asking communities to trust the very same structures that have contributed to their experiences of discrimination (Yancy, 2020). This could have profound impacts on the effectiveness of vaccine implementation efforts among Black/African American populations in the United States.

Measuring the Safety, Efficacy, and Implementation of COVID-19 Vaccines

Given the novelty of and urgent need for COVID-19 vaccines, clinical trials of COVID-19 vaccines have provided results demonstrating safety and efficacy faster than other vaccines previously in development. This was achieved due to the unprecedented level of global collaboration among scientists and innovative advances in genome sequencing and mRNA technology (Le et al., 2020). However, by the time vaccines were available for distribution in December 2020, studies showed that although Blacks/African Americans make up 13% of the United States population, they accounted for just 3% of participants in vaccine clinical trials (Warren, Forrow, Hodge, & Truog, 2020). This poses a threat to the validity, generalizability and trustworthiness of trial results, particularly among communities of color. Similarly, few studies have evaluated the effectiveness of COVID-19 vaccination implementation efforts, particularly among Black/African American populations. Among those that have been published, outcomes used to measure "effectiveness" included incidence of confirmed cases, hospitalization, years of life lost, and death ((Lisewski, 2021); Barbounakis et al., 2021; Islam et al., 2021). These same outcomes were also used in COVID-19 vaccine clinical trials (Polack et al., 2020; Voysey et al., 2021). This highlights an important gap in research; effectiveness of vaccination rollouts refers to the effectiveness of the vaccines as well as the effectiveness of the rollout implementation itself.

By only using outcomes that refer to the vaccines themselves – rather than those relating to vaccines AND vaccination implementation - scientists are ignoring potential outcomes of critical importance to individuals.

Some studies have included outcomes relating to implementation such as number of COVID-19 vaccine doses administered and rate of vaccination (Sah et al., 2021; Aguas 2021). Studies evaluating the effectiveness of vaccine rollouts before COVID-19, such as those for Human Papillomavirus and Dengue vaccination programs, included outcomes of quality-adjusted life years and cost-effectiveness (Taira et al., 2004; Durham et al., 2013), however these outcomes may not sufficiently capture the most important impacts of vaccination rollouts on the lives of individuals receiving the vaccine. The preponderance of literature on COVID-19 vaccination programs focus on identifying potential barriers to vaccine uptake which pose a massive threat to the effectiveness of any vaccination effort (Funk & Tyson 2021; Reinhart 2020; Brennan 2020). Thus, while behavioral studies assessing predictors of vaccination behavior may predict vaccine uptake and inform the development of more tailored – and presumably effective – vaccination programs, outcomes that can be used to measure the effectiveness of a COVID-19 vaccination program during and/or after implementation within a community are lacking.

Existing Measures of Vaccine Hesitancy Used to Inform Development of Vaccine Rollout Efforts

In March 2012, the World Health Organization (WHO) Strategic Advisory Group on Experts (SAGE) Working Group on Vaccine Hesitancy was convened to define the term "vaccine hesitancy," map the determinants of vaccine hesitancy, and develop scientific instruments to measure and address the hesitancy to protect public health (WHO, 2014). The following definition of vaccine hesitancy was developed: "Vaccine hesitancy refers to a delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines. It is influenced by factors such as

complacency, convenience and confidence" (WHO, 2014). The SAGE Working Group's Complacency, Convenience and Confidence (3C's) Model of Vaccine Hesitancy (Figure 1.2) will serve as the basis for the conceptual framework for Phase I of this dissertation.

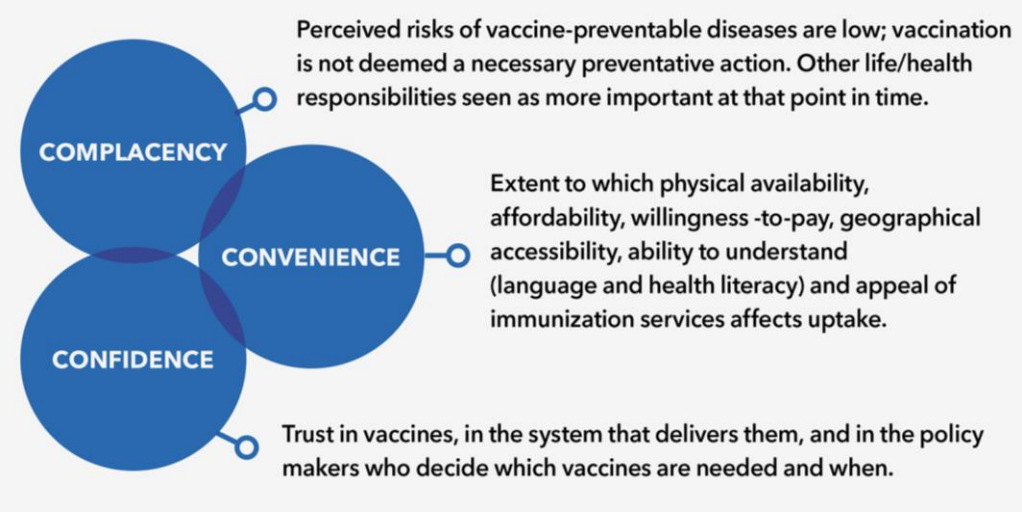


Figure 1.2. SAGE Working Group's Complacency, Convenience, Confidence "3C's" Model of Vaccine Hesitancy (WHO, 2015)

The concept of vaccine hesitancy is specific to sub-groups within populations and is rarely consistent across a population; thus it is critical to first understand who is hesitant about vaccination, what their concerns are, i.e., what reasons are driving their hesitancy, and which geographic, socio-cultural or political context may contribute to the hesitancy (MacDonald 2015; Larson et al., 2015; Domek et al., 2018). Although factors associated with vaccine hesitancy vary depending on the vaccine or immunization program, and some influences are well beyond the scope of an immunization program, it is the responsibility of public health scientists to better understand the determinants of vaccine hesitancy in order to best minimize it (Domek et al., 2018). Hesitancy can vary depending on the particular vaccine or vaccines in question, the individuals and/or groups expressing reluctance, and the socio-cultural context (Domek et al., 2018).

In relation to most other vaccines (e.g., MMR, influenza), factors consistently associated with lower intention to vaccinate include identifying as Black, being of younger age (less than age sixty), having lower educational attainment, and conservative political ideology (Reinhart 2020; Funk & Tyson 2021; Brennan 2021). Interestingly, a February 2021 Pew Research Center national survey suggested that a majority (61%) of Black Americans intended to receive a COVID-19 vaccine or had already received one, up from 42% in November 2020 (Funk & Tyson 2021). In fact, the survey also showed that 49% of Black adults consider COVID-19 a major threat to their personal health, compared with 26% of White adults (Funk & Tyson 2021). While encouraging, these results indicate that there is still more work to be done to improve intention to vaccinate among a substantial proportion of the population. They also suggest that equitable access, rather than attitudes, may be a greater barrier to immunization for communities of color.

Given the size of the US and the wide range of cultural beliefs, political leanings, scientific understanding, levels of trust in government leaders and agencies, and perceived motives of pharmaceutical companies, a one-size-fits-all vaccine rollout effort will not succeed. Thus, to ensure the implementation of an equitable COVID-19 immunization program, evaluations of program effectiveness must address the values and needs that affect vaccination intention and uptake among specific communities. Thus, the effectiveness of a given vaccination effort is inextricably linked to drivers of vaccine hesitancy within the community. Determining which outcomes of importance should be included entails a complex effort that amplifies community perspectives and involves key stakeholders such as public health scientists, US policymakers, federal, state, and local public health officials, private funders, and professional and community organizations.

To measure potential drivers of vaccine hesitancy in the context of COVID-19, high-level health organizations such as WHO and the Centers for Disease Control and Prevention (CDC)

have worked to develop questionnaire items for a common survey tool that can be used globally to allow comparability across countries such as WHO's Vaccine Hesitancy Scale (Shapiro et al., 2018) . The WHO Vaccine Hesitancy Scale has been scientifically validated with relation to other non-COVID-19 vaccines (Shapiro et al., 2018; Luyten et al., 2019; Domek et al., 2018). Most recently, the WHO developed the Behavioral and Social Determinants (BeSD) for Vaccination Framework, which measures factors affecting vaccine uptake (WHO, 2018). The aim of the BeSD is to provide a tool that can be used during immunization program evaluations that can track consistent and comparable data over time (WHO, 2018). Since it was intended specifically for high-income countries, the BeSD was largely developed under the assumption that equitable access was already achieved (Brenner et al., 2020) and has yet to be tested or validated in the context of COVID-19.

Given the complex nature of vaccine hesitancy and the novelty of COVID-19 vaccines, it is likely that these tools are not sufficient to capture key/important outcomes for measuring the effectiveness of COVID-19 vaccination efforts. Tools which measure outcomes that are meaningful to low-income, underserved communities are needed to assess the true scope of effectiveness of COVID-19 vaccine rollout efforts.

1.2 Reflexivity Statement

Since November 2020, I have served as a Research Analyst for the COVID-19 Community Research Partnership (CRP) Study, a CDC-funded study conducted at the University of Maryland, Baltimore School of Medicine in the Center for Vaccine Development. In this capacity, I have reached out to and worked with various community groups throughout Baltimore City. One such group included Sisters Together and Reaching, Inc. (STAR), a faith-based community advocacy organization which aims to advocate and provide optimal health and

wellness to the underserved and at-risk minority communities in Baltimore City. STAR deploys Community Health Workers to mitigate poor health outcomes in these communities for individuals living with chronic disease, addiction or substance abuse and mental health issues. Through my work with the CRP study, I have tracked the COVID-19 vaccine coverage throughout Baltimore City for over a year. Early on, I observed that major disparities in vaccination uptake were forming between neighborhoods that were right next to each other. As shown in Figure 1, in February 2022, over a year after the initiation of COVID-19 vaccine implementation, vaccination uptake in Baltimore City ranged from a 20% to 104% (Baltimore City Health Department, 2022). What was even more jarring was how closely neighborhoods with "high" vaccination uptake (i.e., >50% uptake) and "low" vaccination uptake (i.e., $\leq$50% uptake) aligned with high-income neighborhoods and low-income neighborhoods, respectively (Figure .11). Similarly, neighborhoods with lower vaccination uptake and lower income align closely with neighborhoods consisting of a higher proportion of Black and/or African Americans. These observations suggest that vaccination uptake may be affected by structural or systemic drivers such as poverty in Baltimore City. As such, this research presents an opportunity to investigate and address an important issue in the field of social justice as it aims to highlight and amplify the voices and concerns of individuals that may not be receiving equitable opportunities, access to resources, and benefits of the COVID-19 vaccines.

Community-based participatory research (CBPR) is a collaborative process that aims to eliminate health disparities through equitable community-academic partnerships and engagement. As this dissertation work requires a collaborative approach to research that equitably involves various stakeholders throughout the research process, it aims to uphold following key principles of Community-based Participatory Research (CBPR), as defined by Israel and colleagues (1998):

- Recognizes community as a unit of identity
- Promotes a co-learning and empowering process that attends to social inequalities
- Involves a cyclical and iterative process
- Disseminates findings and knowledge gained to all partners

1.3 Problem Statement

Even before the WHO declared COVID-19 a global pandemic, scientists worldwide were working toward development of a vaccine to fight against SARS-CoV-2 (WHO, 2021). While vaccine development was a core focus of the scientific community during the first year of the pandemic, it was only half the battle when it came to real-world implementation of vaccine rollout efforts. As Walter Orenstein poignantly states, "Vaccines don't save lives. Vaccinations save lives" (Orenstein, 2019). To improve the effectiveness of vaccine rollout efforts, core concerns of community members must be addressed during implementation. Globally, instruments used to measure the effectiveness of COVID-19 vaccination rollout efforts have largely relied on general, clinical outcome measures including vaccine uptake, cases, hospitalizations, and deaths, ignoring other core concerns of target populations (Lisewski et al., 2021; Barbounakis et al., 2021; Islam et al., 2021). Measures of vaccine hesitancy have been used to predict vaccine uptake and inform the development and implementation of COVID-19 vaccination efforts, but there does not yet exist a core set of outcomes that can be used to check whether factors identified as drivers of vaccine hesitancy were sufficiently addressed during the implementation of vaccine rollout efforts and whether the rollout itself was effective.

1.4 Public Health Significance

For over two years, the COVID-19 pandemic has had devastating impacts on families, communities, and nations worldwide. In the United States, the CDC has reported vast disparities in age-adjusted rates of deaths, hospitalizations, and cases (CDC, 2020). For instance, the death

rate among Black individuals is 2–3 times higher than among White individuals (Yancy, 2020). Adverse social determinants of health, lack of institutional trust stemming from racist historical experiences, and barriers to access contribute to an increased risk of exposure, infection, and death among members of these populations (Kim et al., 2020).

Ahead of vaccine rollout in Baltimore City, the Baltimore City Health Department (BCHD) developed a detailed strategy to vaccinate residents against COVID-19 framed through the lens of health equity, "ensuring that every Baltimorean has a fair and just opportunity to get vaccinated" (Dzirasa, 2021). In this plan, the BCDH acknowledges that partners should "recognize the historical and current racism in Baltimore City, injustices within the healthcare system, and other issues that may contribute to vaccine deliberation among residents" (Dzirasa, 2021) Notably, the proposed evaluation of the BCHD strategy only includes variables of vaccine procurement, vaccine provision, and vaccine coverage. These variables were used to monitor and inform vaccine distribution and prioritization. No other discrete, measurable outcomes associated with structural, historical, or social barriers are proposed in this evaluation, highlighting a major gap in current public health practice.

To better understand community-important outcomes related to COVID-19 vaccines, this research utilizes both qualitative and quantitative methods. This dissertation applies a novel approach to developing measures to assess the effectiveness of COVID-19 vaccination efforts, specifically in low-income, minority populations of Baltimore, MD. The research applies factors of vaccine hesitancy to highlight community priorities and perspectives associated with COVID-19 vaccination efforts among low-income minority individuals in Baltimore, MD and explore how high-level researchers studying the safety, efficacy and implementation of COVID-19 vaccines can improve their instruments for this and future vaccine rollouts.

1.5 Objective and Specific Aims

Dissertation Objective

The overall objective of this proposal is to develop a core outcome set (COS) for measuring the safety, efficacy, and implementation of COVID-19 vaccines among Black/African American residents of an urban, low-income community experiencing low levels of vaccine uptake in Baltimore City, Maryland. A COS is a list of recommended outcomes comprising outcomes that are important to professionals (i.e., clinicians, scientists and policymakers) as well as community-important outcomes (Williamson, 2017). Researchers should measure and report all outcomes of a given COS if they are undertaking a research study of a particular topic (Williamson, 2017). These do not need to be the only things a researcher should measure, but rather the 'bare minimum' or 'core' set of outcomes to be measured. COS are often accompanied by a core outcome measurement instrument set, which specifies *how* outcomes should be measured and reported (Williamson, 2017). Developed in 2010, The Core Outcome Measures in Effectiveness Trials (COMET) initiative facilitates the development and application of COSs through its creation of the COMET Handbook (Williamson, 2017). The COMET Handbook provides a detailed protocol to developing a COS and will be used to guide the methodological framework of the proposed dissertation research.

Research Question

Which outcomes are of greatest importance to Black/African American communities in Baltimore, Maryland when deciding whether to receive a COVID-19 vaccine and how can they be used to support equitable distribution and uptake of vaccines in the context of the COVID-19 pandemic?

This dissertation employs both qualitative and quantitative methods across three study phases (Figure 1.3). Each phase corresponds with a separate aim of the dissertation. The first phase

explores perspectives and experiences associated with COVID-19 vaccines through semi-structured interviews with approximately 20 Black/African American community members in a low-income community in Baltimore City, Maryland (Appendices A-C). Thematic analysis and thematic network analysis are conducted. The second phase utilizes a systematic literature review (SLR) to assess the extent to which primary outcomes used in COVID-19 vaccine studies published between December 2019 and March 2022 aligned with factors of vaccine hesitancy. In this phase, factors of vaccine hesitancy are used as surrogate outcomes for "patient-important outcomes," which refer to outcomes that are meaningful to patients. Along with results from the thematic analysis conducted in Phase I, primary outcomes reported in all included studies of the SLR are used to inform the development of a candidate list of outcomes for the Delphi survey used in the third phase. The Delphi method is used to generate a level of consensus among key stakeholders regarding core outcomes associated with vaccine hesitancy and result in the development of a COS. Developed by the RAND corporation in the 1950's, the Delphi method has been used frequently in clinical and social research to generate consensus around a given topic through feedback of iterative, anonymous questionnaires (Williamson, 2017). As the Delphi method outlines, key stakeholders are defined as any individuals directly affected by an issue. Key stakeholders in this study include community members from a low-income community in Baltimore City, Maryland who identify as Black/African American, healthcare professionals, and community health workers (CHWs). At the end of two rounds of survey distribution, a consensus meeting was held with community members and community health workers to finalize the recommended COS.

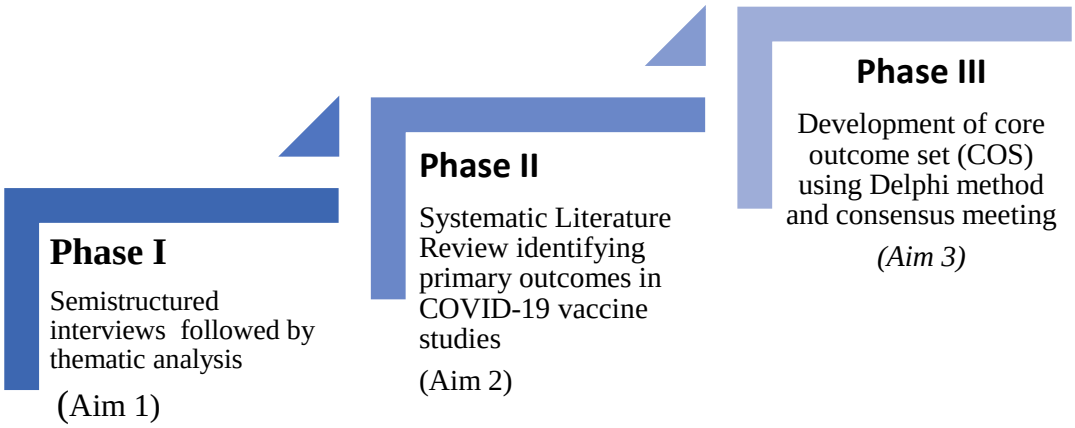


Figure 1.3. Phases of the dissertation process

Specific Aims

Aim 1. To explore perspectives and experiences regarding COVID-19 vaccines among Black/African American community members from a low-income, urban community in Baltimore City associated with low rates of COVID-19 vaccine uptake.

Aim 2. To determine the extent to which existing safety, efficacy, and effectiveness studies on COVID-19 vaccines incorporate factors of vaccine hesitancy in their list of primary outcomes

Aim 3. To generate a level of consensus among key stakeholders (i.e., community members, community health workers, healthcare professionals) of core outcomes for measuring effectiveness of COVID-19 vaccine rollout efforts among low-income, urban populations using Delphi methodology.

1.6 Theoretical Framework

Phase I & II: 3C's Model

The "3 Cs" model, first proposed by the WHO EURO Vaccine Communications Working Group in 2011, is composed of three categories: confidence, complacency, and convenience (Figure 1). In the "3 Cs" model, *vaccine confidence* is defined as trust in: (i) the effectiveness and safety of vaccines; (ii) the system that delivers them, including the reliability and competence of the health services and health professionals and (iii) the motivations of policymakers who decide on the needed vaccines. *Vaccination complacency* exists where perceived risks of vaccine-preventable diseases are low, and vaccination is not deemed a necessary preventive action. Complacency about a particular vaccine, or about vaccination in general, is influenced by many factors, including other life/health responsibilities that may be seen to be more important at that point in time. *Vaccination convenience* is a significant factor when physical availability, affordability and willingness-to-pay, accessibility, ability to understand (language and health literacy) and appeal of immunization services affect uptake. The quality of the service (real and/or perceived) and the degree to which vaccination services are delivered at a time and place and in a cultural context that is convenient and comfortable also affect the decision to be vaccinated and could lead to vaccine hesitancy (WHO, 2014). Of note, each category overlaps with the others to some extent, as shown in Figure 2.

The 3C's model will serve as the conceptual framework for Phase I of this study, informing the design and content of the semi-structured questionnaires. Thus, open-ended questions will focus on factors relating to complacency, convenience, and confidence. In Phase II, categories that make up the 3 C's model will be used to create surrogate "patient-important outcomes," known in clinical research as "characteristics or variables that reflect how a patient feels or functions" (Gaudry et al., 2017).

Phase III: Prediction Theory

Although no existing theoretical framework was used to underpin the Delphi methodology at its initial conception, numerous studies examining the procedure have coalesced to form a theoretical understanding of "predictions", ultimately producing what has been termed, "prediction theory" (Kaplan et al., 1950). McGregor (1938) studied the concept of predictions as a form of psychological inference such that "Any argument from a premise to a conclusion is an inference, and those that are expressed in the future tense are classified as predictions." Cantril (1938) and Kaplan et al., 1950 elaborated on the concept of prediction by focusing on psychological variables related to predictions, such as bias, knowledge, preference. Prediction theory suggests that the accuracy of an individual's prediction depends on a wide set of variables, including that individual's knowledge, preferences, and biases as well as the timing of the prediction (Kaplan et al., 1950). Thus, prediction theory is the theoretical framework behind the Delphi methodology (Sackman, 1974) and will be applied in Phase III to produce consensus of a COS for measuring vaccine hesitancy among a group of stakeholders.

1.7 Key Terms

Adenovirus- DNA viruses that typically cause mild infections involving the upper or lower respiratory tract, gastrointestinal (GI) tract, or conjunctiva. Rare manifestations of AdV infections include hemorrhagic cystitis, hepatitis, hemorrhagic colitis, pancreatitis, nephritis, or encephalitis (Lynch, 2011).

Core Outcome Set- A list of outcomes which key stakeholders have recommended that researchers should measure and report if they are undertaking a research study in a particular area (Williamson et al., 2017).

Coronavirus- Refers to members of the *Coronaviridae* family of viruses which often have a high pathogenicity for animals and humans and make up a class of single-stranded RNA viruses (Dhama et al., 2019).

Delphi Methodology – A methodologic protocol frequently used in clinical and social research to generate consensus around a given topic through feedback of iterative, anonymous questionnaires (RAND, 1963).

Fully Immunized/Vaccinated – Status of an individual that has received all recommended doses of a COVID-19 vaccine that has been authorized or approved by the U.S. Food and Drug Administration (FDA) or is listed for emergency use by the World Health Organization (WHO) (CDC, 2021).

Herd Immunity- A particular threshold proportion of immune individuals that should lead to a decline in incidence of infection (Fine et al., 2011).

Item - A survey question or statement, usually accompanied by response options. This is a form of quantitative data collection (WHO, 2018).

Measure - an item or set of items that provides an indication of the quantity or nature of the phenomenon under study (VandenBos, 2007).

Messenger RNA (mRNA)- a single-stranded nucleotide sequence that carries genetic information from the master molecule DNA in the form of codons (series of three bases which specifies a particular amino acid) (Mishra, 2018).

Vaccine Hesitancy-Vaccine hesitancy refers to a delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines. It is influenced by factors such as complacency, convenience and confidence (WHO, 2014).

Viral Vector-based Vaccine- Non- (or low-) pathogenic viruses that can be used to enable intracellular antigen expression and induce a robust immune response, leading to the elimination of virus-infected cells (Ura et al., 2013).

Chapter 2: Literature Review

2.1 Racial Disparities and COVID-19

To equitably allocate resources to prevent COVID-19 disease, quantification of racial, ethnic, and income disparities is critical. In the Spring and Summer of 2020, national data indicated that Blacks/African Americans, who make up13.4% of the US population, accounted for more than 24% of COVID-19 deaths (Sahin et al., 2020). During this same timeframe, Blacks made up over half of COVID-related deaths in Maryland, despite making up just 30% of the population (Maryland Department of Health, 2020). A recent study in Washington DC showed that the ratio of Black Americans in the population was a significant predictor of COVID-19 death counts (Hu, Roberts, Azevedo, & Milner, 2021). As demonstrated in Figure 1, such patterns likely persist in Baltimore City as well. In December 2021 in Baltimore City, Black/African American individuals were experiencing higher rates of COVID-19 infection and mortality than Whites, with 103.2 cases and 2.3 deaths per 1,000 reported among Blacks and 76.4 cases and 1.5 deaths per 1,000 reported among Whites (Department, 2021a).

These patterns of disparities emerged during COVID-19 vaccine rollout efforts as well. In the first few months of the national vaccine rollout, Black and Hispanic people in the United States were less likely than their White counterparts to have received a vaccine (Ndugga et al., 2020). These disparities have narrowed over time, with similar shares of adults now reporting having received at least one dose of the vaccine across racial and ethnic groups (71% of White adults, 70% of Black adults, and 73% of Hispanic adults) (Ndugga et al., 2021). However, due to a lack of accurate race and ethnicity reporting across states, these numbers may not accurately indicate the true scope of the matter.

By November 2021, race/ethnicity data were known for only 63% of people (adults and children) who had received at least one dose of the vaccine (Ndugga et al., 2021). At that time, CDC did not publicly report state-level data on the racial/ethnic composition of people vaccinated (CDC, 2021). Overall, across 43 states that were collecting data on race and ethnicity, 56% percent of White people had received at least one COVID-19 vaccine dose, similar to the rate for Hispanic people (54%) but higher than the rate for Black people (49%) (Ndugga et al., 2021). Collecting comprehensive standardized data across states is vital to monitor for equitable vaccine uptake.

Achieving high vaccination rates across communities is critical for maintaining broad protection from COVID-19. In turn, this will mitigate the disproportionate impacts of the virus on people of color and prevent existing racial health disparities from widening further (Ndugga et al., 2021). To this end, the CDC (2021) has indicated that vaccine equity is an important goal, with equity defined as "preferential access and administration to those who have been disproportionately affected by COVID-19."

Importantly, vaccine hesitancy is a significant barrier to vaccine uptake, and consequently, equitable vaccine coverage among communities (Willis, 2021). Vaccine hesitancy refers to a broad spectrum of attitudes and behaviors ranging from complete refusal of a vaccine to delayed uptake of the vaccine (WHO, 2014). A Pew survey conducted in 2021 showed that 49% of Black adults consider COVID-19 a major threat to their personal health, compared with 26% of White adults (Ndugga et al., 2021), indicating that there is still a need to improve intention to vaccinate among a substantial proportion of the population. These findings also suggest that equitable access, rather than attitudes, may be a greater barrier to immunization for communities of color (Ndugga et al., 2021).

2.2 Social Determinants of Health and COVID-19

The World Health Organization defines the term "social determinants of health" (SDOH) as "the conditions in which people are born, grow, live, work, and age that are shaped by the distribution of money, power, and resources at global, national, and local levels and are mostly responsible for health inequities (i.e., disparities, or the unfair and avoidable differences in health status seen within and between countries.)" (WHO, 2021). Communities characterized by low socioeconomic status, high housing density, and poor access to healthy foods (i.e., adverse SDOH) such as those experiencing homelessness and/or unemployment have similarly suffered increased risk of COVID-19 exposure, infection, and poorer health outcomes (Yancy 2020).

Structural barriers contribute to significant COVID-19-related health disparities among Black/African American communities. For instance, in the early weeks of the pandemic, testing and diagnoses were critical to surveillance and effective mitigation of disease transmission (Kim et al., 2020). However, with only a limited supply of COVID-19 tests, states were forced to control the number of individuals getting tested. To this end, different states implemented a variety of policies and programs, such as requiring physician prescriptions or referrals for testing, providing "drive-thru" testing for individuals who had access to a vehicle, or charging money for COVID-19 tests (Kim et al., 2020). Given that previous literature has shown that Black/African American populations are less likely to have health insurance and a primary care physician and more likely to rely on public transportation than on a personal vehicle, these policies and programs laid the groundwork for the disparities in COVID-19 morbidity and mortality we see today (Kim et al., 2018). Additionally, at the start of the pandemic, CDC recommendations indicated that exposed or symptomatic individuals waiting for COVID-19 test results should quarantine themselves until their results came back, potentially preventing individuals from going to work or school for up to

10 days (CDC, 2020). This was understandably disproportionately impactful on low-income groups that simply cannot afford to miss school or work. Such quarantine may have deterred members of low-income populations from even getting tested in the first place. The United States' inability to provide free and accessible testing to many of its citizens in the early months of the pandemic set the stage for continued systematic failures for many of the nation's underserved communities. To reduce risk of exposure to the virus, patients with non-COVID-19 health problems opted to avoid healthcare facilities (Kim et al., 2018). Patients from Black/African American communities including racial and ethnic minorities have been shown to have an increased prevalence of common, non-COVID-19 health conditions compared to non-Hispanic Whites, and a high percentage of them have undiagnosed non-COVID-19 health conditions, putting them at greater risk of COVID-19 itself. (Kim et al., 2018).

In March 2020, behavioral recommendations such as social distancing and lockdowns, both aimed at mitigating the spread of COVID-19, forced non-essential services, travel, much of retail and commerce to shut down. The impact of these shutdowns led to massive economic hardship and unprecedented job losses particularly among those at the lower rungs of the socioeconomic ladder (Lopez et al., 2021). It was estimated that approximately one-third of all renters and homeowners could not pay their rent or mortgage (Lopez et al., 2021). Black, Hispanic, and American Indian persons are more likely to live in crowded conditions, in multigenerational households, and have jobs that cannot be performed remotely, placing them and other underserved communities at greater risk for economic, housing and food insecurity, increased crime, and excessive physical and mental health problems (Lopez et al., 2021).

In December 2019, the state of Maryland reported 2.7 million jobs. By December 2020, the state reported that approximately 124,700 jobs had been lost due to the pandemic (US Bureau

of Labor Statistics, 2020). Similarly, the Baltimore Police Department reported 180 shooting incidents as of April 4, 2020, a 2.0% increase compared to 2019 (Baltimore Police Department, 2020).

While racial disparities in health outcomes have been clearly associated with COVID-19 in the literature (Rubin-Miller et al., 2020; Kim et al., 2020; CDC 2020), it is important to note that these disparities are not due to race – a social, not biological construct. These differences in health outcomes (e.g., mortality, hospitalization, infection) are due to external drivers of disparity, including the built environment (e.g., building designs, availability of sidewalks and parks, air quality) in which communities live, quality of education, job opportunities, etc. (Dickinson et al., 2021; Hu et al., 2021). Underlying reasons for racialized health disparities can be better contextualized with a more nuanced understanding of institutional racism in America and the disparities it perpetuates. The term 'institutional racism' is used in sociology to account for "attitudes and practices that have led to racist outcomes through unquestioned bureaucratic procedures" (Murji, 2007).

2.3 Social Determinants of Health in Baltimore City, Maryland

Baltimore is a diverse city, with 62.35% of its population identifying as Black/African American, 30.46% identifying as White, 2.58% identifying as Asian and 0.32% identifying as either American Indian and Alaska Native or Native Hawaiian and Other Pacific Islander (US Census, 2019). Of those, 5.29% identify as Hispanic. American Indians and Alaska Natives are most likely to be living in poverty with 34.84% living below the poverty line followed by 25.59% of Black/African American individuals and 11.9% of Whites living below the poverty line (US Census, 2019). Of the individuals identifying as Hispanic, 22.95% live below the poverty line (US Census, 2019). In 2019, 24.2% of people in Baltimore lived below the poverty line ($23,850 for a

family of four) compared to just 9.9% of people in Maryland (US Census, 2019). Among individuals 25 years and older in the city, approximately 15% never graduated from high school and 16.75% received their bachelor's degree (US Census, 2019). According to the US Census (2019), the lowest rate of bachelor's degree attainment in Baltimore is among Blacks/African Americans at just 16.55%. Whites and Asians, on the other hand, have the highest rates of bachelor's degree attainment at 57.91% and 73.37%, respectively (US Census, 2019).

To understand how SDOH and the built environment contribute to COVID-19 related health disparities in Baltimore City, a contextual understanding of the community is required. As shown in Figure 1, poverty has become concentrated in predominantly Black/African American communities in the City while affluence has been entrenched in predominantly White communities in the City, a phenomenon known as "The Black Butterfly," in which predominantly Black/African American communities in East and West Baltimore are referred to as the "wings" of the butterfly and the predominantly White communities running through the center of Baltimore make up the body of the butterfly (Brown, 2020). Despite having over 60% of its population identifying as Black/African American (US Census, 2019), Baltimore City is often the subject of focus in published literature regarding institutional racism (McLeod 2017; Crutchfield et al., 2020). Much of the existing literature examines Baltimore's public institutions, including its systems of education, urban planning, criminal justice and healthcare (Brown, 2020; Thomas, 1976; Trounstine 2018; Western et al., 2009; Garland 2001). Structural racism, – or the "macro-level conditions that limit opportunities, resources, power and well-being of individuals and populations" (NIH, 2021) and "mutually reinforcing systems of housing education, employment, earning, credit, medical, and criminal justice" (Bailey et al., 2017) - institutional racism, and the

resulting adverse SDOH associated with them continue to have implications on the health of low-income, Black/African American Baltimoreans.

In healthcare, Baltimore City is home to world-class medical research institutions including the Johns Hopkins Hospital. For decades, people living in East Baltimore's poorest neighborhoods surrounding Johns Hopkins Hospital have voiced distrust and unease with the institution (Goold et al., 2002). In 2001, the Baltimore Court of Appeals likened a lead paint study conducted by researchers from Johns Hopkins Bloomberg School of Public Health to the Tuskegee Syphilis Study; the study was conducted in East Baltimore in which more than 100 families were incentivized to live in homes with varying levels of lead reduction to determine whether cheaper methods of containing lead would keep the toxin out of children's bodies (Farfel and Chisolm, 1990; *Grimes vs. Kennedy Krieger Institute Inc,* 2001*)*. The court found that researchers failed to warn families of the health risks of living in the homes and that the researchers did not inform the families of elevated blood-levels in a timely fashion (*Grimes vs. Kennedy Krieger Institute Inc,* 2001). The resulting distrust among Black/African American Baltimoreans in the healthcare systemd has been compounded by other incidents in Baltimore's history including the failure of the biomedical community to acknowledge Henrietta Lacks, an African American woman, as the source of an invaluable research cell line developed at Johns Hopkins University (Nguyen et al., 2021). The repeated calling into question of ethics, trust and respect in the healthcare system has left some of the poorest communities in Baltimore with justified skepticism and mistrust of healthcare institutions and medical professionals in the area.

These instances of institutional racism in Baltimore City provide insight into how some local communities continue to experience poor social determinants of health and may - understandably so - be suspicious of, and mistrust, the intentions of medical and public health

personnel. As shown in other studies, this type of racism exists, affecting social, institutional and cultural domains that all interact and reinforce one another, perpetuating health inequities throughout the City (Dickinson et al., 2021).

2.4 Implications of Social Determinants of Health on Vaccine Uptake

Adult immunization rates for other vaccines (e.g., seasonal influenza) remain suboptimal, especially among Blacks/African Americans (Groom et al. 2014; Quinn et al, 2019). There is a persistent racial disparity in influenza immunization rates where Black/African American adults are significantly less likely to be vaccinated than White adults (Centers for Disease Control and Prevention (CDC), 2016). During the 2015-16 influenza season, only 37% percent of Black/African American adults were immunized, compared to 45% percent of White adults (CDC, 2016).

Existing literature suggests that no single factor is responsible for the observed racial differences in vaccination; instead, it appears that multiple pathways function simultaneously to contribute to differential vaccine uptake (Quinn et al., 2016), underscoring the real threat of structural and institutional racism in the United States. Racially comparative studies have identified several key factors that are significantly different between racial groups, and contribute to lower uptake among African Americans, including: vaccine attitudes and beliefs (Harris, et al., 2006; Lindley, et al., 2006; Wooten, et al., 2012); knowledge (Lindley et al., 2006); access to vaccinations (Lee, et al., 2009; Lin et al., 2006); trust in health care providers and vaccines (Quinn et al., 2017; Musa et al., 2009; Quinn et al., 2009) risk perception (Quinn et al., 2017); and racial discrimination (Bleser, et al., 2016). Variables including age, health status, and socio-economic status (SES) have also been shown to be significant factors in vaccine uptake (Nagata et al., 2013; Yeung, et al., 2016).

Studies that have focused exclusively on vaccination among the Black/African American adult population identified salient concerns among members of these communities. For instance, Cameron et al. (2009) found that fear of vaccine side effects was common among older Blacks/African Americans, and that fear and anxiety contributed to lower vaccine uptake. Similarly, in focus groups, older Blacks/African Americans related concerns about vaccine safety and efficacy that were exacerbated by a sense of mistrust towards the health care system (Wray et al., 2007).

Several studies have found a significant correlation between SES and vaccine uptake; as education and income increase, the likelihood of receiving a flu shot also increases (Linn, et al., 2010; Mulinari et al., 2018). Patients who regularly see a provider are also more likely to be vaccinated, as are adults with comorbid conditions (Yeung et al., 2016).

Evidence of health care providers' differential treatment of Blacks/African Americans has been shown to be a substantial factor in vaccine uptake (Williams & Wyatt, 2015). Previous research indicates that a lack of ethnic diversity and cultural competence among physicians and medical researchers is a major contributor to Black/African American mistrust of medicine, and likely influences the lack of representation among Black and Latinx populations in clinical trials (Nguyen et al., 2021).

In one study examining vaccine hesitancy toward COVID-19 vaccines among African Americans, participants cited "concerns about the safety of a potential COVID-19 vaccine" as a reason for believing vaccine development was rushed and therefore unsafe (Momplaisir et al., 2021). Participants linked concerns around the vaccine's safety and efficacy to the safety of vaccines in general, offering the influenza vaccine as an example of a vaccine they perceived as ineffective and carrying the risk of actual infection (Momplaisir et al., 2021). Participants also

expressed considerable and well-founded mistrust of the medical establishment, scientific research communities, and pharmaceutical companies, based on their knowledge of historic mistreatment and unethical research practices that adversely impacted black patients (Momplaisir et al., 2021). Overall, prevalent health beliefs toward a COVID-19 vaccine were driven by skepticism around the way vaccines are manufactured and work, personal experiences with other vaccines, and the vaccine's ability to cause infection (Momplaisir et al., 2021). Another study on vaccine attitude among African Americans suggests that medical mistrust around COVID-19 is high and may be a barrier to the uptake of COVID-19 treatment and future vaccination among Blacks/African Americans living with HIV (Bogart et al., 2021). Mistrust was widespread across the sample, most of whom were sexual minority individuals, and did not significantly vary by most sociodemographic characteristics—although those with less than a high school education showed higher mistrust (Bogart et al., 2021). Moreover, those who had higher levels of medical mistrust around the COVID-19 government response, as well as around COVID-19 origins and treatment, were less willing to obtain treatment or a future vaccine (Bogart et al., 2021).

2.5 Theoretical Frameworks for Vaccine Hesitancy

High vaccine uptake rates are needed for community-level immunity to be achieved and sustained. In the past decade, small, geographic clusters have been associated with outbreaks or resurgence of measles, mumps, Haemophilus influenzae b, pertussis and polio in countries where these diseases had previously been controlled (Salmon et al., 2015). In the context of COVID-19, even in geographic regions with overall high vaccine uptake rates, clusters where the rates of uptake are lower than required, may leave communities which reside in those clusters at greater risk for infection, hospitalization, and death (Mollalo & Tatar, 2021).

To evaluate the effectiveness of vaccination efforts, an improved understanding of issues pertaining to community concerns regarding vaccines and vaccination and how these factors vary among different communities or subpopulations is required (Salmon et al., 2015). Standardized measurement tools that specifically address community-level concerns would facilitate a more contextualized, effective quantification of vaccine hesitancy. To date, several conceptual models have been developed to provide a framework for such measurement tools.

2.5.1 The "3 C's Model"

The World Health Organization's Strategic Advisory Group of Experts (SAGE) on Immunization defines vaccine hesitancy as "a delay in acceptance or refusal of vaccines despite availability of vaccination services". Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines. It is influenced by factors such as complacency, convenience, and confidence (3 C's)" (WHO, 2014).

In the "3Cs" model, "Complacency" exists where perceived risks of vaccine-preventable diseases are low, and vaccination is not deemed a necessary preventive action (WHO, 2014). Complacency about a particular vaccine or about vaccination in general is influenced by many factors, including other life/health responsibilities that may be seen to be more important at that point in time (WHO, 2014). Self-efficacy (the self-perceived or real ability of an individual to take action to vaccinate) also influences the degree to which complacency determines hesitancy (WHO, 2014).

"Convenience" is measured by the extent to which physical availability (i.e., supply), affordability and willingness-to-pay, geographical accessibility, ability to understand (language and health literacy) and appeal of immunization programs affect uptake (WHO, 2014). The quality of the service (real and/or perceived) and the degree to which vaccination services are delivered at

a time and place and in a cultural context that is convenient and comfortable also affects the decision to be vaccinated and could lead to vaccine hesitancy (WHO, 2014).

"Confidence" is defined as trust in: 1) the effectiveness and safety of vaccines; 2) the system that delivers them, including the reliability and competence of the health services and health professionals; and, 3) the motivations of the policy-makers who decide on the needed vaccines (WHO, 2014).

In developing the "3 C's Model", the SAGE Working Group assessed several existing conceptual models for understanding and grouping of vaccine hesitancy determinants (WHO, 2014). Models were considered and reviewed for complexity and global applicability (WHO, 2014). Their factors were considered and assessed for potential usefulness in informing the development of vaccine hesitancy indicators, survey questions and interventions for use at the global and country levels (WHO 2014). Thus, the key constructs of complacency, convenience, and confidence provide broad enough definitions to include a wide scope of causes for hesitancy and applicability among many different communities worldwide.

That being said, the SAGE Working Group acknowledges that, "While most of the current research on predictors of vaccine hesitancy focus on social and cognitive factors, too narrow a research approach may constrict the spectrum of potential strategies conceived to address vaccine hesitancy at the individual, community and population levels." (WHO, 2014). While vaccine hesitancy studies can be identified in all regions, studies focusing specifically on low- and middle-income communities within high-income countries are particularly scarce, suggesting that existing evidence does not sufficiently measure concerns and needs of Black/African American communities as they relate to vaccines and vaccinations.

2.5.2 Theories of Health Behavior

Health behavior change theories have been used in the vaccine hesitancy literature to understand the range of possible factors that could promote vaccine uptake by decreasing vaccine hesitancy (Kenzig & Mumford, 2021). Several behavior change theories that have been used to understand the mechanisms of health behavior change in the context of vaccine hesitancy include the Theory of Reasoned Action/Theory of Planned Behavior (TRA/TPB), the Health Belief Model (HBM), and Transtheoretical Model (TTM) (also known as Stages of Change) (Rosenstock, 1974; Prochaska & DiClemente 1982; Ajzen 1991; Bandura 1977). The theoretical constructs that have correlated with vaccine intention and/or uptake include knowledge, attitudes (specifically, perceived benefits and perceived severity or risks), cues to action, and perceived behavioral control (Schmid et al., 2017). Notably, few studies examining the impacts of these theories have been used among Black/African American communities specifically (Quinn et al., 2016).

Theory of Reasoned Action/Theory of Planned Behavior

Much of the existing literature on the connection between vaccine hesitancy and theoretical constructs focuses on behavioral intention (i.e., intention to vaccinate), which is rooted in the Theory of Reasoned Action (TRA). Within TRA, constructs of attitudes and subjective norms precede intention, which ultimately leads to behavior. The Theory of Planned Behavior (TPB), differs from TRA only in that perceived control also immediately precedes to intention on the causal pathway (Ajzen & Fishbein, 1985). Xiao & Wong (2020) found that individual cognitive attitudes related to the risks and benefits of vaccines were significantly correlated with intention to vaccinate (Xiao & Wong, 2020). Subjective norms, which are developed from both normative beliefs (i.e., beliefs about the normative expectations of other people) as well as motivation to comply, have also been successful in promoting vaccination in developing countries (Jarrett et al.,

2015). Several studies on parental vaccine hesitancy have shown promise in leveraging the beliefs and attitudes of parents who vaccinate to counter vaccine hesitancy and refusal and to promote vaccination as a social norm (Schoeppe et al., 2017; Colorado Parents for Vaccinated Communities, 2017).

The Health Belief Model

The Health Belief (HBM) focuses almost exclusively on cognitive influences on behaviors and was originally developed to explain preventive health behaviors including immunizations (Rosenstock, 1974). Perceived threat of disease (as determined by perceived susceptibility and perceived severity of disease), self-efficacy (i.e., the level of a person's confidence in his or her ability to successfully perform a behavior), cues to action (i.e., stimulus needed to trigger the decision-making process to accept a recommended health action), and perceived benefits of action (i.e., a person's perception of the effectiveness of various actions available to reduce the threat of illness or disease) and barriers to action (i.e., a person's feelings on the obstacles to performing a recommended health action) all inform likelihood of performing the change (Rosenstock, 1974). In a study comparing the HBM to the TPB in predicting human papillomarirus vaccine uptake in young adult women, TPB consistently outperformed HBM (Gerend and Shepard 2012). Notably, however, fear-based interventions aimed at increasing perceived threat of disease have not been shown to be a significant driver of vaccination behavior, and fear-based interventions have been found to be ineffective and, in some cases, counterproductive (decreasing intent to vaccinate; Olson et al., 2020).

Transtheoretical Model (Stages of Change)

Given the large number of theories through which vaccine hesitancy has been investigated, and with no one theory currently emerging as the "best," some scientists have analyzed vaccine hesitancy using TTM (i.e., stages of change) instead (Slater 1999; Leask et al., 2012). TTM has

most commonly been used to study sustained health behavior changes such as smoking cessation, exercise, alcohol treatment, and weight control (DiClemente et al, 1991; Marcus et al., 1992; DiClemente & Hughes, 1990; O'Connel & Velicer, 1988).

The stages of change theory provides a conceptual framework for understanding the process of behavior change, where behavior change occurs in five cyclical, not necessarily contiguous, stages: precontemplation (not considering change), contemplation (considering change), preparation (preparing to modify behavior), action (successful behavior change), and maintenance (maintaining changed behavior) (DiClemente & Velasquez, 2002). The theory anchors behavioral intent to vaccinate along each stage and identifying which theoretical constructs are most relevant to where individuals are in the behavior change process (Slater, 1999). In the field of vaccine hesitancy, TTM has predominantly been used to assess Human Papillomavirus (HPV) vaccine uptake (Chang 2014; Paiva et al., 2014), and to inform interventions which promote HPV vaccine uptake (Aldossri et al., 2021). These studies show that individuals in the pre-contemplation phase have the lowest self-efficacy and that those in the maintenance phases usually have the highest (Chang 2014; Paiva et al., 2014; Aldossri et al., 2021). Thus, interventions which aim to improve self-efficacy may be the most effective.

2.6 Critical Race Theory and Public Health Critical Race Praxis

A growing body of public health literature aims to advance understandings of racism as a SDOH and explore the relationships between racism and observed health disparities. Critical Race Theory (CRT) refers to a "decentralized movement among scholars, researchers and activists that coheres around a set of tenets regarding racialization, marginalization, and the role of critical race theorists in producing knowledge about societal inequities." (Delgado & Stefancic, 2017). CRT comprises four core tenets including: (i) racialization [i.e., understanding how socially constructed

racial categories dictate or affect the ordering of groups in society (Brown et al., 2023)] , (ii) social location [i.e., an individual's position within a social hierarchy (Mullings & Schulz, 2006)], (iii) race consciousness [i.e., acknowledgement of racial dynamics at an individual- and social-level(Ford & Airhihenbuwa, 2010)] and (iv) an aim to eliminate racial inequities (Ford & Airhihenbuwa, 2010). Since the 1980's, CRT has been applied frequently in academic investigations involving racialized exposures, populations, covariates and/or outcomes (Ford & Airhihenbuwa, 2010). However, given the legal origins of CRT and the complexities associated with proper methodological application, scientific public health studies are often unable to truly uphold all four core tenets of CRT, a key component of legitimate CRT application. Public Health Critical Race praxis (PHCR) was developed to facilitate public health researchers in carrying out health equity research while remaining grounded in CRT.

PHCR applies CRT in a way that upholds scientific standards for rigor while drawing on the vast amount of CRT-associated literature produced in fields outside of public health (Ford & Airhihenbuwa, 2010). PHCR offers a structured methodology that combines theory, experiential knowledge, and activism to eliminate health inequities in a process that applies four areas of "focus:" (i) Contemporary patters of racial relations (i.e., describing characteristics of the existing racial hierarchy); (ii) Knowledge production (i.e., identifying disciplinary norms that may unintentionally bias results derived from the research); (iii) Conceptualization and measurement (i.e., deciding how to operationalize key concepts while accounting for the implications); and (iv) Action (i.e., apply knowledge gained to determine which actions need to be taken to eliminate inequities) (Ford & Airhihenbuwa, 2010).

2.7 Conclusion

Thus far, vaccine hesitancy research has utilized a number of behavior change theoretical models which have centered on individual attitudes, beliefs and internal thought processes. However, it can be said that these theories, while relevant to a point, may limit the scope of understanding we stand to gain regarding effectiveness of vaccine rollout efforts, particularly among Black/African American populations, and do not sufficiently convey community-level concerns or needs. The "3 C's" framework provides broader constructs that attempt to incorporate social and contextual factors and potentially capture the wider scope of vaccine hesitancy.

In Baltimore, Maryland, a diverse city with a unique history of institutional racism and resulting adverse social determinants of health and health disparities, the COVID-19 pandemic has disproportionately affected Black/African American communities, particularly communities of color. In addition to a delay in vaccine acceptance among Black/African American communities at the start of the pandemic, clusters of low vaccination rates persist in the City (Baltimore City Health Department, 2021). To better understand the concerns around COVID-19 vaccines among those hit hardest by this pandemic, it is critical that local public health scientists utilize systematic methodology to elicit, assess, and prioritize the needs of those they aim to serve. The systematic nature of this technique would facilitate its replication in other instances of pandemic preparedness and response efforts. With the generation of specific outcomes of importance among Black/African American communities, public health practitioners can more effectively implement interventions to serve those communities. It is, after all, vaccination, not just vaccines, that save lives.

Chapter 3: "It's like a luxury even though it's free": Perspectives on COVID-19 vaccines among Black/African American Adults in East Baltimore

3.1 Abstract

Background: In December 2021, approximately one year after COVID-19 vaccines were first rolled out in the US, disparities in COVID-19 vaccine uptake were observed across neighborhoods in Baltimore City, Maryland. To understand why these disparities persist in Baltimore City, this study employs qualitative methods to explore the process by which residents in a low-income, predominantly Black community decided whether to receive a COVID-19 vaccine.

Methods: Semi-structured interviews were conducted with residents of a low-income, predominantly Black community with approximately 40.0% COVID-19 vaccination uptake as of December 2021. Data were analyzed using inductive thematic analysis. Subgroup analyses comparing vaccinated and unvaccinated participant responses as well as thematic network analysis were also conducted.

Results: Four predominant themes emerged relating to COVID-19 vaccine uptake decision making: (I) Safety and efficacy of vaccines, (II) Perceived importance of COVID-19 vaccines in relation to pre-existing community needs, which was divided into two subthemes, a) Environmental injustice and (b) Personal health concerns, (III) Access to trustworthy, understandable information, and (IV) Physical access to vaccines. Participants acknowledged that physical availability of COVID-19 vaccines was not a major barrier to uptake, however concerns related to finding trustworthy and understandable information, particularly about the safety and efficacy of the vaccines were common areas of concern. "Trusted sources of information" was a major component of decision-making and was associated with all emergent themes.

Conclusion: Participants' views of the importance of getting a COVID-19 vaccine, in relation to other important needs or demands in their daily lives, elicited important social and contextual

factors specific to this community and others like it. Public health researchers should empower trusted sources of information for members of this community, including other community members, community healthcare workers and community leaders to collaborate on effective solutions to reduce disparities in vaccine uptake.

3.2 Background

Since the World Health Organization declared COVID-19 a global pandemic in March 2020, the US has recorded over one million COVID-19 related deaths (WHO, 2022). Despite having had three safe and efficacious COVID-19 vaccines approved for emergency use by the U.S. Food and Drug Administration by February 2021 (Oliver et al., 2021; Self et al., 2021; Sharifian-Dorche et al., 2021), the US continues to experience high rates of COVID-19 infections and COVID-19 related deaths (WHO, 2022). To better understand why some communities experience lower levels of vaccine uptake than others, vaccine hesitancy – the unwillingness to be vaccinated against a disease, even if proven safe and effective (Alcendor, 2021) – has been studied among many communities in the US (Beshears, Choi, Laibson, Madrian, & Reynolds, 2016; W. S. Chou & A. Budenz, 2020; Famuyiro, Ogunwale, des Bordes, & Raji, 2021; Fisher et al., 2020; Fridman, Gershon, & Gneezy, 2021; Hsieh, Rak, SteelFisher, & Bauhoff, 2022; Khubchandani et al., 2021).

As described by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Working Group on Vaccine Hesitancy, "Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines. It includes factors such as complacency, convenience and confidence. "(MacDonald & Hesitancy, 2015). A depiction of these factors can be found in the SAGE Working Group's "3C's Model" (Figure 1.2), which describes "confidence" as trust in various attributes of the vaccine, "complacency" as when perceived risks of the disease are low and vaccination is not perceived as necessary for health, and "convenience" as physical

availability, affordability, accessibility, understandability of information about the vaccines (e.g., health literacy) (MacDonald & Hesitancy, 2015). As suggested by Quinn et. al (2016), the 3C's Model incorporates broader, more contextual factors than other theoretical models of vaccine hesitancy, allowing for the assessment of a wide ranging set of factors (Quinn, Jamison, Musa, Hilyard, & Freimuth, 2016).

Recent studies have proposed that vaccine hesitancy be perceived as a decision-making process, rather than a degree of willingness, that is affected by the context in which it is taking place (Peretti-Watel, Larson, Ward, Schulz, & Verger, 2015). Although factors of vaccine hesitancy contribute to how individuals arrive at a decision to get vaccinated or not, the factors themselves often derive from community-level or environmental factors (Salmon, Dudley, Glanz, & Omer, 2015). Subtle or nuanced concerns among members of a given community may play a substantial role in vaccine uptake decision-making. As such, it is critical that context-specific factors that may contribute to disparities in vaccine uptake be understood. In doing so, the needs and concerns of community members are placed at the center of public efforts, facilitating strong collaboration and partnerships between public health practitioners, researchers, and community members.

In Baltimore City, Maryland, disparities in vaccine uptake have been observed across neighborhoods. By December 2021, some neighborhoods in Baltimore experienced vaccination rates of over 90% while other neighborhoods, primarily in East and West Baltimore, experienced vaccination rates as low as 20% (Figure 1.1, Appendix D) (Department, 2022b). COVID-19 cases, hospitalizations and deaths surged in early January 2022 (Department, 2022a), suggesting that although the City had achieved high vaccination status overall, much of the disease burden may have fallen onto communities with low vaccine uptake. Notably, many of the neighborhoods reporting greater than 95% coverage, such as Inner Harbor/Federal Hill, Mt. Washington, and Fells

Point are located in central Baltimore and composed of primarily high-income, White populations (Figure 1.1, Appendix A) (Department, 2022c). In contrast, many neighborhoods reporting less than 40% coverage, such as Sandtown/Winchester, Midway/Coldstream, and Franklintown, were located in East and West Baltimore and were composed of primarily low-income, Black populations (Department, 2022c).

Baltimore City is Maryland's poorest city, with 21.1% of its residents - and 25.6% of its Black residents - living below the poverty line (U. S. C. Bureau, 2020). Non-Hispanic Black individuals account for a majority of the population (62.8%) and non-Hispanic White individuals account for 27.7% (U. S. C. Bureau, 2020). As evidenced by other disparities in COVID-19 vaccine uptake observed throughout the country, different communities face different challenges and/or harbor different beliefs regarding COVID-19 vaccines (Ritu Agarwal et al., 2021; B. P. Murthy et al., 2021). Studies have shown these disparities to be associated with region of residence (urban/rural), socioeconomic status, political ideology, and race/ethnicity, among other demographic characteristics (Ritu Agarwal et al., 2021; Hughes et al., 2021; B. P. Murthy et al., 2021; Reitsma et al., 2021). Importantly, structural racism, defined as inequitable access to goods, services and opportunities among racial groups, has played a critical role in generating disparities associated with these demographic characteristics (Zeng et al., 2022).

Studies assessing vaccine uptake in the context of other vaccines have identified patterns of racial disparities: For example, in 2016, a study found that African American adults were significantly less likely to be vaccinated against influenza than White adults (Quinn et al., 2016). In 2019, a study on Human Papillomavirus (HPV) vaccine uptake found that while minorities were more likely than Whites to initiate HPV vaccination, they were less likely than Whites to adhere to the full series (Spencer, Calo, & Brewer, 2019). Another study examining maternal influenza vaccine uptake in 2019 found that non-Hispanic Black women had 19% lower odds of receiving a

provider recommendation for influenza vaccine during pregnancy and were 30% less likely to receive an influenza vaccine during pregnancy, compared with their White counterparts (Arnold, Luong, Rebmann, & Chang, 2019).

In the context of COVID-19 vaccines, Blacks and Hispanics across the US have been less likely than Whites to receive a COVID-19 vaccine, though these disparities have narrowed over time (Nambi Ndugga, 2022). However, studies have also shown that willingness to receive a COVID-19 vaccine among Black and Hispanic individuals has increased faster than that of White people (Padamsee et al., 2022). These findings, coupled with national data demonstrating that lower income individuals are less likely than those of higher income to become vaccinated against COVID-19 (Tyson, 2021), suggest that reasons for racial and socioeconomic disparities in vaccine uptake are not yet well understood.

Few studies have examined the reasons for observed patterns of COVID-19 vaccine uptake disparities in urban, low-income cities across the United States and, to date, there have been no studies examining this phenomenon in Baltimore City (Abedi et al., 2021; Zeng et al., 2022) Greater insight into the perspectives and experiences of Black residents in low-income neighborhoods with low vaccination uptake would inform the development and implementation of tailored interventions and services for the benefit of the community, both in Baltimore City and across the country in comparable communities with similar semi-urban, mid/low socioeconomic status. To fill this gap, this study employs qualitative methods to understand the process by which residents in a low-income, predominantly Black community decided whether to receive a COVID-19 vaccine. In doing so, this research aims to better understand why such disparities persist in Baltimore City.

3.3 Methods

3.3.1 Sampling Frame Description

To understand community members' perspectives on and experiences with COVID-19 vaccines in Baltimore City, Maryland, semi-structured interviews were conducted. Community members were recruited at the McElderry Park Community Center (MPCC) in East Baltimore. The MPCC is located within the Madison/Eastend community statistical area (CSA). The Baltimore City Department of Planning develops CSAs by combining demographic statistics and geographic locations collected from the Census Bureau in ways that match Baltimore City's social and contextual understanding of community boundaries (Department, 2017). In Madison/Eastend CSA, COVID-19 vaccine uptake was recorded at 39.0% in December 2021 (Figure 2) and 49.9% by August 2022. The median household income in Madison/East End is $27,454 with 45.2% of families living in poverty and over a quarter of individuals aged 16 years or older unemployed (Department, 2017). Approximately 90% of the population is Black and/or African American (Appendix A). The Baltimore City Health Department estimates that 40% of the CSA is covered by food deserts (areas characterized by poor access to healthy, affordable foods) and that 1,744.4 buildings remain vacant per 10,000 housing units (compared with 562.4 vacant houses per 10,000 housing units across Baltimore City) (Department, 2017). The most common illnesses among community members in the CSA include chronic diseases such as heart disease and cancer, drug- and/or alcohol-induced illnesses, and HIV/AIDS (Department, 2022c).

3.3.2 Recruitment

Using purposive sampling methods, community members were invited to participate in semi-structured, in-depth interviews. Community health workers (CHWs) from Sisters Together and Reaching (STAR), a community- and faith-based organization that aims to address inequities

in health and social services to African American women and their families in Baltimore City, assisted with recruitment. STAR has a longstanding presence in the community and its CHWs interact with community members daily.

While advertising a STAR-sponsored HIV testing clinic held at MPCC, CHWs walked around the neighborhood and handed out study flyers (Appendix B) that included a description of the study, compensation information, and a QR code with a link to an online screening questionnaire. Interested community members scanned the QR code on their mobile device and completed the screening questionnaire via Qualtrics. Eligibility criteria assessed in the screening questionnaire included identifying as African American and/or Black, residing in Madison/Eastend in Baltimore City, and being at least 18 years of age (Appendix A). Other demographic variables such as education level and income were gathered in the screening questionnaire but were not regarded as inclusion/exclusion criteria.

To ensure perspectives from vaccinated and unvaccinated community members were both represented, quota sampling was employed such that approximately equal numbers of vaccinated and unvaccinated participants were recruited (e.g., n=10 vaccinated participants and 10 unvaccinated participants, +/- 2 participants). Similarly, to ensure representation among male and female genders, approximately equal numbers of self-identifying males and females were recruited. Quota sampling was not applied to other demographic variables as members from the community were likely to experience similar levels of education and income. CHWs assisted community members in completing the online screening questionnaire on their mobile devices. Completed screening questionnaires were reviewed by the Principal Investigator of the study. Eligible participants were contacted via phone or invited to participate in the study.

3.3.3 Ethics

All participants provided informed consent to participate in the study. An institutional review board (IRB) approved the qualitative phase of this work at University of Maryland College Park. To enroll in our qualitative study, all participants were asked to sign an informed consent form upon arrival for the semi-structured interviews. Consent forms were provided to all participants on a tablet and read out loud to the participant prior to data collection. All participants were informed that participation was voluntary and that they were allowed to skip any questions or end the interview at any time. To protect confidentiality, all interviews were conducted in a private room at the MCPP CHWs remained at the MCPP to facilitate interviews, if needed.

3.3.4 Data Collection

The 3C's Model provided a framework from which the semi-structured interview guide was developed. Each construct of the model informed the development of several open-ended questions aimed at exploring participant's decisions about COVID-19 vaccination (Appendix C). Prior to recruitment, the interview guide was pilot tested among six STAR CHWs. CHWs were asked to review the questions and provide comments on four criteria: (i) comprehensibility of the question (e.g., ambiguity in phrasing, unknown terminology, overly complex language); (ii) ability to recall event (e.g., whether the question is asking for something overly specific or too long ago); (iii) biased question phrasings (e.g., leading questions), and (iv) acceptability of questions (e.g., whether a question made the respondent uncomfortable or upset). The CHWs were asked to pilot test the questions because they are members of the same community, regularly interact with community members, and have conducted interviews, support groups, and focus groups themselves with community members. Any suggestions or changes were addressed in the final interview guide. This final version was again reviewed by STAR CHWs prior to recruitment.

Interviews were conducted at MCPP in March 2022 in a private room in the community center. A CHW was present at the MCPP to facilitate, if needed. Four interviews were held on a separate day at STAR headquarters in East Baltimore, depending on participant preference and availability. Each interview was recorded using a digital voice recorder and lasted approximately 30-45 minutes. Interviews were subsequently transcribed into a Word document.

3.3.5 Data Analyses

Data were analyzed using inductive thematic analysis. Thematic analysis is a method for systematically identifying, organizing, and interpreting themes across a data (Braun & Clarke, 2006). The thematic analysis took an inductive approach, deriving concepts and themes from the content of the raw data. This research did not aim to develop a theory, as grounded theory analytic methods yield, and instead aimed to identify overarching themes related to the COVID-19 vaccination decision-making processes and the relationships between them, if any. Thus, while the constructs of the WHO's 3 C's Model informed the development of the questionnaire used in the semi-structured interviews, thematic analysis of the qualitative data used no such theoretical framework.

The thematic analysis process used in this study adhered to methods outlined by Braun & Clark (2006) (Braun & Clarke, 2006). The researcher first read through each transcript, familiarizing herself with the data and noting down any initial ideas in the process. The researcher then re-read each transcript, coding relevant excerpts. Each code was entered into a "codebook" which displayed extracted data excerpts with corresponding "codes." Each excerpt was marked with the transcript number so that the researcher could refer to the raw data if needed. Because new codes emerged when each transcript was reviewed during the coding process, all transcripts were re-read and re-coded according to the final codebook structure. During the initial review of

raw data, a saturation matrix was developed (see Appendix E). Theoretical saturation is often regarded as the point at which new data no longer yields new codes (Guest, Namey, & Chen, 2020). The saturation matrix serves to visualize patterns among participants and determine whether further data collection is necessary (Kerr, Nixon, & Wild, 2010). When it was determined that saturation was achieved, related codes were collated into categories and the categories were then collated into themes (Braun & Clarke, 2006). The themes were reviewed and refined, until clear and distinct labels for each theme were generated. A subgroup analysis of the saturation matrix among vaccinated and unvaccinated participants was also conducted, following the same steps as outlined above.

To check whether the resulting themes aligned with coded extracts and account for links or relationships between themes, a thematic network analysis was subsequently conducted. Thematic network analysis is a systematic method of organizing thematic analysis of qualitative data (Attride-Stirling, 2001). While thematic analysis aims to elicit themes from a given set of raw data, thematic network analysis adds to this, systematically developing a structure of relationships among emerging themes (Attride-Stirling, 2001). Construction of thematic networks involves (i) arranging categories and themes so that categories identified during the thematic analysis are grouped with their corresponding theme; (ii)) illustrating the relationships between categories and themes such that categories function as “nodes” in a network and lines connect these “nodes” to one another if a participant expressed a relationship between categories during an interview ; and (iii) reviewing the network to verify that categories and corresponding themes aligned meaningfully while categories with other themes were either distinct or related in a way supported by the data (Attride-Stirling, 2001).

3.4 Results

Twenty eligible individuals participated in this study. Participant characteristics are represented in Table 1. Fifty-five percent of the sample was female and one participant identified as" third gender." Participant ages ranged from 25 to 74 years, the majority falling within the 55-74 year old age bracket. All participants resided in East Baltimore with 85% reporting less than $25,000 annual income. Among participants, 50% were fully vaccinated and 10% partially vaccinated. Forty percent of participants were unvaccinated.

Table 3.1. Demographic characteristics of study participants

Age	**n (%)**
18-24	0 (0.0%)
25-39	3 (15.0%)
40-54	4 (20.0%)
55-69	11 (55.0%)
70+	2 (10.0%)
N/A	0 (0.0%)
Gender	
Male	8 (40.0%)
Female	11 (55.0%)
Non-binary/Third gender	1 (5.0%)
Ethnicity	
Hispanic/Latino	1 (5.0%)
Non-Hispanic/Latino	16 (80.0%)
Mixed Ethnicity	1 (5.0%)
Unknown	2 (10.0%)
Average Household Income	
<$25,000	17 (85.0%)
$25,000-$50,000	3 (15.0%)
$50,000-<$75,000	0 (0.0%)
$75,000-<$100,000	0 (0.0%)
≥$100,000	0 (0.0%)
Highest Education Level Achieved	
High School, No Diploma	8 (40.0%)
High School, Diploma	7 (35.0%)
1 or More Years of College, No Degree	3 (15.0%)
Associate's Degree	1 (5.0%)
Bachelor's Degree	0 (0.0%)
Graduate School Degree	0 (0.0%)
Graduate Equivalency Degree (GED)	1 (5.0%)
Vaccination Status	
Fully Vaccinated + booster*	5 (25.0%)
Fully Vaccinated, no booster**	5 (25.0%)
Partially Vaccinated***	2 (10.0%)
Unvaccinated	8 (40.0%)

* Fully vaccinated + booster refers to individuals who received the second dose in a two-dose COVID-19 vaccine primary series or one dose of a single-dose COVID-19 vaccine primary series approved or authorized for use in the US. This includes participants that also received a booster
** Fully vaccinated, no booster refers to fully vaccinated individuals who did not receive a booster
*** Partially vaccinated refers to individuals who have not received the second dose in a two-dose COVID-19 vaccine primary series approved or authorized for use in the US.

Using inductive thematic analysis, four predominant themes emerged relating to COVID-19 vaccine uptake decision making. These themes include: (I) Safety and efficacy of vaccines, (II)

Perceived importance of COVID-19 vaccines in relation to pre-existing community needs, (III) Access to trustworthy, understandable information, and (IV) Physical access to vaccines. The second theme was divided into two subthemes: (a) Environmental injustice and (b) Personal health concerns. These themes are described in detail below along with a subgroup analysis among vaccinated and unvaccinated respondents. Finally, observed links between themes are described (Figure 7).

3.4.1 Theme I: Safety and Efficacy of Vaccines

Participants expressed numerous concerns regarding the safety and efficacy of COVID-19 vaccines and how these concerns affected their decision to get a vaccine. These concerns primarily focused on the risk of potential harms associated with the vaccines. These included concerns regarding pain, bruising, or muscle damage at the injection site, fever or illness associated with getting the vaccine, and any long-term side effects from the vaccines. For instance, an unvaccinated female participant (age 59) noted that she had a "fear of needles" and would not get the vaccine, opting to use natural remedies, such as vitamin supplements, to prevent COVID-19 infection instead. A vaccinated female participant (age 74), who also mentioned that she does "not like needles," selected the J&J vaccine over the other options because it would "only require one shot instead of two." Another vaccinated participant described a conversation she had with an unvaccinated neighbor:

> *"I was talking to a young man down the street from me the other night and we were talking about how the masks are coming off now and I told him we still got to be careful, we need to wear them somewhat and he was like …he just came out the hospital for his breathing...so I said you get your shot?*

And he said oh no uh uh! I don't do needles, I won't get the shot. I told the doctors I'd rather get COVID than get the shot."

– ***Vaccinated Female, 67***

Others discussed concerns specific to COVID-19 vaccines, primarily the adverse events associated with vaccination. Many discussed the concerns around not knowing the long-term health implications of the vaccine and wanting to see first-hand how the vaccines affected others in their community:

"I wanted to wait and see how it worked for others first. There were concerns about the J&J so I was really against it for a while. My concerns were mainly around the safety of the vaccines and I felt like they would compromise my immune system more because I noticed that people around me who were getting the vaccine would get sick after."

-Unvaccinated Female, 25

Participants were also concerned about the speed with which COVID-19 clinical trials themselves were held and the reliability of the results. Given the extreme political pressure and time constrains vaccine developers were under, participants discussed the potential effects these conditions had on the vaccine products' safety:

"It was way too quick. The speed of it was concerning. And there just being different variants and boosters, it was too much."

-Unvaccinated Female, 32

"My reaction was how could you make a vaccine so fast? We've had other problems going on like cancer and nobody's been able to make a vaccine that quick. So how can that be? So I decided to wait a little bit and see how it works. Somebody else had got the shot and I wanted to see how long it

lasted and how it was feeling. They got a shot and didn't feel good the first day but then it went down and they were fine. So I felt better to get it."

-Vaccinated Male, 65

Concerns about specific vaccine ingredients and potential side effects associated with these were also brought up as a major barrier to vaccine uptake. Many participants discussed that they were already taking drugs for other conditions and were concerned about how the vaccine would affect those medications:

"I heard that certain vaccines killed certain people after they took the shot. Those people could have been allergic to something in the vaccine or had a bad reaction to its interaction with something else."

1. ***-Unvaccinated Female, 59***

Another participant, an HIV-positive woman, discussed her concerns about how her HIV medications and medications for other co-morbidities would interact with the vaccine:

"You know, it's like alright, went from 20 pills a day being [HIV] positive to one pill a day. In menopause, already having hot flashes to my new HIV medicine heightens your hot flashes…and I'm so sick of pills I'm a recovering addict. I think I've took more pills clean than I took using… And it was like I took all of this medicine all of these pills for years. Still taking. So I'm like okay and then you want me to get a vaccine. I don't know what the hell it is. I can only speak for me. I don't know what it is and how it's gonna affect me."

-Unvaccinated Female, 61

Only one unvaccinated participant did not directly address potential side effects, although this individual did discuss concerns related to differences in safety among the different COVID-

19 vaccines offered, how the vaccines were developed, the speed with which the vaccines were developed and whether or not the dose/spacing between shots was safe:

> *"Nobody's vaccine is the same. Moderna, Pfizer, J&J…which one is best? Which one is right? I know they aren't the same! And why is that? What's the real difference?"*
>
> ***-Unvaccinated Male, 48***

One participant felt that the safety concerns of the vaccine outweighed the safety concerns of COVID-19 itself:

> *"Because its head on and you'll definitely get it. The COVID might not even be here so there's a chance I'll be fine."*
>
> ***-Unvaccinated Third Gender Individual, 35***

Several participants expressed questions and associated complacency regarding whether the vaccines sufficiently worked to prevent COVID-19 among the public. Some participants described instances in which people they knew people who became infected and sick with COVID-19 post-vaccination, causing further questions regarding efficacy:

> *"[My friend] told me they didn't feel well after. And they have to still take covid tests. And they have to take a booster. And then another booster. So it's like what's the point? There's only a 50/50 chance it's going to work. I came to realize that even if I got the vaccine, I can still get covid. So I felt what is the point? If I've had it and I can get it again anyway, the vaccine isn't any other guarantee. So why do something experimental? "*
>
> ***-Unvaccinated female, 32***

The need for subsequent boosters added further doubt as to the efficacy of the COVID-19 vaccines, as well as the motivations or intentions of vaccine producers:

> *"And now they are talking about booster shot after booster shots. Are they watering down the vaccines so that they can keep making money off of us by making us get shots? You know what I mean? Are they just going to keep making vaccines when they could have stopped it from the get-go? Haha conspiracy theories."*
>
> ***– Unvaccinated Male, 48***

> *"Some didn't, some people still won't take the test because they think its putting the covid in them. I heard people say they weren't going to go to the hospital because that's where they were infecting people with COVID."*
>
> ***-Vaccinated Female, 62***

Another participant expressed concern that people taking the vaccines were being used as part of an experiment and that information regarding what is known and not known about the safety and efficacy of vaccines did not seem transparent:

> " *I wish they would have been more clear that in the beginning it wasn't a one and done vaccine. That it's not totally effective and that you'll need a booster. They should have been more honest about that. They should have been a little more clear so that people could expect the virus will mutate and that we are kind of guinea pigs."*
>
> ***-Unvaccinated Female, 25***

Yet another participant with pre-existing comorbidities was concerned that the vaccine would harm them because they had a compromised immune system already.

People who were healthier than me were having symptoms for like 15, 20 minutes and so when I heard that I thought, I definitelycan't get [the vaccine]. More questions about the vaccine ingredients, and other than 15 minute sicknesses, what side effects 5 years from now, 10 years from now.

-Unvaccinated Third Gender Individual, 35

3.4.2 Theme II: Perceived importance of COVID-19 vaccination in relation to preexisting needs

Several basic needs were brought up during the interviews as being of greater importance or urgency to participants than COVID-19. These basic needs played a role in how participants perceived the importance of getting a COVID-19 vaccine and occurred at two levels: community needs relating to the persistence of environmental injustices and individual needs relating to preexisting health concerns. As such, two sub-themes emerged: Persistent environmental injustices and personal health needs

3.4.2.1 Subtheme: Persistent environmental injustice

Participants discussed how their own life experiences and community structure impacted their decision whether to get a COVID-19 vaccine. One participant, a homeless woman who had received a partial COVID-19 vaccination, expressed her concerns regarding housing in relation to the pandemic:

"There's no point in getting a COVID-19 vaccination if you're going to have to lie outside. We just moved into an abandoned home because we got evicted during the pandemic. We are dealing with no heat, so much mold. That's what I worry about. And I have a pitbull. A lot of places won't let us in with that dog. I lost my job during the pandemic. The housing has made it so scary. The effects of the pandemic are scarier than the disease itself."

– Partially vaccinated female, 56

Addiction was also brought up as a problem faced by the entire community that may serve as a barrier to COVID-19 vaccine uptake. When talking about addicts in her neighborhood, one participant said:

"*Drugs. That's the problem. They don't care about anything else. Trust me, I'm an abuser*."

– Unvaccinated female, 59

This participant felt that she was at higher risk of contracting COVID-19 due to her surroundings (i.e., having many neighbors that are drug users) and was more favorable towards COVID-19 vaccines as result:

"The community I live in is mostly drug infested, it was concerning me because of my surroundings. The filth, the germs, kids running around, needles and stuff laying around. Like I said, the community is drug infested. That's why I thought it'd be real serious if I were to get it. I was very concerned about my surroundings. I could be exposed easily with the needles. I want to protect me."

-Vaccinated Female, 62

This same participant went on to say:

"When they found out that this was that serious and happening in a drug area, I think they should have gone into these communities first. So much exposure risk here because of the drugs. Because I feel like they should have come here earlier because they are high risk. They could have saved more lives."

In response to being asked whether public health officials should continue pursuing COVID-19 as a major threat to the community, one participant, a 57-year old vaccinated female said, "No. They should focus on crime." One unvaccinated participant felt that public health officials should have enforced vaccination more consistently using mandates, which would override feelings of complacency toward vaccines:

> "*We have each state making their own rules and restrictions. And people traveling from one state to another. They should have done a nationwide mandate for every state. Because people traveling. Because at least I'd know that everyone else was vaccinated too and my risk for getting COVID-19 is very low. But the way it is now, what's the point in getting the vaccine if anyone can cross state lines and still infect me? Doesn't make sense."*
>
> ***-Unvaccinated Male, 48***

On the topic of incentives being provided, both negative and positive reactions were expressed, underscoring the complexity of the issue:

> *"People don't want to do anything unless they get something from it. Because people here do drugs for the money. They should've offered money or something because then people would've done it."*
>
> ***-Vaccinated Female, 62***

An unvaccinated participant felt that financial incentives offered at her work to get vaccinated made her more skeptical of the vaccines and less likely to receive one:

"It made me more suspicious. Like, you want to pay me to take a vaccine that people don't know much information on? I just felt suspicious with how hard they were pushing."

-Unvaccinated Female, 32

Concerns about racism inherent within the medical system were also expressed. The same unvaccinated participant explained why she was less willing to visit health clinics in general:

"Different people of different ethnicities get different treatment. For example, I have anxiety. It would be harder for me to get treatment for anxiety than a 40-year-old white woman. And that's just the way that it is."

-Unvaccinated Female, 32

Other participants expressed similar sentiments about racism causing a barrier to trust between members of the community and health professionals. They expressed wanting to hear from other community members and community health workers. When asked who they want to talk to about COVID-19 vaccines to become more informed, one participant stated:

"Anyone who is from the community who knows what they are talking about. Black lives matter, all that. It's community. I think if people came out and spoke on the street, people would listen."

-Vaccinated Female, 62

"The community center is a good place. I came here today because I trust it."

-Vaccinated Male, 59

3.4.2.2 Sub-theme 2: Personal health needs

Several participants in the community discussed health issues they were already facing prior to the pandemic and how those threats compared to their perceived threat of COVID-19 disease:

"I think is the fear right now is my comorbidities that I already have. I'm [HIV] positive. My blood pressure's high, sugar, diabetes. So it's all of those things that I'm concerned about right now. I don't know how those things will be with the vaccine. …Can I really keep up with all this stuff that's going in me right now? All the medicines I take my blood pressure medicine, I have HIV medicine. I have vitamins, aspirin and metformin for my diabetes to get those numbers down."

-Unvaccinated Female, 61

Some participants had previous experience with COVID-19 and this made a few more unwilling to get a COVID-19 vaccine:

I think there still other things that need to be worked out with it and I am honestly so afraid of getting sick again. I was so sick. Yes, I'm so scared of being sick. I see others who get it and they are out for a few days. I think it's just the fear now. COVID-19 traumatized me. I've never been that sick before.

-Unvaccinated Female, 25

One vaccinated participant initially felt that he did not want to jeopardize his preexisting health issues with getting the vaccine:

"*Yes, I was concerned that it would affect a condition I was born with like my asthma. What if the vaccine triggers something? Then I just got out of that. I just got it taken care of. I just decided to get it done. Get it out of the way. I want to be around my babies. I want to live for them."*

-Vaccinated Male, 43

Mental health was also addressed as an issue that was prioritized above COVID-19 prevention:

"I guess in the beginning, I think it was selfish that people were putting their social needs above safety. And I understand that because social health contributes to mental health but it was selfish."

-Unvaccinated Female, 25

Another person described their mental health issues during the pandemic and finding it difficult to leave the house to get a vaccine after lockdown:

"*Think I started getting depressed because I worked from home for eight months. I live alone. So it was very lonely. And even when I thought about going out it seemed like I got like. I think I kind of got programmed to be alone."*

-Unvaccinated Female, 61

3.4.3 Access to understandable, trustworthy information

When asked about how individuals trust government-produced information, such as that from the CDC and FDA, participants expressed a range of perspectives. Many of those who expressed total trust in federal public health agencies also expressed a lack of understanding about the vaccines, but felt that the lack of understanding was secondary to the total trust they had in the information provider. For instance, when one participant, a vaccinated female age 74, was asked whether she regarded federal agencies as trusted sources of information, she responded with "I trust them." When asked what convinced her to get the vaccine, she responded "Because if they weren't any good, they wouldn't have offered them in the first place."

Those who expressed skepticism expressed an underlying belief that the government as a whole was not trustworthy in many situations extending beyond just the pandemic:

"I don't trust them so much. The government downplays the severity of things if they don't want to cause a panic. They don't want to see controversies or riots. So they'll say something that is real, real devastating, they will say its not bad because they don't want to cause panic or chaos. So not so much with the government, I don't really trust them. A lot of the things going on today, the government has a hand in it"

–***Vaccinated Male, 44***

"I don't really trust them because they are biased, obviously. I would probably want to hear from someone who is very against it and someone who is for it and take the middle information."

- ***Unvaccinated Female, 25***

This same participant expressed concern over the language that was used by public health officials to describe the vaccine's effectiveness:

"I wish they would have been more clear that in the beginning it wasn't a one and done vaccine. That it's not totally effective and that you'll need a booster. They should have been more honest about that. They should have been a little more clear so that people could expect the virus will mutate and that we are kind of guinea pigs. They put so much weight on the initial shots. They made it seem like an end-all, get the shot and you'll be good. But now with the booster, it seems almost unnecessary and like I don't trust them even more now."

- Unvaccinated Female, 25

Other participants expressed a similar sentiment:

" I don't even understand why it's being called a vaccine. It's like the flu shot. There's no guarantee. It's not, "if you get this vaccine, you won't get COVID". It's not a guarantee. They should have called it a preventative shot instead of a vaccine. It felt like they were selling a lie."

-Unvaccinated Female, 32

This same participant described getting her information on COVID-19 vaccines primarily from watching YouTube videos, stating, "*There's a guy who is a doctor and he does vaccine videos in Barbershops on YouTube and I like watching him. That was pretty cool*." A desire to have community-based workers or known healthcare providers provide information about the vaccines directly to the community were described as well:

"I mean they gave out pamphlets and information but everybody can't read, you know? They need to communicate it in a way people can understand it. So if someone could educate us or something and share the information, they could've saved a lot of lives. Anyone who is from the community who knows what they are talking about. Black lives matter, all that. It's community. I think if people came out and spoke on the street, people would listen. A lot of people aren't educated enough so you just don't know. A lot of people here could be sick and you just don't know. Cuz they don't tell anybody. Because there's shame associated with it. Just like HIV. They won't tell you. It's selfish. Save a life, don't take a life."

-Vaccinated Female, 62

Similarly, participants expressed a desire to have been given more opportunities to learn about and understand the information and placed particular emphasis on wanting the youth in the community

to better understand COVID-19 and COVID-19 vaccines: “They could have had classes and have somewhere to involve the young people so that would help a great deal.” (Vaccinated Male, 59) When asked what they would suggest public health officials could do better to share vaccine-related information, one participant responded:

> *“I feel like they’d get to a lot of them if they came into the communities. I feel like if we had a doctor here to talk to us and really explain the legal things and the medical things, people would listen.”*
>
> ***-Vaccinated Female, 67***

When asked for their most trusted sources of information, one participant, a vaccinated female aged 74 said “community health workers.” When asked about getting information from their primary healthcare provider, another participant, an unvaccinated 48-year old male, responded, “He’s a little skeptical too. He don’t know what to believe.”

Another participant expressed difficulty trusting information given by their healthcare provider, explaining that they visit their provider so infrequently due to cost barriers, they weren’t sure if they could trust them.

> *“I only see them every 5 months or 6 months. Plus then I’ve got to go get my blood drawn, etc. Everything takes money. And now the prices of everything have gone up. My gas bill this month was $300. That’s all the money I have. I can’t afford to do things that require more money.”*
>
> ***-Vaccinated Male, 59***

Finally, participants expressed confusion and skepticism regarding the motivations and funding behind the vaccines:

"Where is the money going? Who is benefitting from this? A million dollars a year, this is a big deal. They should be more transparent about the money."

– Unvaccinated Male, 48

Participants expressed a desire for greater transparency in information regarding who is responsible for the development of the vaccines, how consumers can hold producers accountable for any harms resulting from the vaccine, and how these mechanisms are funded. Concerns relating to rumors regarding how the vaccines function or malfeasance on the part of vaccine developers and providers were also expressed:

"The only thing people keep saying is they're putting that stuff in me, shooting stuff in us so they can always know our whereabouts."

-Vaccinated Female, 67

"Because I'm not read up on it, I'll be honest. If it don't come from a professional, I don't pay no mind. I just didn't follow up on it because I knew I didn't want it. I'm just scared because they must be giving me a little bit of the disease, so how do they know that won't make me sick?"

-Unvaccinated Female, 50

Others addressed stigma associated with some of the vaccines offered. A vaccinated male, age 59, said, "I saw the J&J is not good that's what I've seen on the news. There's a stigma with it." This sentiment was echoed several times by other participants.

3.4.4 Physical access to vaccines

Overall, most participants felt that Baltimore City had done a satisfactory job in making the vaccines available to members of their community, and that access was not a significant barrier

to uptake in their community. For instance, when asked if the vaccine was at all difficult to access, one participant responded:

> *"No! It wasn't hard for any of us. But the lines were just long. They make you wait there for 10 minutes to make sure you are okay."*
>
> ***–Vaccinated Female, 74***

When asked about whether they felt Baltimore City could have done more to make the vaccine easier to access, the same participant responded,

> "*I think they've done plenty enough. It's easy to get it. It's people mindset, not access that was the issue. It was easy. I got the vaccine at the church right across from me and the booster from an open clinic on Jefferson. So it was easy."*

Similarly, when asked if access was a barrier to getting the vaccine, another participant, a 32-year old unvaccinated female, stated: **"**No, they had mass vax sites everywhere. Most places you can just pop in and get a vaccine." However, this was not the case for all participants. One participant that identified as homeless described her struggle receiving both doses of the vaccine. When asked what she felt was a barrier to access for the vaccines, she replied:

> *"Transportation. If you don't have transportation and you don't have money to get anywhere, how are you supposed to get anywhere? That's a problem. You have to pay to get on the bus. It used to be free but its not anymore."*
>
> ***– Vaccinated Female, 56***

When asked about mobile clinics in the area, she went on to say: "Yeah, but the mobile clinic didn't go everywhere. Like I've never seen it here in this neighborhood."

This woman reported receiving her first shot, but not her second. When asked why, she responded, "We moved and I didn't have transportation to get back." Another partially vaccinated participant shared a similar sentiment stating:

> *"Because the complex I was living in, the mobile clinic said they would come back, but they never showed up."*
>
> ***-Vaccinated Male, 59***

Another participant reported that while physical or geographical access was not a significant problem, other barriers associated with access likely played a role:

> *"I think in places like Baltimore, in low-income neighborhoods, they have lower vaccines because they don't have time. It's like a luxury even though its free. It's not just access, it's the cost of time. You have to be prepared to take time off of work if you get sick from it."*
>
> ***-Unvaccinated Female, 32***

3.4.5 Thematic Network Analysis

In thematic analysis, an emergent theme comprises several categories. To explore patterns embedded within the qualitative data, thematic network analysis of the contextual associations between categories produced a thematic map (Figure 3.1). A "contextual association" is identified when a participant discusses two distinct categories in relation to one another during an interview. For example, in the quote in which a vaccinated male participant aged 58 stated that "*I only see [a doctor] every 5 months or 6 months. Plus, then I've got to go get my blood drawn, etc. Everything takes money. And now the prices of everything have gone up. My gas bill this month was $300. That's all the money I have. I can't afford to do things that require more money,"* he was explaining why he could not afford to see a doctor more frequently and does not have a doctor he

knows he can trust. As such, in thematic network analysis, this relationship between "cost" and "trust" is depicted with a line between "health provider costs" and "trusted sources of information." The existence of a relationship between two categories as described in the transcripts are depicted for each relevant relationship through thematic network analysis.

The category with the highest number of contextual associations was "trusted sources of information" (7 associations identified). Associations between the "trusted sources of information category" and at least one other category corresponding with the other remaining themes were identified through this analysis). No contextual associations emerged between the "vaccine coverage" category and any other categories. Other associations were found between "Covid-19 infection" and "stigma" as well as between "time as a cost" and "long wait times/side effects post-vaccination." "Health literacy" was associated with "Dissemination of safety and efficacy information" and "What is not known about the safety and efficacy of vaccines."

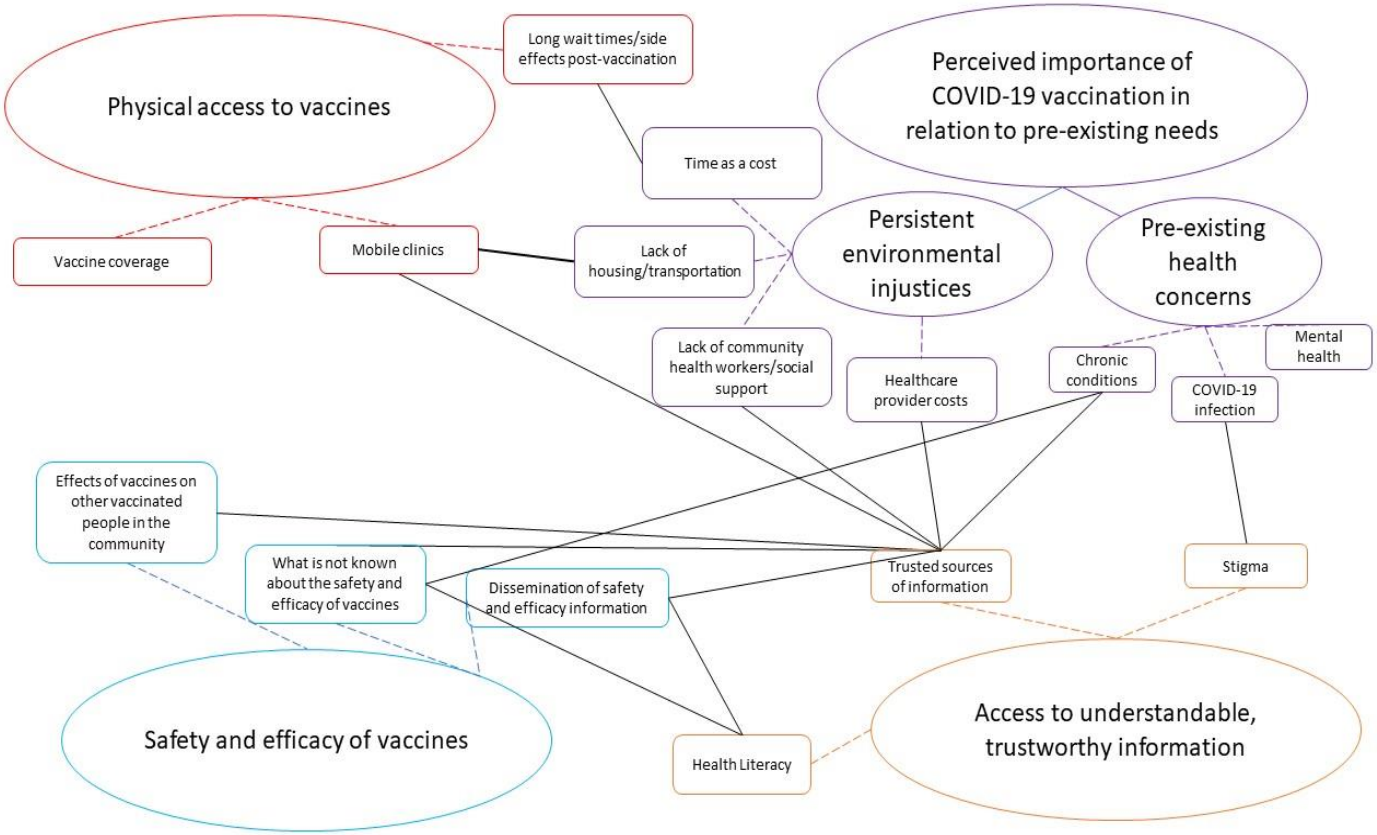


Figure 3.1. Thematic network or "map" of critical components in the COVID-19 vaccine decision-making process **Ovals surround emergent themes and rectangles surround categories. Ovals connected to rectangles with a dashed line of the same color denote emergent themes and the categories of which they are made up. Rectangles connected to other rectangles with a black solid line denote relationships between categories. Rectangles outlined in light blue indicate categories that make up the "Safety and efficacy of vaccines" emergent theme. Rectangles outlined in orange indicate categories that make up the "Access to understandable, trustworthy information" theme. Rectangles outlined in purple indicate categories that make up the "Access to understandable, trustworthy information" theme. Rectangles outlined in red indicate categories that make up the "Physical access to vaccines" theme.

3.4.6 Subgroup Analysis: Vaccinated and Unvaccinated Participants

A saturation matrix completed during thematic analysis was subsequently analyzed for subgroup analysis, comparing the percentage of vaccinated and unvaccinated participants that brought up issues pertaining to each theme during their semi-structured interviews. As shown in Appendix F (i), unvaccinated participants more frequently brought up concerns related to safety and efficacy in their discussion of vaccine decision-making than their vaccinated counterparts.

Appendix F (ii) depicts percentage of vaccinated and unvaccinated participants that addressed persistent environmental injustices. Unvaccinated participants more frequently addressed all issues except for those relating to housing and young people not getting a vaccine. Unvaccinated participants were the only participants to address issues of "racism," "crime," and "time away from work due to side effects" in their interviews. Similarly, Appendix F (iii) shows the percentage of vaccinated and unvaccinated participants that addressed pre-existing health needs. Unvaccinated participants were the only participants to address "HIV/AIDS" and "Mental health impacts of vaccines." An equal proportion of vaccinated and unvaccinated individuals addressed "personal experience with COVID-19 vaccines" and a greater proportion of vaccinated participants mentioned the "threat of COVID-19" than unvaccinated participants.

Regarding issues of access to understandable, trustworthy information, unvaccinated participants addressed issues relating to "Money trail/big pharma," "What we don't know" and "frequency of doctor visits" while vaccinated participants did not address these issues at all (Appendix F [iv]). Only vaccinated participants addressed issues relating to "stigma," "literacy," and "trust in local news." In comparison with vaccinated participants, a greater percentage of unvaccinated participants brought up "trusting family", "cost of seeing a healthcare provider", "microchip/government tracking/conspiracy theories" and "trust in local healthcare providers."

With regard to physical access to vaccines, codes of "availability of mobile clinics" were addressed only by vaccinated participants. A greater proportion of vaccinated participants referred to transportation to the vaccination site, ease of access to the vaccine, and availability of the vaccines (Appendix F [v]). Only unvaccinated participants addressed "long lines."

3.5 Discussion

This study amplifies the voices of members of a low-income, predominantly Black community in Baltimore City, Maryland that experienced a lower proportion of COVID-19 vaccine uptake than neighboring communities. Their voices provide unique insight into the perspectives and experiences of an understudied population and describe critical components of their decision-making process for COVID-19 vaccine uptake. With constructs of the 3C's Model providing the guiding framework for the semi-structured interviews, perspectives and experiences related to the convenience of COVID-19 vaccines, complacency toward COVID-19 vaccines, and confidence in COVID-19 vaccines were elicited from each participant. All (vaccinated and unvaccinated participants) acknowledged that physical availability of COVID-19 vaccines was not a major barrier to uptake, however concerns related to finding trustworthy and understandable information, particularly about the safety and efficacy of the vaccines were common areas of concern. Participants' views of the importance of getting a COVID-19 vaccine, in relation to other important needs or demands in their daily lives, elicited important social and contextual factors specific to this community and others like it. Based on these factors, some participants felt that getting a COVID-19 vaccine was extremely important while others expressed that it was not a major priority.

To sufficiently explore emerging themes in the data as well as the contextual connections between them, this research applied three analytic approaches in its methodology: a thematic

analysis of qualitative data, a quantitative subgroup analysis assessing differences in codes used between vaccinated and unvaccinated participants and a thematic network analysis of qualitative data. The implications of the results of each of these methods will be discussed below, as they pertain to each emergent theme, followed by study limitations and public health recommendations.

3.5.1 Safety & Efficacy of Vaccines

As shown through prior vaccine hesitancy studies, concerns regarding the safety and efficacy of vaccines have factored heavily into vaccine decision-making (Ljungholm, 2021; Soares et al., 2021). Pain at the injection site and adverse effects were the predominant safety concerns associated with the vaccines. Skepticism regarding the ability of the vaccines to adequately prevent infection or disease were reported as common barriers to uptake. These findings are in line with theoretical models that apply constructs of "perceived risk" and "perceived benefits" in vaccine uptake decision-making processes (Gerend & Shepherd, 2012; Quinn et al., 2016). This also resonates with the "confidence" construct of the 3C's model and, as shown in thematic network analysis, is associated with issues of trust. Interestingly, both vaccinated and unvaccinated participants referred to concerns about the safety and efficacy of the vaccines, although subgroup analyses revealed that more codes on the topic were addressed by unvaccinated than vaccinated participants. This suggests that unvaccinated participants may have had a wider range of concerns than vaccinated individuals, which may have served as a greater barrier to uptake.

For several individuals, seeing that others were able to recover from the side effects of the vaccine after a day or so made them feel more encouraged to get the vaccine. First-hand observations provided a source of trustworthy information. As vaccine hesitancy exists on a spectrum (MacDonald & Hesitancy, 2015), it is evident that some hesitant individuals may want

to wait and see the long-term effects (e.g., effects after 3-4 years) of the vaccine before deciding to get it.

Results of the thematic network analysis suggest that participants would have felt greater trust in sources that acknowledged what was not known about COVID-19 vaccines, such as long-term effects. This has been found to be true in other studies as well, although this transparency has also been shown to be associated with lower uptake (Petersen, Bor, Jorgensen, & Lindholt, 2021). Notably, individuals reported wanting to observe these effects among their fellow community members for themselves rather than relying solely on the reporting of side effects from federal or state public health officials or scientists. This resonates with findings from the thematic network analysis in which the "trusted sources of information" category was contextually linked to "effects of COVID-19 vaccines on other members of the community." These findings suggest that providing community members with testimonials or video diaries of neighbors experiencing the vaccination process may be beneficial for improving vaccine uptake.

3.5.2 Perceived importance of COVID-19 vaccines in relation to preexisting needs: Persistent Environmental Injustices

The results from this study underscore the fact that many members of this community face specific, important contextual barriers or challenges to vaccine uptake including homelessness, drug addiction, lack of transportation, and poverty, all of which are consequences of persistent environmental injustices. In Baltimore City, longstanding institutional and structural factors, including racism and classism, perpetuate a concentration of negative social determinants of health within the City's low-income, predominantly Black neighborhoods as compared to high-income, predominantly White neighborhoods (Dzirasa, 2021). Through this research, instances of poverty, lack of transportation, low literacy, homelessness, racism, and limited access to healthcare were

highlighted by participants as factors that hinder vaccine uptake. Notably, instances of crime, racism and taking time away from work were only cited by unvaccinated individuals while only vaccinated individuals brought up instances of homelessness. While this does not indicate that any of these conditions are relevant to only one subgroup, they do highlight significant challenges to members of this community. “Lack of housing/transportation and “time as a cost” were contextually related to physical availability of vaccines, indicating a need to focus more on providing job security in case of side effects from vaccination and for time taken from work to get vaccinated. Additionally, mobile health vaccination clinics may need to be more closely evaluated to examine areas of strengths and weaknesses. This would serve to better monitor instances of follow up and returning to communities. Lack of community health workers (CHWs) and costs of seeing doctors were again representative of environmental barriers to access to understandable, trustworthy information. In the latter instance, the fact that participants with lower income are less likely to have health insurance, makes them less likely to have regular visits with a physician. As such, these individuals are also less likely to develop trust with a doctor, which limits their access to information.

As reported in other studies, vaccine rollouts must adapt to the specific context in which they are implemented (Alcendor, 2021; Quinn et al., 2016). To this end, researchers must understand the contextual challenges faced by community members. Urgent, immediate concerns such as secure housing and being able to work (i.e., not taking a day/time off due to side effects from the vaccine) were priorities that eclipsed COVID-19 vaccine uptake among several study participants.

3.5.3 Perceived importance of COVID-19 vaccines in relation to preexisting needs: Pre-existing health needs

Prior to the pandemic, individuals suffering from chronic conditions, mental health conditions, and/or opioid or alcohol addiction were already socially vulnerable, facing higher rates of poverty, comorbidities and death (Walters, Seal, Stopka, Murphy, & Jenkins, 2020). Minority community members dealing with opioid addiction or HIV/AIDS have been found to experience increased stigma and discrimination that have been associated with poor health outcomes (Grollman, 2014; Turan et al., 2019). Similarly, vaccinated participants in this study described feeling a sense of stigma around COVID-19 infection in the community, which heightened their worry that they could be infected without knowing they were interacting with a COVID-19 infected individual. This may have served as a motivating factor for these participants. During the pandemic, mental health pressures, coupled with the need to maintain adherence to ongoing medication regiments, such as a daily pill taken for HIV/AIDS, seemed overwhelming for some individuals. In fact, mental health issues and HIV/AIDS were brought up only by unvaccinated participants, suggesting that these serve as important barriers to vaccine uptake within this community. The thought of taking a vaccine that might upend their usual regiment was enough to prevent some participants from getting vaccinated. Thematic network analysis revealed that chronic conditions were contextually related to finding trustworthy sources of information, as participants expressed great difficulty being able to trust the makers of COVID-19 vaccines when they have been suffering with chronic conditions like HIV/AIDS for decades, and no vaccine has yet been produced.

These findings add to the evidence base, suggesting that efforts to engage more closely with high-risk communities already dealing with pre-existing health conditions during vaccine

rollout efforts should be made. These efforts should include CBPR methods to build authentic collaborations and partnerships with the community. Early onset, bidirectional efforts between public health institutions and communities could empower individuals already dealing with pre-existing disease to manage their health regiments, while addressing community-important concerns.

3.5.4 Access to understandable, trustworthy information

Perspectives on trust in federal health agencies such as the CDC and FDA indicate a need to bring understandable, trustworthy information to this community. As shown in the thematic network analysis, "trusted sources of information" was contextually linked to categories associated with physical availability of vaccines, perceived importance of COVID-19 vaccination in relation to pre-existing needs, and safety and efficacy of vaccines. This category had the highest number of connections to other categories, suggesting that "trust in sources of information" plays a critical role in the decision-making process.

This aligns with other studies which have shown that "trust" is closely linked to environmental justice, institutional racism, health equity, and health literacy (Gamble, 1997; Sullivan et al., 2022). As such, it is important that more resources (time, individuals, and money) be devoted to earning the trust of low-income communities of color. For instance, providing sustained funding to those who have daily interactions and advocate for the health of the community, such as CHWs. Understanding deeply rooted, pre-existing needs and concerns related to social determinants of health are critical to engendering health equity, particularly during public health crises. CBPR provides an excellent space to elevate community voices through engaged collaborative research that shines a light on the many associated factors of "trust."

The constantly evolving science around COVID-19 and the COVID-19 vaccines likely played a role in generating skepticism among the public. This challenge will arise again in future outbreaks or pandemics involving novel pathogens, underscoring the need for public health researchers and practitioners to identify lessons learned from the COVID-19 pandemic and address health communication needs accordingly. Participants reported confusion toward information they had received regarding the harms of COVID-19 and COVID-19 vaccines, the longevity of the vaccines, the efficacy of the vaccines. As in other studies, our results suggest that as time went on, and more changes to the science took place, some participants became increasingly frustrated with the changing language and communications put out by public health agencies, and therefore less trustworthy of the information being shared (Ljungholm, 2021). Importantly, the health literacy of this community may have needed greater attention during vaccine rollout and advocacy efforts. Vaccinated and unvaccinated participants alike expressed a desire to have a health professional come and speak with them directly, answering their questions and providing a safe, open forum for discussion. Given the contextual connections made between community health workers and trusted sources of information in the thematic network analysis, and a substantial body of evidence demonstrating their utility, CHWs could play a pivotal role in ensuring that community members have access to clear, understandable information regarding vaccines. Currently, with patchwork funding schemes posing a major threat to their sustainability, CHWs have not yet been systematically incorporated into the US healthcare system. Sustainable, streamlined funding for CHWs is needed to ensure that their services can benefit those in greatest need.

3.5.5 Physical access to vaccines

Overall, participants reported sufficient vaccine access, a finding that is in-line with other research regarding COVID-19 vaccine rollout in the United States (Karim, 2020). Most participants described easy access to the vaccines and widespread availability, suggesting that coverage of COVID-19 vaccines was satisfactory. This may not have been the case when vaccines first became available, a year earlier in 2021, and was likely not the case for everyone in the community. A few participants noted difficulties related to accessing mobile clinics, suggesting that more could have been done to ensure that that coverage of mobile clinics was sufficient and reliable. Greater consideration for transient populations, such as the homeless, may also be required, particularly if individuals need two doses to receive the full benefits of the vaccine. Additionally, concerns relating to "time as a cost" was discussed as a barrier to uptake and was associated with physical access to the vaccines. Participants reported that needing to work or take care of children after receiving a vaccine and having the ability to take time off from work to go and wait in long lines to get the vaccine were important to their decision to receive a COVID-19 vaccination.

3.5.6 Limitations

One limitation of this research is that it took place approximately one year after COVID-19 vaccines were first rolled out to the public in Baltimore, Maryland. As such, participants' perspectives about the introduction of the vaccines, their decision-making processes, and their experiences were expressed retrospectively, allowing for recall bias in responses. However, as vaccines were still being rolled out and disparities in vaccine uptake continue to persist within this community, perspectives discussed also provide information about the progress of vaccine rollout and the current issues still in play. A second limitation is that this study was conducted in a specific

community with its own contextual challenges and facilitators, making the results of this study not widely generalizable. However, there are many communities in the US with similar demographics, health disparities, historical context and comparable vaccine uptake disparities, for which these results may apply (Zeng et al., 2022). This study provides insight into the specific needs of one such community, providing a framework for tailoring interventions that aim to increase vaccine uptake.

3.5.7 Public Health Recommendations

Public health researchers have a responsibility to ensure that information that may factor into the public's decision-making processes for vaccine uptake are well studied and public health practitioners must make sure that the information is communicated to the public in a way that is both understandable and trustworthy. Thus, studies evaluating the effectiveness of vaccine rollout efforts should ensure that they examine outcomes of importance to communities of interest. To this end, researchers must place a greater emphasis on understanding contextual factors prior to rollout implementation.

Studies of context will also inform public health practitioners striving to provide information to the public. Not all members of the public accept information equally, nor do they have equal levels of trust or health literacy. As such, underserved communities may fall through the cracks and not receive critical information in a form they are able to access or understand. Communities facing hardships such as poverty, addiction, or HIV, should be provided additional resources and services to ensure that vaccination is a realistic priority. A lack of awareness or understanding of critical information is a clear and present barrier to vaccine uptake for members of this community. Public health practitioners should allocate more resources to disseminating

information through partnerships with trusted sources including local leaders and community health workers.

Additionally, to get a better sense of the challenges faced by specific communities in vaccine uptake, public health researchers should engage, partner and collaborate with communities of interest using methods of CBPR such that community members are empowered to voice their perspectives and experiences and are involved in all stages of the research process. The needs identified through these methods, which serve to authentically frame the issues and contexts in which they exist, should be incorporated in further studies evaluating vaccine rollout efforts. For instance, several participants in this study wanted to wait and see how the vaccine affected others before deciding to take the vaccine themselves, suggesting that perceived risk and perceived benefits should be assessed repeatedly, over time, during phases of a vaccine rollout to determine whether it is improving as it likely affects uptake. Additionally, the connection outlined in this study between effects on other community members and trusted sources points to a desire to know from trusted sources (i.e., other community members themselves) how the vaccines have affected them. Thus, measures of effects among members of the community should be gathered during evaluations of vaccine rollouts using metrics and instruments supported by the community members themselves. Given the many connections between "trusted sources of information" and other categories, future research should conduct mediation/moderation analysis with this variable to determine the extent to which trust plays a role in decision-making. Furthermore, finding ways to supply trusted sources of information should be a priority for public health practitioners.

3.6 Conclusion

Taken together, the results of this research indicate that while most community members viewed "physical availability/accessibility of the vaccine" favorably, "access to trustworthy,

understandable information" was largely viewed as a challenge, as were "prioritizing the vaccine in relation to other needs" and addressing concerns regarding "safety and efficacy of the vaccines." Overall, unvaccinated participants reported a wider scope of concerns than vaccinated participants and "trusted sources of information" was most frequently related to other thematic concepts, suggesting that trust is an important factor in the decision-making process among members of this community.

To ensure this study was inclusive of a broad range of perspectives, an approximately equal number of vaccinated and unvaccinated individuals participated in the study, allowing for differing views on COVID-19 vaccines to still be elicited. Subgroup analyses also provided a more nuanced understanding of responses, and highlighted similarities and differences between groups. Of great importance to public health researchers is the need to understand local context and address factors contributing to vaccine hesitancy in communities experiencing disproportionately lower rates of vaccine uptake. To this end, public health researchers and practitioners should partner with trusted local leaders such as faith leaders and community health workers as well as community members themselves to fully understand needs, concerns, and existing resources within the community. By doing so, researchers can elevate the voices of the community, ensuring that their voices are heard, and their experiences and perspectives are valued. This will inform the development of more tailored, effective critical services (e.g., mobile clinics) and should prioritize the identification and dissemination of information that addresses issues of importance to specific communities. Increased funding for community health workers and community centers is central to the sustainability of such partnerships. To this end, public health researchers should uphold principles of CBPR and empower community members, healthcare workers and community leaders to collaborate on effective solutions to reduce disparities in vaccine uptake.

Chapter 4. Addressing factors of vaccine hesitancy through inclusion of patient-important outcomes in COVID-19 vaccine studies: A systematic literature review

4.1 Abstract

Background: Studies evaluating the safety, efficacy and effectiveness of COVID-19 vaccines often use different primary outcomes, units of measure, and lack outcomes that are meaningful to patients and the public. This systematic literature review aims to determine the extent to which primary outcomes of existing studies on COVID-19 vaccines align with patient-important outcomes (PIOs) derived from the 3C's Model of vaccine hesitancy.

Methods: The Cochrane COVID-19 Study Register and Google Scholar were searched for relevant titles and abstracts. Full-text screening of the identified articles was conducted. Data extracted from articles meeting inclusion criteria included title and year of publication, the study design, sample size, sample demographics, and primary outcomes reported.

Results: A total of 56 articles published between December 30, 2019, and March 30, 2022, were included in this review. A comparison of the list of extracted primary outcomes (N=20) with a list of PIOs derived from the 3C's Model of vaccine hesitancy suggests that 85% (n=17) of primary outcomes in COVID-19 vaccine-related studies aligned with factors of vaccine hesitancy.

Conclusion: Further research should be done to develop a context-specific, core set of outcomes that include PIOs identified directly by those who stand to benefit from COVID-19 vaccines. To ensure that results of these studies remain useful to scientists, but also meaningful to the general public, these PIOs should be included in safety, efficacy, and effectiveness studies.

4.2 Background

Globally, coronavirus disease 2019 (COVID-19) has claimed the lives of over 6 million people, with over one million of those deaths occurring in the United States alone (WHO, 2022). In response to the pandemic, the United States partnered with national governments, biomedical industries, inter-governmental organizations, and other members of the international community

to collaborate in an unprecedented effort to rapidly develop safe and efficacious COVID-19 vaccines (WHO, 2022). During 2020, over 200 COVID-19 vaccines were in development worldwide (Thompson et al., 2021). By December 11, 2020, the US Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for an mRNA vaccine produced by Pfizer-BioNTech (CDC, 2022). Soon after, on December 19, 2020, an EUA was issued to another mRNA vaccine produced by Moderna and on February 27, 2021, Johnson & Johnson (J&J)'s viral vector vaccine was also issued an EUA (CDC, 2022). An EUA allows for the use of unapproved medical products (or approved medical products for unapproved uses) in instances of serious or life-threatening diseases or conditions due to a declared public health emergency, such as COVID-19, for which there are no sufficient, approved, or available alternatives (Philip R. Krause & Marion F. Gruber, 2020). To issue an EUA, the FDA must determine that the known and potential benefits of the vaccine outweigh its known and potential risks and that the vaccine is able to prevent serious or life-threatening disease (Philip R. Krause & Marion F. Gruber, 2020).

Effectively communicating a favorable benefits-risk assessment can instill confidence and prevent complacency among hesitant members of the public, as can ensuring convenient, equitable access to the vaccines (Philip R. Krause & Marion F. Gruber, 2020). Research has shown that studies which include patient-important outcomes (PIO's), defined as "outcomes that are meaningful to patients and reflect how they feel, function, or survive" (Gaudry et al., 2017; Pino, Boutron, & Ravaud, 2012; Wittes, Lakatos, & Probstfield, 1989), provide more trustworthy conclusions compared to those using laboratory or clinical outcomes alone (Lai et al., 2020). In the past few decades, researchers have been increasingly urged to implement interventions based on their effect on patient-important outcomes (PIOs) such as death, adverse clinical events, quality of life, or access (Yordanov, Dechartres, & Ravaud, 2018). In the context of COVID-19 vaccine

studies, for which a formal list of PIO's does not yet exist, factors associated with vaccine hesitancy may serve as surrogate outcomes for PIOs, as these factors reflect "areas of importance to the public" (Pino et al., 2012; Wittes et al., 1989). Inclusion of PIO's in vaccine studies could play a critical role in achieving increased vaccine uptake.

The World Health Organization (WHO) Strategic Advisory Group on Experts (SAGE) Working Group on Vaccine Hesitancy defines the term vaccine hesitancy as: "a delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex, varying across time, place, and vaccines. It is influenced by factors such as complacency, convenience and confidence" (MacDonald, 2015). The SAGE Working Group's Complacency, Convenience and Confidence (3C's) Model of Vaccine Hesitancy (Figure 1.1) offers insight into these three constructs associated with factors of vaccine hesitancy.

The concept of vaccine hesitancy is context-specific, depending on a particular population's primary concerns, and which geographic, socio-cultural or political context may contribute to hesitancy (Domek et al., 2018; Larson, Jarrett, Eckersberger, Smith, & Paterson, 2014; MacDonald, 2015). As shown in Figure 1, factors related to "confidence" in the 3C's model include trust in the developers of vaccines, the vaccines themselves, and the system delivering the vaccines. Factors related to "convenience" include cost, transportation, accessibility, and literacy. Finally, factors related to "complacency" include perceived risk or threat of disease, perceived benefits and harms of vaccination such as injury, disability, death or pain, and how one's personal needs are prioritized in relation to vaccination.

These factors can be used as PIOs in clinical and implementation studies which measure vaccine safety, efficacy, and effectiveness. Table 1 provides a description of the different types of

studies involved in vaccine development and rollout efforts as well as vaccine hesitancy constructs from the WHO 3C's Model that will be used as proxies for PIOs in this study (MacDonald, 2015).

Table 4.1. Objectives of vaccine studies and corresponding vaccine hesitancy factors to be applied as PIOs.

Type of Study	Study Description and Primary Objective(s)	Corresponding Construct from 3C's Model	Vaccine hesitancy factors to be applied as PIOs
Safety Clinical Trial (Phase I)	The vaccine is given to a small number of people. This is the first trial in humans. Primary objectives are to test dosage, safety, and stimulation of the immune system. (FDA 2018).	**Confidence**	• Injury, death, disability, or pain
		Complacency	• Perceived risk/harm of COVID-19 disease • Perceived risk/harm of COVID-19 vaccines
Expanded Clinical Trial (Phase II)	The vaccine is given to hundreds of people across different population groups to see how and if the vaccine behaves differently in them. Primary objectives are to test further the safety and stimulation of the immune system. (FDA 2018)	**Confidence**	• Injury, death, disability, or pain
		Complacency	• Perceived risk/harm of COVID-19 disease • Perceived risk/harm of COVID-19 vaccines • Perceived benefits of COVID-19 vaccine
Efficacy Clinical Trial (Phase III)	The vaccine is given to thousands of people to monitor how many become infected or develop the disease in comparison to a placebo control group. Additional safety monitoring is conducted as well. Primary objective is to establish whether the vaccine can protect against the virus. (A COVID-19 vaccine will have to protect at least 50 percent of those who received the vaccination to be deemed effective by the U.S. Food and Drug Administration.) (FDA 2018)	**Confidence**	• Injury, death, disability, or pain • Perceived benefits of COVID-19 vaccine
		Complacency	• Perceived risk/harm of COVID-19 disease • Perceived risk/harm of COVID-19 vaccines
Effectiveness /Impact Evaluation	Measures vaccine rollout effects in the target population by assessing the progress in the program objectives. Primary objectives are to show the degree to which the program is having an effect on the target population's knowledge, attitudes, beliefs and behaviors. (Salabarría-Peña, Douglas, Brantley, & Johnson, 2022)	**Confidence**	• Trust in the system and people who deliver the vaccines • Trust in the motivations behind the policy makers in charge of rollout • Trust in sources of information • Injury, death, disability, or pain • Perceived benefits of COVID-19 vaccine

	Complacency	• Prioritization of COVID-19 vaccination in relation to other life needs • Perceived risk/harm of COVID-19 disease • Perceived risk/harm of COVID-19 vaccines
	Convenience	• Social support/acceptability • Access to understandable information • Cost • Eligibility • Geographic accessibility/Transportation availability • Ability to take time off from work • Physical availability of the vaccine • Appeal of immunization services

Given the distinct primary objectives of safety, efficacy, and effectiveness studies, study designs may differ among them. In clinical trials, randomized controlled trials (RCTs) offer the strongest evidence of causality in safety and efficacy because they largely control for other factors that may influence study outcomes, thereby maximizing internal validity (Mazzucca et al., 2018; Meissner, 2022). However, because effectiveness studies place a greater focus on external validity, implementation-related barriers and facilitators, and factors leading to uptake across settings and populations, RCTs are not always ideal in these instances (Mazzucca et al., 2018). RCTs incur high cost and time commitments and randomization may not be feasible in a real-world setting (Mazzucca et al., 2018). Often, observational and quasi-experimental study designs are used to evaluate effectiveness outcomes in the scientific literature (Singal, Higgins, & Waljee, 2014).

Another persistent issue among clinical studies is the longstanding concern about unequal representation of minority patients in clinical trials, with US trials frequently under-enrolling racial/ethnic minorities or not reporting minority enrollment at all, leading to biased,

ungeneralizable results (V. H. Murthy, Krumholz, & Gross, 2004; Turner, Steinberg, Weeks, Rodriguez, & Cullen). COVID-19 vaccine trials highlighted these disparities. For instance, although Black individuals make up approximately 13% of the U.S. population, they represent 21% of COVID-19 deaths and comprised just 3% of enrollees in vaccine trials (Warren et al., 2020). Effectiveness studies, which are commonly carried out at the community- or population-level (i.e., regarding real-world implementation within a given setting), rather than at that of the individual, may have a more difficult time reporting individual demographics, as collecting demographic data from an entire population may not be feasible. Nevertheless, to ensure that trials and evaluative studies are representative of the populations they intend to serve, scientists should report approximate demographic breakdowns of the communities being studied (Borno, Zhang, & Gomez, 2020). According to ClinicalTrials.gov, primary outcome(s) can be defined as "the outcome measure(s) of greatest importance specified in the protocol." (NIH, 2022). Determining a list of primary outcomes prior to study onset is critical because these outcomes inform the design, sample size and duration of the study.

This systematic literature review aims to determine the extent to which current safety, efficacy, and effectiveness studies on COVID-19 vaccines incorporate PIOs (as described in the 3C's model of vaccine hesitancy) in their list of primary outcomes.

4.3 Methods

A systematic literature review was undertaken following a structured search and screening process outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Figure 1). Searches for studies published between December 2019 and March 2022 were conducted using the Cochrane COVID-19 Study Register (which

comprises the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, Embase, ClinicalTrials.gov, WHO International Clinical Trials Registry Platform, and medRxiv) and Google Scholar. The search terms pertained to studies evaluating the safety (Phase I clinical trials), efficacy (Phase III clinical trials), and/or effectiveness of COVID-19 vaccines administered in the US (Pfizer-BioNTech BNT162b2, Johnson & Johnson JNJ-78436735, and Moderna mRNA-1273). Search terms also pertained to studies assessing both safety and stimulation of immune system (i.e., "expanded studies) that were considered Phase II clinical trials (as described in Table 1).

Table 2 reports the full list of search terms and their corresponding inclusion criteria for each type of study. Inclusion criteria for clinical trials relating to safety and efficacy (i.e., Phase I, Phase II, or Phase III clinical trials) were as follows: (i) studies were conducted with a US sample population including adult participants; (ii) studies evaluated COVID-19 vaccines authorized for distribution in the US; (iii) study designs included protocols for randomized trials, systematic reviews, meta-analyses, or experimental designs; (iv) primary study objectives were to evaluate vaccine safety, stimulation of immune system, and/or vaccine efficacy. Inclusion criteria for studies relating to effectiveness of vaccine rollout efforts were as follows: (i) studies were conducted with a US sample population; (ii) studies evaluated implementation of COVID-19 vaccine rollout efforts in the US (not modelling studies of hypothetical rollout strategies); (iii) study designs included evaluation protocols, systematic reviews, meta-analyses, experimental designs, quasi-experimental designs or observational designs; (iv) primary study objectives were to evaluate the effectiveness of the implementation of COVID-19 vaccine distribution program(s). Exclusion criteria for all types of studies included: (i) articles conducted

in countries other than the US or (ii) articles pertaining to COVID-19 vaccines not approved in the US with EUA or full FDA approval.

Table 4.2. Search terms used in database searches for systematic literature review

Primary study objective	Search terms used
To evaluate the safety of COVID-19 vaccine(s) and/or stimulation of immune system	*COVID-19 vaccine, vaccination, side effects, adverse effects, risks, safety,*
To evaluate the efficacy of COVID-19 vaccine(s)	*COVID-19 vaccine, vaccination, COVID-19 protection, efficacy*
To evaluate the effectiveness of COVID-19 vaccine(s)	*COVID-19 vaccination, rollout, allocation, distribution, uptake, effectiveness, implementation, impact, evaluation*

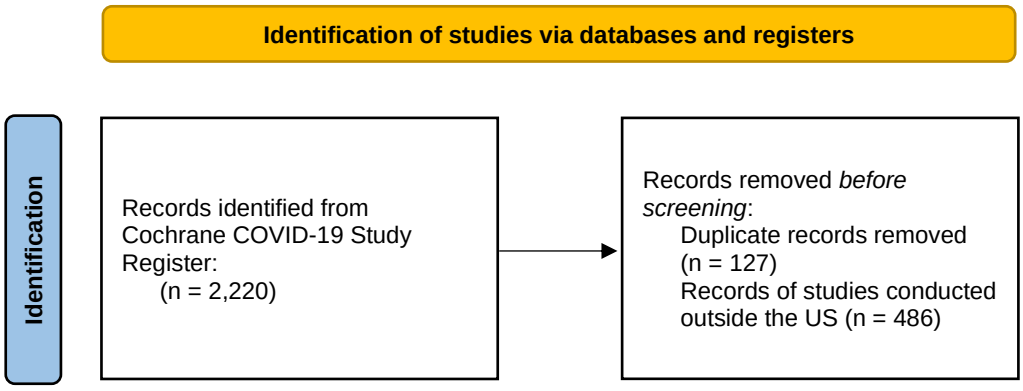
The screening process comprised four steps: First, titles and abstracts of articles generated from search terms were screened for relevance and extracted, if appropriate. Second, all extracted articles were entered into a reference manager software (EndNote) so that duplicate articles could be identified and eliminated. Third, full-text screening of the extracted articles was conducted to ensure only those meeting inclusion criteria were retained. Finally, to identify and exclude any duplicate studies under different titles, all articles meeting inclusion criteria were reviewed again. Relevant data extracted from included articles were recorded in Excel, including the title and year of publication, the study design, sample size, sample demographics, and primary outcomes reported.

To assess alignment, PIO's derived from the 3C's Model of vaccine hesitancy were compared with primary outcomes extracted from included studies. PIOs were determined to align with primary outcomes of interest in included studies if: (i) the primary outcome of a study provided an example or instance of a PIO (e.g., "adverse event" and "perceived risk of COVID-19 vaccine"); (ii) the description of a primary outcome of a study had the same meaning of a given PIO (e.g., "Willingness to become vaccinated" and "Intention of becoming vaccinated"); or (iii) if the primary outcome and PIO directly match in name and meaning.

4.4 Results

A total of 2,220 studies were located after the initial search (see Figure 2). After search results were filtered to include only those conducted in the US and duplicate results were removed, 1,607 studies remained. Inclusion/exclusion criteria were then applied to the remaining titles and abstracts, resulting in the exclusion of 1,419 studies and leaving 188 remaining studies. After conducting full-text screening, 78 articles were retained. An additional 22 articles were excluded during data extraction because they met exclusion criteria not identified during the full-text screening including evaluations of hypothetical rollouts (i.e., modelling studies), qualitative studies, and those not conducted in the US. A total of 56 articles published between December 30, 2019, and March 30, 2022 were included in this review.

Among the 31 effectiveness evaluation studies, 11 studies reported race/ethnicity demographic data. Among these, the percentage of White participants ranged from 14.1% to 92.5%. The percentage of participants identifying as Black/African American ranged from 1.7 to 48.9%.



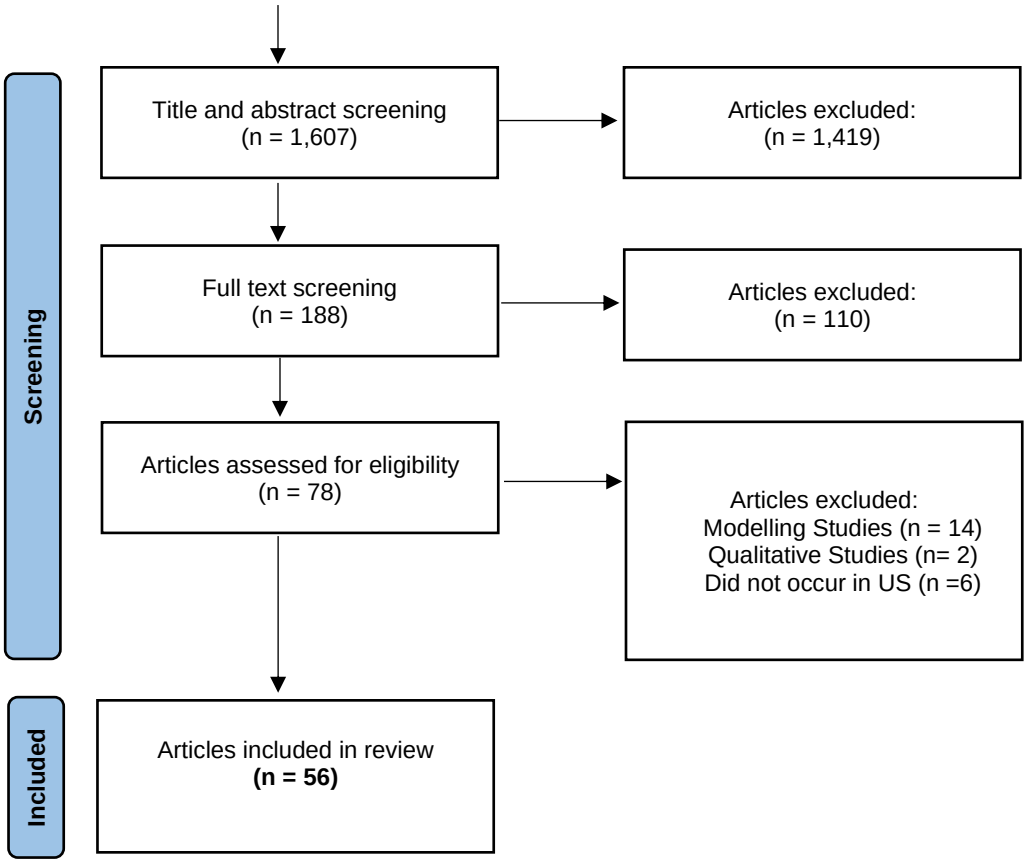


Figure 4.1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram. Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Included studies examined safety, efficacy, and/or both (i.e., "Expanded" or "Phase II" Clinical Trials), and effectiveness of the COVID-19 vaccines approved in the United States (see Appendix G). Study designs included Phase I, II and III clinical trials of the Pfizer-BioNTech BNT162b2, Johnson & Johnson AD26.COV2. S and/or Moderna mRNA-1273 vaccines and observational, quasi-experimental and experimental studies effectiveness evaluations assessing rollout efforts in a US-based sample. Demographic information including race/ethnicity breakdown of study participants were reported in 24 of 56 (49.0%) studies (not including 7 protocols as these could not report any participant information). Among the 23 included Phase I,

II, and II studies that reported race/ethnicity data (N=13), most participants identified as White, ranging from approximately 60% to 100%. Participants identifying as Black/African American ranged from 0% to 13%. Participant income was not reported as a key demographic factor in any of the studies assessed (Appendix G).

As shown in Table 3, primary outcomes related to safety trials (Phase I) and expanded trials (Phase II; n=10) included any reactogenicity, i.e., adverse events (e.g., unsolicited, solicited, serious, immediate, special interest, medically attended – see Appendix G for definitions) (80%), death (2%), new-onset chronic medical conditions (70%), and tolerability (2%). Notably, "death" was often included as a serious adverse event. Immunogenicity, or the indication of biomaterial being detected by the body's immune system as a foreign object thereby provoking an immune response of some kind, was a primary outcome of all expanded trials. Efficacy studies (N=14) most frequently used time to COVID-19 infection (42.9%) and laboratory-confirmed COVID-19 infection or COVID-19 cases (4.29%) as primary outcome measures. Additionally, all efficacy studies included adverse events and immunogenicity-related outcomes as either primary or secondary outcomes. Primary outcomes used in effectiveness studies were most commonly those related to vaccine uptake (N=11), vaccine coverage (N=5), COVID-19 related hospitalizations (N=8), COVID-19 deaths (N=3), COVID-19 population-level infection (N=5). One effectiveness study (Ehde et al., 2021) included outcomes related to vaccine hesitancy such as intention to receive vaccination, perceived risk of COVID-19 infection, trust in information sources, and perceived concern in the COVID-19 vaccine. Other effectiveness studies included disparities in vaccine uptake which looked at associations between demographic variables and vaccine uptake. In these instances, the dependent variable was vaccine uptake although the primary outcome was reported as disparities in vaccine uptake. Descriptions of vaccine uptake and vaccine coverage

were the same (i.e., proportion or percentage of the population receiving a COVID-19 vaccine), only differing in label.

Table 4.3. Primary outcomes of included studies and corresponding PIOs derived from 3C's model

Primary Outcomes of included studies	Number and authors of corresponding studies	Corresponding vaccine hesitancy-derived PIOs
Reactogenicity/adverse events (Includes solicited, unsolicited, serious, medically-attended AEs)	**N= 10;** (Thomas et al., 2021); (ModernaTX, Biomedical Advanced, National Institute of, & Infectious, 2020); (BioNTech, 2020b); (Jackson et al., 2020; NIAID, 2020); (Izikson et al., 2022; Thomas et al., 2022); (Anderson et al., 2020) (BioNTech, 2020a; Pasteur, 2021b)	Perceived risk/harm of COVID-19 vaccines (e.g.,injury, death, disability, or pain)
Prevention of death post-vaccination	**N=5** (Thomas et al., 2021); (Di Fusco et al., 2022); (Greene et al., 2022); (McLaughlin, Khan, Pugh, Swerdlow, & Jodar, 2022); (McNamara et al., 2022)	Perceived risk/harm of COVID-19 disease Perceived benefits of COVID-19 vaccine
Prevention of laboratory confirmed/cases of moderate to severe/critical COVID-19 post-vaccination	**N=2** (B. Prevention, 2020); (Thomas et al., 2021)	Perceived benefits of COVID-19 vaccine
Prevention of laboratory confirmed infection/cases of COVID-19 post-vaccination)	**N= 12** (Moreira Jr et al., 2022); (Polack, Thomas, Kitchin, Absalon, Gurtman, Lockhart, Perez, Pérez Marc, et al., 2020); (Thomas et al., 2021); (Blaiszik, Graziani, Olds, & Foster, 2021); (Blaiszik et al., 2021; Brunelli et al., 2021); (McLaughlin et al., 2022); (McNamara et al., 2022); (Nanduri et al., 2021); (Rosenberg et al., 2022); (Tartof et al., 2021); (Young-Xu, Zwain, Powell, & Smith, 2021)	Perceived benefits of COVID-19 vaccine
Dose-dependent response	**N=1** (Anderson et al., 2020)	Perceived risk/harm of COVID-19 vaccines (e.g., injury, death, disability, or pain) Perceived benefits of COVID-19 vaccine
Prevention of confirmed COVID-19 participants with and participants without evidence of prior infection	**N=1** (Polack, Thomas, Kitchin, Absalon, Gurtman, Lockhart, Perez, Pérez Marc, et al., 2020)	Perceived benefits of COVID-19 vaccine
Time to first occurrence of COVID-19 post-vaccination	**N=5** (ModernaTX et al., 2020); (Baden et al., 2021); (El Sahly et al., 2021); (Sadoff et al., 2021); (Gilbert et al., 2021);	Perceived benefits of COVID-19 vaccine
Time to first occurrence of moderate-severe COVID-19 post-vaccination	**N=1** (Sadoff et al., 2021)	Perceived benefits of COVID-19 vaccine

Tolerability	**N=1** (BioNTech, 2020b)	Perceived risk/harm of COVID-19 vaccines (e.g.,injury, death, disability, or pain)
Immunogenicity	**N=8** (BioNTech, 2020b); (Jackson et al., 2020); (Achiron et al., 2022); (Sablerolles et al., 2022); (Mateus et al., 2021); (Izikson et al., 2022); (Pasteur, 2021a); (BioNTech, 2020b)	Perceived benefits of COVID-19 vaccine
Proportion of vaccine uptake	**N= 15** (Acharya & Dhakal, 2021);(R. Agarwal et al., 2021); (Berk et al., 2021); (Berry et al., 2022) (Hagan, Dusseau, Crockett, Rodriguez, & Long, 2021); (Hao & Shao, 2022); (Hughes et al., 2021; Marquez et al., 2021; Ritter et al., 2021) (Roghani & Panahi, 2021); (Viswanath et al., 2021; H. Wang et al., 2021);(Cheng & Li, 2022) (Gharpure et al., 2021) (Sehgal, 2021)	*Relates to all constructs
Prevention of COVID-19-related hospitalizations	**N=8** (Bajema et al., 2021); (Brunelli et al., 2021); (Di Fusco et al., 2022);(Greene et al., 2022); (Moline et al., 2021); (Rosenberg et al., 2022); (Tartof et al., 2021; Wright et al., 2022)	Perceived benefits of COVID-19 vaccine
COVID-19 population-level infection/incidence rate	**N=5** (Brunelli et al., 2021); (Donadio, Choudhary, Lindemer, Pawlowski, & Soundararajan, 2021); (Li, Li, Rice, Su, & Yang, 2021); (Puranik et al., 2022); (H. Wang et al., 2021)	Perceived benefits of COVID-19 vaccine
Vaccination rate	**N=2** (Donadio et al., 2021); (Thirumurthy, Milkman, Volpp, Buttenheim, & Pope, 2022)	*Relates to all constructs
Vaccine willingness/intention	**N=1** (Ehde, Roberts, Humbert, Herring, & Alschuler, 2021)	Prioritization of/need for COVID-19 vaccination in relation to other life needs Willingness to become vaccinated
Vaccine coverage	**N=5** (Hagan et al., 2021); (Hughes et al., 2021); (Marquez et al., 2021); (Moline et al., 2021); (Z. Wang et al., 2021)	*Relates to all constructs
Perceived risk of COVID-19 infection	**N=1** (Ehde et al., 2021)	Perceived risk/harm of COVID-19 disease
Trust in information sources	**N=1** (Ehde et al., 2021)	Trust in sources of information
Perceived concern over the COVID-19 vaccine	**N=1** (Ehde et al., 2021)	Perceived risk/harm of COVID-19 vaccines (e.g. Injury, death, disability, or pain)

*Proportion of vaccine uptake does not align with just one construct, but instead may be related to all constructs of vaccine hesitancy within the 3C's model.

A comparison of the list of extracted primary outcomes (N=20) from the included studies with the list of factors or PIOs derived from the 3 C's Model of vaccine hesitancy (Figure 4.2), shows that 85% (n=17) of primary outcomes corresponded with factors of vaccine hesitancy. Included primary outcomes most frequently related to the PIO "Perceived risk/harm of COVID-19 vaccines" (e.g., injury, death, disability, or pain) and "Perceived benefits of the vaccine" (e.g., protection from disease, protection from infection). These were mostly addressed in Phase I, II and III studies. Effectiveness studies most frequently measured vaccine uptake as their primary outcome, for which no single PIO directly corresponds. One effectiveness study measured four PIOs including trust in information sources, willingness to receive a vaccination, and prioritization of/need for COVID-19 vaccination in relation to other life needs. PIO's derived from the 3 C's Model that did not correspond to any of the primary outcomes included: "Trust in the system and people who deliver the vaccines";, "Trust in the motivations behind the policy makers in charge of rollout"; "Social support," "Access to understandable information"; "Cost"; "Eligibility"; "Geographic accessibility/Transportation availability"; "Ability to take time off from work"; "Physical availability of the vaccine"; "Appeal of immunization services" and "Willingness to become vaccinated."

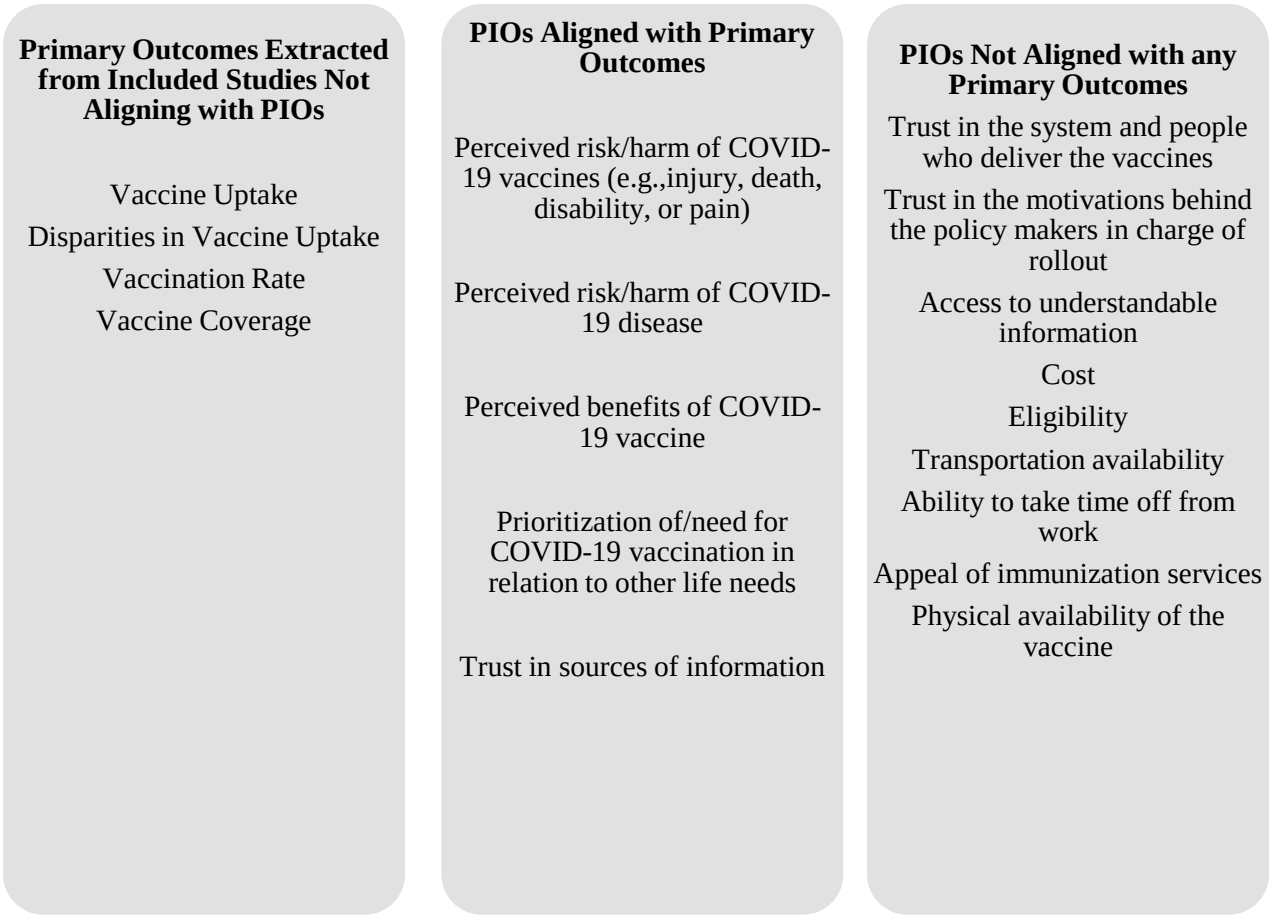


Figure 4.2. Diagram of PIO alignment with extracted primary outcomes from included studies

4.5 Discussion

This systematic literature review aimed to identify primary outcomes extracted from studies that evaluated the safety, efficacy and effectiveness of COVID-19 vaccines in the US and assess the extent to which they aligned with PIOs derived from the 3C's Model of vaccine hesitancy. Fifty-six studies evaluating the safety and efficacy of COVID-19 vaccines were identified, with five PIOs aligning with extracted primary outcomes. Nine PIOs did not align with any extracted primary outcomes from the included studies. Since a systematically

developed list of PIOs has not yet been developed for COVID-19 vaccine studies, this systematic literature review utilized factors of vaccine hesitancy to develop proxy PIOs.

4.5.1 Strengths

Since the COVID-19 pandemic began, vaccine hesitancy studies have been used to predict which population groups would be accepting of vaccines and to identify factors associated with vaccine hesitancy (Lucia, Kelekar, & Afonso, 2021; Sallam, 2021). The results of these studies have been used by public health practitioners to inform the design and implementation of interventions to improve vaccine uptake and distribution ((W.-Y. S. Chou & A. Budenz, 2020; Soares et al., 2021). However, factors of vaccine hesitancy have never been used as proxy measures for PIOs, despite their fitting the definition of PIOs as "outcomes that are meaningful to patients and reflect how they feel, function, or survive."(Gaudry et al., 2017) This is the first study of its kind to do so, analyzing the existing literature in the context of COVID-19 vaccine PIOs. Given the high demand for rapid, ongoing research on the safety, efficacy and effectiveness of COVID-19 vaccines as well as the increasing threat of novel emerging pathogens in a globalized world, this review provides an innovative method to incorporate PIOs in COVID-19 vaccine studies and highlights key gaps in the existing literature. Disseminating the results of safety, efficacy and effectiveness studies which address constructs associated with vaccine hesitancy could improve vaccine uptake, particularly among more hesitant populations.

The findings from this systematic literature review align with existing studies indicating that racial and ethnic minority groups are under-represented in clinical trials (Andrasik et al., 2021; Crawley, 2001; Hussain-Gambles, Atkin, & Leese, 2004; Salman, Nguyen, Lee, & Cooksey-James, 2016). Furthermore, our results indicate that demographic information regarding participants' socioeconomic status or other social determinants of health are often not included in

clinical trials, limiting the true generalizability of such studies. Effectiveness evaluations that reported demographic information such as race/ethnicity data demonstrated greater equity in terms of representation than Phase I, II, or III clinical trials, suggesting that population-level studies may be more generalizable. However, this indicates that safety and efficacy data, often assessed during Phase I, II, and III clinical trials, may not be generalizable to all groups in a given population. This may cast doubt on the results of such studies if sufficient sample sizes of minority groups were not included (Warren et al., 2020), which could lead to distrust in the results of the trials among members of under-represented groups, a result that would affect implementation of vaccine rollout efforts greatly.

4.5.2 Limitations

This study had several limitations. First, although COVID-19 was a global pandemic, this study focuses only on US-based studies with US-based participants. As such, it precludes other studies which may have been conducted elsewhere in the world which may have included a wider scope of outcomes. That being said, COVID-19 vaccine rollouts varied substantially across the globe in terms of dates of initiation, supply, demand, types of COVID-19 vaccines offered, infrastructure, etc. Thus, it was determined that this systematic literature review would provide a more focused and accurate representation of the alignment of primary outcomes with PIOs if it limited studies to those conducted in the United States alone.

Second, while this study applied vaccine hesitancy factors and constructs associated with the 3C's Model of vaccine hesitancy as PIOs, numerous other health behavior theories have been used to understand the mechanisms of health behavior change in the context of vaccine hesitancy. All vaccine research – whether it be studies of safety, efficacy, or effectiveness – aim to ultimately result in uptake of a safe and efficacious vaccine. The existing literature points to several

theoretical constructs that correlate with vaccine uptake that are not explicitly addressed in the 3C's model, such as knowledge (Lindley et al., 2016), attitudes (Harris, Mauro, Andresen, Zimet, & Rosenthal, 2022; Lindley et al., 2016; Mattson, 1999), cues to action (i.e., the specific stimuli necessary to trigger appropriate health behavior, (Mattson, 1999)), and perceived self-efficacy (i.e., individuals that are confident in their capability to perform healthy behaviors are more likely than those who are not to fulfill that self-perception ((Bandura, 1977; Schmid, Rauber, Betsch, Lidolt, & Denker, 2017). The 3 C's Model was selected because it is widely used across studies in the existing literature as an inclusive framework for understanding factors of vaccine hesitancy and because of its development by the WHO SAGE Working Group, which examined the existing literature extensively in its development; much of the existing vaccine hesitancy literature identifies other key factors that contribute to vaccine hesitancy that are included in the 3C's Model, including access to vaccinations (Linn, Guralnik, & Patel, 2010), trust in health care providers and vaccines (Musa, Schulz, Harris, Silverman, & Thomas, 2009; Quinn et al., 2016), perceived benefits of the vaccine, and perceived severity of the disease or risks associated with the vaccines (Harris et al., 2022; Lindley et al., 2016).

4.5.3 Public Health Implications

The results of this systematic literature review suggest that public health researchers should do more to: (i) incorporate PIOs in safety, efficacy, and effectiveness trials of COVID-19 vaccines, (ii) ensure that study samples in any clinical trial or effectiveness evaluation include a diverse set of participants and sufficient data regarding social determinants of health (e.g., socioeconomic status, education, neighborhood and built environment, etc.), and (iii) develop a systematically and scientifically derived list of PIOs in the context of COVID-19 vaccines. Given the complex nature of vaccine hesitancy and the novelty of COVID-19 vaccines, it is likely that outcomes currently

used in evaluating COVID-19 vaccine safety, efficacy and effectiveness do not sufficiently capture outcomes that are meaningful to vaccine hesitant communities. Inclusion of PIOs in COVID-19 vaccine studies would address concerns resulting in vaccine hesitancy and facilitate better assessment of the true scope of effectiveness of COVID-19 vaccine rollout efforts.

The paucity of demographic information including SES and race/ethnicity among study participants clearly indicates that results of these studies are not generalizable to all groups and therefore may garner low levels of confidence and compliance among underserved populations. Furthermore, incorporation of methods that engage patients and communities of interest, such as those upheld through community-based participatory research (i.e., the collaboration among scientific researchers and members of the community to address diseases and conditions disproportionately affecting underserved populations), would ensure that PIOs are understood and applied at all stages of vaccine research (Israel et al., 2019).

The safety, efficacy and effectiveness outcomes identified through this systematic literature review align with several of the constructs highlighted in the 3C's Model, which we used as proxy or surrogate PIOs. However, further research should be done to develop a context-specific, core set of outcomes that include PIOs identified directly by those who stand to benefit from the vaccine. To ensure that results of these studies remain useful to scientists but also meaningful to vaccine users (e.g., patients, the public) as they make their decision whether to receive a COVID-19 vaccine, these PIOs should be included in safety, efficacy, and effectiveness studies. Identification and inclusion of PIOs in vaccine research should be regarded as a necessary first step in the research process and recognized as a step toward improving social justice for underserved populations. As in other studies which aim to identify PIOs, further research should focus on qualitative and quantitative methods and focus on specific populations, preferably those

that are most hesitant and/or disadvantaged, to generate a thorough and complete list of PIOs in the context of COVID-19 vaccines.

Chapter 5. Developing a Core Outcome Set for use in Safety, Efficacy and Implementation Studies of COVID-19 Vaccines through collaboration with Black/African American communities in Baltimore City

5.1 Abstract

Background: Baltimore City is the second poorest city in Maryland. Disparities in vaccine uptake among proximal neighborhoods within Baltimore city suggest an association between income and vaccine uptake, with poorer, predominantly Black neighborhoods commonly reporting lower levels of vaccine uptake than affluent neighborhoods. Currently, there is no consensus on which outcomes play a critical role in vaccine uptake decision-making among Black populations living in low-income communities, such as Baltimore City. The objective of this study was to develop a core outcome set (COS) for use in studies evaluating COVID-19 vaccines that incorporates outcomes of importance to Black community members in Baltimore City.

Methods: A Delphi study with relevant stakeholders was conducted to prioritize outcomes from a candidate list of core outcomes. Results were shared with community participants after each round. After two rounds of the Delphi survey, a face-to-face consensus meeting was held with community members and community health workers to finalize the recommended COS.

Results: The final COS included 19 outcomes across four "domains." These domains included: (i) Is the vaccine safe?; (ii) Does the vaccine work in my body?; (iii) Does the vaccine work in my community?; and (iv) Outcomes Nominated During Consensus Meeting for Inclusion in COS

Conclusion: Core outcomes identified under the "Is the vaccine safe?" and "Does the vaccine work in my body?" domains are already incorporated into COVID-19 vaccine studies. Other core outcomes, however, particularly those in the "Does the vaccine work in the community?" domain and those identified during the consensus meeting pertaining to trustworthiness have not been

thoroughly addressed in vaccine effectiveness studies, suggesting that future efforts to improve equitable vaccine uptake should address these outcomes of importance.

5.2 Background

Since the World Health Organization declared COVID-19 a global pandemic in March 2020, the United States has recorded over one million COVID-19 related deaths (WHO, 2022). As of August 2022, 67.4% of the US population (anyone 5 years or older) has been fully vaccinated (i.e., received their first and second doses in a two-dose series, such as the Pfizer-BioNTech and Moderna vaccines, or received the single-dose J&J/Janssen vaccine) (C. f. D. C. a. Prevention, 2022). With approximately 76.0% of its residents fully vaccinated, the state of Maryland has one of the highest percentages of fully vaccinated residents in the country (Services, 2022). However, several counties within Maryland remain far below this vaccination percentage. In the ten counties with the lowest vaccination rates in the state, percentages of fully vaccinated residents range from 51.0% to 66.8% (Services, 2022). Interestingly, nine out of these ten counties also contend with the highest poverty rates in the state (U. C. Bureau, 2020).

One of these counties, Baltimore City is the second poorest city in Maryland (U. C. Bureau, 2020). Just 63.4% of Baltimore City residents are fully vaccinated (Department, 2022b). Disparities in vaccine uptake among proximal neighborhoods within Baltimore city suggest an association between income and vaccine uptake, with poorer neighborhoods commonly reporting lower levels of vaccine uptake than affluent neighborhoods (U. S. C. Bureau, 2020; Department, 2022b). More than 60% of Baltimore residents identify as Black and/or African American (U. S. C. Bureau, 2020). Just as low-income neighborhoods have reported lower vaccination uptake, many of these same low-income neighborhoods also have been shown to have greater proportions of Black populations compared with high-income neighborhoods (U. S. C. Bureau, 2020).

Despite efforts to reduce barriers to access though equitable vaccine distribution in Baltimore City (Department, 2021b; Health, 2021), it is possible that vaccine rollout efforts may have insufficiently addressed access needs in low-income communities, as has been observed in previous vaccine rollout efforts and in other COVID-19 vaccine studies (Cheng & Li, 2022; Feiring et al., 2015; Schmidt et al., 2021; Shono & Kondo, 2015). Attitudes and beliefs resulting in delay or refusal of vaccine uptake, also known as vaccine hesitancy (MacDonald & Hesitancy, 2015), may also serve as important barriers to vaccine uptake. National vaccine hesitancy studies have shown little to no difference in intention to get vaccinated among racial/ethnic groups (Funk, 2021; Tyson, 2021). However, previous studies on other vaccines have shown that, due to historical context, personal experience with medical care, and various permutations of systematic racism- defined as the "system of structures, policies, practices, and norms that construct opportunities and assigns values based on one's phenotype" (Jones, 2002; Rivara & Fihn, 2020)- racial minority groups tend to experience lower trust in medical institutions (Gamble, 1997; Quinn et al., 2016; Salmon et al., 2015; Sullivan et al., 2022). In these studies, these social structures have served as barriers to vaccine uptake for some racial minority groups. Concerns about the safety, efficacy and speed with which COVID-19 vaccines were developed have also been shown to be barriers to vaccine uptake among members of all races (Ljungholm, 2021; Padamsee et al., 2022) .

Since vaccine distribution began in December 2020, Blacks and Hispanics in the United States have been less likely than Whites to receive a COVID-19 vaccine, though these disparities have narrowed over time (Nambi Ndugga, 2022). However, national studies have also shown that willingness to receive a COVID-19 vaccine among Black and Hispanic individuals has increased faster than that of White people (Padamsee et al., 2022). These findings, coupled with national data demonstrating that lower income individuals are less likely than those of higher income to

become vaccinated against COVID-19 (Tyson, 2021), suggest that reasons for disparities in vaccine uptake are multidimensional and nuanced. While COVID-19 vaccine rollout efforts in the United States continue to be evaluated, currently, there is no consensus on why vaccine uptake disparities persist in Baltimore City or which outcomes play a critical role in vaccine uptake decision-making among Black populations living in low-income communities.

This research aims to address this important gap in our understanding of vaccine uptake/hesitancy. The objective was to develop a core outcome set (COS) for use in studies evaluating COVID-19 vaccines that incorporates outcomes of importance to community members in Baltimore City. A COS is a minimum set of outcomes to be measured in all studies of a specific intervention (Fally, Mathioudakis, Digby, & Williamson, 2022; Williamson et al., 2017). A COS ensures that outcome measures used in research studies are relevant and important to users of the research (e.g., patients, public) and remain consistent across studies of the same intervention among similar populations (Williamson et al., 2017). Ensuring that outcomes are important to the users enhances the utility of the research. Consistency of outcome measures across studies allows results to be aggregated through meta-analyses, generating more scientifically robust conclusions (Dodd et al., 2021).

Primarily used in the context of clinical treatments and devices in healthcare, COSs have been developed for many healthcare interventions (Clearfield, Miller, et al., 2021; Haywood, Griffin, Achten, & Costa, 2014; Orbai et al., 2017; Smith et al., 2018; van‘t Hooft et al., 2016; Webbe et al., 2017). The Core Outcome Measures in Effectiveness Trials (COMET) Initiative, a research collaboration that provides guidance for COS development methodology outlines the following components to include in COS development: (i) systematic review identifying outcomes measured in previous studies; (ii) qualitative studies to identify outcomes considered important by

patients; and (iii) Delphi surveys distributed to stakeholders of the research aiming to prioritize outcomes; and (iv) consensus meeting involving all stakeholders to finalize the COS (Williamson et al., 2017). This methodology incorporates several elements of community-based participatory research (CPBR), a term used to represent collaborative approaches to research that equitably involve members of the community, community representatives, and researchers in all aspects of the research process and in which all stakeholders contribute and share decision-making and ownership (Barbara A Israel, 2005). Specifically, this research builds capacity within communities, empowering community members to voice their opinions and share their experiences.

Although COVID-19 COS development studies have been underway since the start of the pandemic, they have largely focused on outcomes related to COVID-19 treatment rather than prevention and none have focused on engagement with low-income populations (Cochrane, 2020; Dinglas, Cherukuri, & Needham, 2020; Fally et al., 2022; M. Hoffman & Holland, 2022; Jin et al., 2020; Munblit et al., 2022; Tong et al., 2021). Prevention trials for COVID-19 include a variety of interventions (e.g., mask wearing, social distancing, COVID-19 vaccines), outcomes, and instruments (Dodd et al., 2021). The COS-COVID-PCARE Study recently developed a core outcome set for the evaluation of prevention interventions for COVID-19 in care homes – institutions that look after individuals that are unable to care for themselves - evaluating outcomes used in trials of pharmacologic and non-pharmacologic interventions (Shepherd et al., 2022). Our study builds on this research, applying Delphi methodology and community-based participatory research methods to generate the first COS for COVID-19 vaccine studies among low-income, Black community members in Baltimore City.

5.3 Methods

This research applied a four-step protocol for in the development of a COS as outlined in the Core Outcomes Measures in Effectiveness Trials (COMET) Handbook: (i) conduct a systematic review to identify existing outcomes measured in studies; (ii) conduct qualitative research to identify outcomes considered important to patients (iii) conduct Delphi study with relevant stakeholders to prioritize outcomes; and (iv) hold a face-to-face consensus meeting to finalize the recommended COS (Williamson et al., 2017).

5.3.1 Participants

Using purposive sampling methods, a multi-stakeholder group of participants including community members, healthcare professionals (i.e., clinicians and researchers), and community health workers was recruited. These three stakeholder groups were selected based on stakeholder recommendations outlined in the Core Outcome Set-STAndards for Development (COS-STAD), a set of guidelines developed to uphold the quality of COSs through the identification of minimum standards for the design of a study (Kirkham et al., 2017). Of the eleven COS-STAD criteria, those relating to stakeholder participants include: (i) those who will use the COS in research (i.e., healthcare researchers); (ii) clinicians with experience of patients with the condition (i.e., healthcare providers); (iii) patients with the condition or their representatives (i.e., community members and community health workers). In this case, “the condition” refers to COVID-19 vaccine uptake (Kirkham et al., 2017).Thus, healthcare professionals (includes healthcare researchers and healthcare providers), community health workers, and community members will make up the three stakeholder groups in this study (Table 1).

This sampling frame aligns with several guiding principles of CBPR, including "acknowledging the community as a unit of identity" and "involving an empowering and power-sharing process that attends to social inequalities" (Barbara A Israel, 2005). This means valuing the opinions and perspectives of the community throughout this research and providing a platform for those opinions and perspectives to be hears. As such, healthcare professionals including public health researchers and clinicians, community health workers, and community members living in East Baltimore made up this multi-stakeholder group. Recruitment strategies and inclusion criteria for each stakeholder group are outlined in Table 1.

Table 5.1. Delphi participants by stakeholder group, inclusion criteria and recruitment strategy.

Stakeholder Group	Inclusion Criteria	Recruitment Strategy
Community Members	• Identify as Black and/or African American • Lives in a low-income community in Baltimore City, MD • Able to read and write in English • Over the age of 18	Community leaders in Baltimore City working with STAR will assist in recruiting community members as participants for this study from existing support groups that mean weekly at STAR headquarters.
Healthcare Professionals/Researchers	• Clinicians or behavioral science researchers • Able to read and write in English • Over the age of 18	Researchers and clinicians will be identified by the researcher and emailed requests for participation along with hyperlinks to consent forms and online survey (on Qualtrics).
Community Health Workers or Community Leaders	• Self-reported members of the community • Able to read and write in English • Self-reported community health worker or community leader working with STAR • Over the age of 18	Community health workers or leaders working with STAR will be recruited by the researcher using flyers and word of mouth.

Although there are no strict rules on sample size determination for research studies utilizing Delphi technique, existing studies typically range from between eight and 80 participants (Hallowell & Gambatese, 2010; Ogbeifun, Mbohwa, & Pretorius, 2016). To ensure that community perspectives were preserved in the Delphi process, quota sampling was used to ensure the community member stakeholder group was 3 times the size of the other two stakeholder groups,

thus giving this group's perspectives more weight during survey analysis. Given the size of the community support group we would be recruiting from (approximately 30 individuals) and the fact that we aimed to have a community stakeholder group that was approximately 3 times the size of the other stakeholder groups, we aimed to recruit between 20 and 30 participants. This type of weighting has been used in previous studies to preserve community- or patient-important outcomes during the Delphi process (Clearfield, Miller, et al., 2021; Clearfield, Tambor, Janssen, & Messner, 2021). All community member and community health worker participants received a $20 gift card for each completed survey and a $40 gift card for participation in the consensus meeting.

5.3.2 Identification of Outcomes

A list of candidate or potential outcomes for the COS was generated from the results of a systematic literature review and semi-structured interviews with community members of low-income neighborhoods in Baltimore City. The systematic literature review was used to achieve Step 1 in the COMET protocol (conduct a systematic review to identify existing outcomes measured in studies (Williamson et al., 2017)) by systematically searching and aggregating a list of outcomes that are already in use in COVID-19 vaccine studies.

Semi-structured interviews were conducted to achieve Step 2 in the COMET protocol (i.e., conduct qualitative research to identify outcomes considered important to patients (Williamson et al., 2017)). Results from these interviews supplemented the systematic literature review to ensure that included candidate outcomes in the COS reflected outcomes pertaining to community members' own lived experiences, beliefs and behaviors regarding COVID-19 vaccines. Qualitative data from the semi-structured interviews were assessed using inductive thematic analysis and emergent themes were used in the candidate list of outcomes. Overall, participants from an East Baltimore community (vaccinated and unvaccinated individuals) were individually

interviewed using semi-structured questionnaires to identify concerns or issues that were consequential in their COVID-19 vaccine decision-making process.

5.3.3 Delphi Process and Voting

To achieve Step 3 in the COMET protocol (conduct Delphi study with relevant stakeholders to prioritize outcomes (Williamson et al., 2017)), we elicited views about important outcomes using a modified Delphi consensus process. This method allows the candidate list of outcomes to be prioritized by relevant stakeholders iteratively, reducing the number of outcomes in the list over multiple rounds of online voting (Williamson et al., 2017). Healthcare professionals voted on outcomes using Qualtrics software while community members and community healthcare workers were provided with printed surveys, which they completed by hand with pen or pencil at a local community center in East Baltimore.

To accommodate differences in literacy levels among these stakeholder groups, the candidate list was pilot tested by three community health workers that did not participate in this study. These community health workers were asked to rate each outcome and provide suggestions, questions or concerns regarding wording, question order, and language used. At the time of the first round of survey completion, each outcome was read aloud by the researcher and community member participants were encouraged to ask clarifying questions as needed. In addition to each outcome being read aloud, examples of each outcome, which were developed in response to comments made during pilot testing, were also read and participants rated each outcome on a Likert scale of 1-9. This scale allows outcomes to be graded in accordance with their level of importance. Analytically, scores of 1 to 3 signified "limited importance", 4 to 6 "important but not critical", and 7 to 9 "critical" (Bennett et al., 2012; Clearfield, Miller, et al., 2021; Harman et al., 2015; Williamson et al., 2017). While score groupings (e.g., 1-3 or "limited importance" grouping) did

not differ analytically, a 1-9 scale provided a wider gradient with which each participant can identify. At the end of the survey, participants were given the opportunity to suggest changes or additional outcomes they felt should be added to the list. Any suggestions or changes given by participants during the in-person surveys were reviewed by the researcher and, if distinct from existing included outcomes, were added to the list of candidate outcomes for the second round. Survey responses from community members and community health workers were manually input into the Qualtrics online survey and summary statistics were conducted using data from all three stakeholder groups.

Statistical achievement of consensus for each outcome depends on a predetermined list of consensus criteria (Table 2). Outcomes receiving ratings from 7 to 9 by <70% of all voters were eliminated from consideration (i.e., outcome excluded), unless the community member stakeholder group average score was 7 or higher. Retaining outcomes which achieve an average score of ≥ 7% consensus among community members only has been done in previous studies to ensure that community-important outcomes are not excluded and are instead thoroughly considered (Clearfield, Miller, et al., 2021). The ≥70% threshold for consensus is based on recommendations in the COMET handbook (Williamson et al., 2017).

Table 5.2. Criteria for consensus after each round

Status	*Criteria*
OUTCOME RETAINED: Consensus to keep outcome in final COS	An outcome in which >70% of all voters rated the outcome with a score of 7, 8, or 9 ("critical importance")
OUTCOME RETAINED: Consensus achieved among community members to keep outcome in final COS	An outcome in which <70% of all voters rated the outcome 7,8, or 9, BUT the stakeholders in the community group gave the outcome an average rating of ≥70%.
OUTCOME EXCLUDED: Consensus to eliminate outcome from final COS	An outcome in which <70% of voters rated the outcome 7,8, or 9 AND the community stakeholder group average rating was <70%.

The list was reduced over two rounds of voting with the second round taking place with community members and community health workers one week after the first round, at the same location. Prior to disseminating the second survey, the researcher presented a PowerPoint presentation of feedback and summary scores from all stakeholders from Round 1 to community members and community health workers. The summary scores included mean scores (rounded to the nearest integer) for each outcome included in the study reported by stakeholder group. Considering that community members may not be well versed in interpreting descriptive statistics, the researcher presented summary statistics on a PowerPoint presentation and provided images to assist with the plain language summary. The researcher also provided an overview of the study objective and definitions of the terms "outcomes" and "core outcome set." This was followed by a description of the analysis process and a review of the results from Round 1 of survey distribution.

5.3.4 Consensus Meeting

After the second round of Delphi surveys were complete, an in-person consensus meeting was held comprising community health workers and community members. To reduce response bias,

healthcare professionals were not included in this meeting as power dynamics could cause some community members to be less open. After brief introductions, the researcher again presented an overview of the study objective, and the aims and agenda of the consensus meeting. The terms "outcomes" and "core outcome set" and a description of the analysis process was reviewed. The researcher then presented results from Round 2 of the survey distribution.

Participants were asked to discuss items receiving "high consensus," "community-important outcomes" and "excluded outcomes" sequentially. Employing nominal group technique (NGT)- a highly structured face-to-face group interaction used to empower participants to provide an opportunity to share their opinions with other stakeholders (Bessa et al., 2019)- participants were asked to again vote on the final list of included outcomes. The entire meeting was audio recorded. Using a Discussion Guide, participants were asked clear, open-ended questions regarding the final COS. The Discussion Guide was developed based on review of consensus meetings from other COS development studies (Clearfield, Miller, et al., 2021) These questions provided participants with the opportunity to: (i)rescue" or save an outcome that had been eliminated in a previous round and put it back into the COS, (ii) suggest combinations of outcomes, and (iii) refine or amend definitions of outcomes currently on the list. For each question, participants were given 10-15 minutes to write down key ideas silently and independently. The researcher then conducted a round-robin recording of ideas in which participants were asked to share their ideas one at a time, and each idea was recorded, and visually displayed, on a Power Point slide by the facilitator. Serial discussion took place such that each idea was discussed in turn for the purpose of clarification and for highlighting proposed COS strengths and weaknesses.

At the end of the meeting, participants were asked to rank order each of the suggested outcomes by level of importance in open discussion. The group went through the rankings and determined

together which ideas were most important. After the ratings of the entire group were recorded, a brief discussion was held to address any areas needing further clarification.

5.4 Results

5.4.1 Participants

Twenty-seven voters participated in the first round of the Delphi consensus process: seven community health workers, 15 community members, and five healthcare professionals (three clinicians and two healthcare researchers) (Table 1). Community members were recruited through an HIV support group facilitated by STAR community healthcare workers. Most community member participants were female (66.6%), over the age of 55 (80.0%) and were fully vaccinated and had received at least one booster (66.6%). The support group met in person at STAR headquarters on a weekly basis. Community health workers were all recruited through STAR. Healthcare professionals were recruited from the University of Maryland College Park and the University of Maryland Baltimore using snowball sampling via email request. Of the participants that completed the first round, five community health workers (71.4% retention), 14 (93.3% retention) community members and four healthcare professionals (80% retention) completed the second-round survey (Total N=23, 85.1% retention). Six community health workers (57.7% retention from round 1) and ten community members (66.6% retention from round 1)) participated in the final consensus meeting (Total N=16, 59.3% retention from round 1).

5.4.2 Identification of Outcomes

A list of candidate outcomes was developed from a systematic literature review and semi-structured interviews. To identify outcomes through a systematic literature review, we searched for studies published between December 2019 and March 2022 using the Cochrane COVID-19

Study Register (which comprises the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, Embase, ClinicalTrials.gov, WHO International Clinical Trials Registry Platform, and medRxiv) and Google Scholar. Outcomes from each included study were included in the candidate list of outcomes for this study. Semi-structured interviews complemented the systematic literature review, ensuring that community perspectives, experiences and concerns were included in the candidate list of outcomes. In total, 37 outcomes were included in the candidate list of outcomes in the first-round survey (Appendix H). Community health workers who pilot tested the candidate list suggested that examples be provided for several outcomes, (e.g., for "local adverse event" outcome, "pain at the injection site" was included as an example) and these were ultimately included in the candidate list for the first-round survey.

Table 5.3. Participant Demographics for Delphi Process

	Community Members (n=15)	**Community Health Workers (n=7)**	**Healthcare Professionals (n=5)**
Age			
18-24	0 (0.0%)	0 (0.0%)	0 (0.0%)
25-39	2 (13.3%)	0 (0.0%)	3 (60.0%)
40-54	1 (6.7%)	2 (28.6%)	1 (20.0%)
55-69	8 (53.3%)	5 (71.4%)	1 (20.0%)
70+	1 (6.7%)	0 (0.0%)	0 (0.0%)
N/A	3 (20.0%)	0 (0.0%)	0 (0.0%)

Gender			
Male	5 (33.4%)	3 (42.9%)	1 (20.0%)
Female	10 (66.6%)	4 (57.1%)	4 (80.0%)
N/A	0 (0.0%)	0 (0.0%)	0 (0.0%)
Race			
Asian	0 (0.0%)	0 (0.0%)	3 (60.0%)
American Indian or Alaska Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Native Hawaiian or Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)
Black or African American	15 (100.0%)	7 (100.0%)	2 (40.0%)
White	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other or Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ethnicity			
Hispanic/Latino	0 (0.0%)	0 (0.0%)	1 (20.0%)
Non-Hispanic/Latino	4 (26.7%)	2 (28.6%)	4 (80.0%)
Mixed Ethnicity	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown or Not Reported	11 (73.3%)	5 (71.4%)	0 (0.0%)
Average Household Income			
<$25,000	9 (60.0%)	1 (14.3%)	0 (0.0%)
$25,000-<$50,000	4 (26.7%)	1 (14.3%)	0 (0.0%)
$50,000-<$75,000	0 (0.0%)	2 (28.6%)	0 (0.0%)
$75,000-<$100,000	0 (0.0%)	2 (28.6%)	2 (40.0%)
≥$100,000	0 (0.0%)	1 (14.3%)	3 (60.0%)
N/A	2 (13.3%)	0 (0.0%)	0 (0.0%)
Highest Education Level Achieved			
High School, No Diploma	3 (20.0%)	1 (14.3%)	0 (0.0%)
High School, Diploma	5 (33.4%)	2 (28.6%)	0 (0.0%)
1 or More Years of College, No Degree	3 (20.0%)	1 (14.3%)	0 (0.0%)
Associate's Degree	2 (13.3%)	1 (14.3%)	0 (0.0%)
Bachelor's Degree	0 (0.0%)	2 (28.6%)	0 (0.0%)
Graduate School Degree	0 (0.0%)	0 (0.0%)	5 (100.0%)
Graduate Equivalency Degree (GED)	0 (0.0%)	0 (0.0%)	0 (0.0%)
N/A	2 (13.3%)	0 (0.0%)	0 (0.0%)
Vaccination Status			
Never Vaccinated	1 (6.7%)	1 (14.3%)	0 (0.0%)
1st Dose Only	1 (6.7%)	1 (14.3%)	0 (0.0%)
1st and 2nd Dose Only	2 (13.3%)	2 (28.6%)	2 (40.0%)
1st and 2nd Dose and Booster	10 (66.6%)	3 (20.0%)	3 (60.0%)
N/A	1 (6.7%)	0 (0.0%)	0 (0.0%)

5.4.3 Delphi Survey and Voting

The Delphi process took place over the course of two rounds of surveys and the COS was finalized at a subsequent consensus meeting with community members and community health workers (Figure 5.1). The first round of surveys (Delphi Round 1) was distributed to community members and community health workers during an HIV support group meeting. A researcher

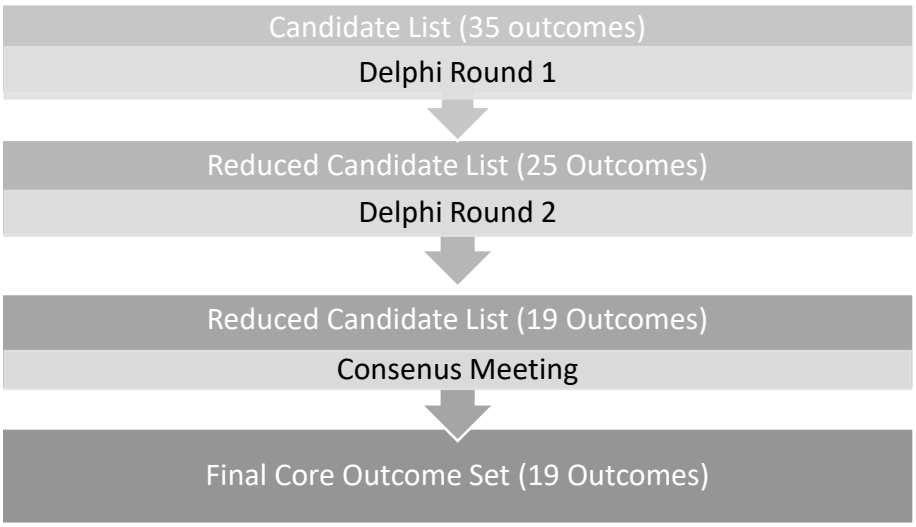


Figure 5.1. Overview of the Delphi process, a consensus process to prioritize outcomes of importance related to COVID-19 Vaccines

presented information regarding the purpose, aims, and scale description to the participants using PowerPoint. After addressing any questions, the researcher handed out paper copies of the survey to all participating adults and read each outcome out loud, one at a time. After each outcome was read, participants were given the opportunity to ask a question among the group or write a comment or question on the paper itself next to the item. Seventeen outcomes were retained because they received a score of 7, 8 or 9 by $\geq$70% of all voters and eleven outcomes were retained because participants in the community members stakeholder group gave the outcome an average rating of

≥7 (Table 5.4). Nine outcomes were excluded. Thus, a total of 25 outcomes were included in the Round 2 survey. No suggestions for additional outcomes were provided during the first round.

In the second-round survey, nineteen outcomes were retained; fourteen outcomes received a score of 7, 8 or 9 by ≥70% of all voters from the three stakeholder groups and five outcomes were retained because the community members stakeholder group gave the outcome an average rating of ≥7. The remaining nine outcomes were excluded. The outcomes were classified as "community-important outcomes" if the average score of a given outcome was between 7 and 9 among the community member stakeholder AND if the average score of at least one other stakeholder group was less than 7 (Figure 5.2).

Table 5.4. Results from Round 1 survey of Delphi process

Status	Criteria	Outcomes

		In your opinion, when deciding whether to get the COVID-19 vaccine, how important was it for you to know…
OUTCOME RETAINED: Consensus to keep outcome in final COS	**An outcome in which ≥70% of all voters rated the outcome with a score of 7, 8, or 9 ("critical importance")**	Injuries/illness anywhere in the body post-vaccination Unexpected injuries/illness post-vaccination Life threatening injuries/illnesses post-vaccination Likelihood of experiencing injury/illness post-vaccination Long-term side effects post-vaccination Likelihood of experiencing injury/illness after taking different COVID-19 vaccines brands Whether vaccine prevents COVID-19 disease How long COVID-19 vaccine remains effective in body Whether new antibodies against COVID-19 can be detected in the body after COVID-19 vaccination How protective each dose of a COVID-19 vaccine is How protective COVID-19 vaccines are against different variants (e.g., Omicron, Delta) The proportion of people in your community who choose to wear masks in indoor spaces or when within 6 feet of other people Trustworthiness of the healthcare provider administering the COVID-19 is. Trustworthiness of the information being shared about COVID-19 vaccines is. Number of COVID-19 related deaths in the community Number of COVD-19 related cases in the community Number of COVID-19 related hospitalizations in the community
OUTCOME RETAINED: Consensus achieved among community members to keep outcome in final COS	**An outcome in which <70% of all voters rated the outcome 7,8, or 9, but the stakeholders in the community group gave the outcome an average rating of ≥7.**	Injury at point of injection post-vaccination Severity of illness/injury (i.e., pain) post-vaccination Dose effect of vaccine Ability to tolerate injury/illness post-vaccination Injuries/illness post-vaccination with concomitant medications Ability of the vaccine to produce an immune response in the body Whether or not the COVID-19 vaccine prevents COVID-19 disease better than other existing vaccines How to hold vaccine producers accountable for any injury or symptoms How the vaccines were produced so quickly Trustworthiness of the state/federal government Where to find clear, understandable, and transparent information about the COVID-19 vaccines
OUTCOME EXCLUDED: Consensus to eliminate outcome from final COS	**An outcome in which <70% of voters rated the outcome 7,8, or 9 AND the community stakeholder group average rating was <7.**	The number of people in your community that receive a COVID-19 vaccine The number of days individuals should plan to take off from work The cost of transportation to get to the vaccine site The cost of receiving the COVID-19 vaccine from a trusted health provider Reliability of local social worker and community health workers Comparing COVID-19 vaccine to natural methods of prevention Whether high-risk groups are offered specialized opportunities for vaccination The proportion of people in your community willing to get vaccinated The proportion of people in your community NOT willing to get vaccinated

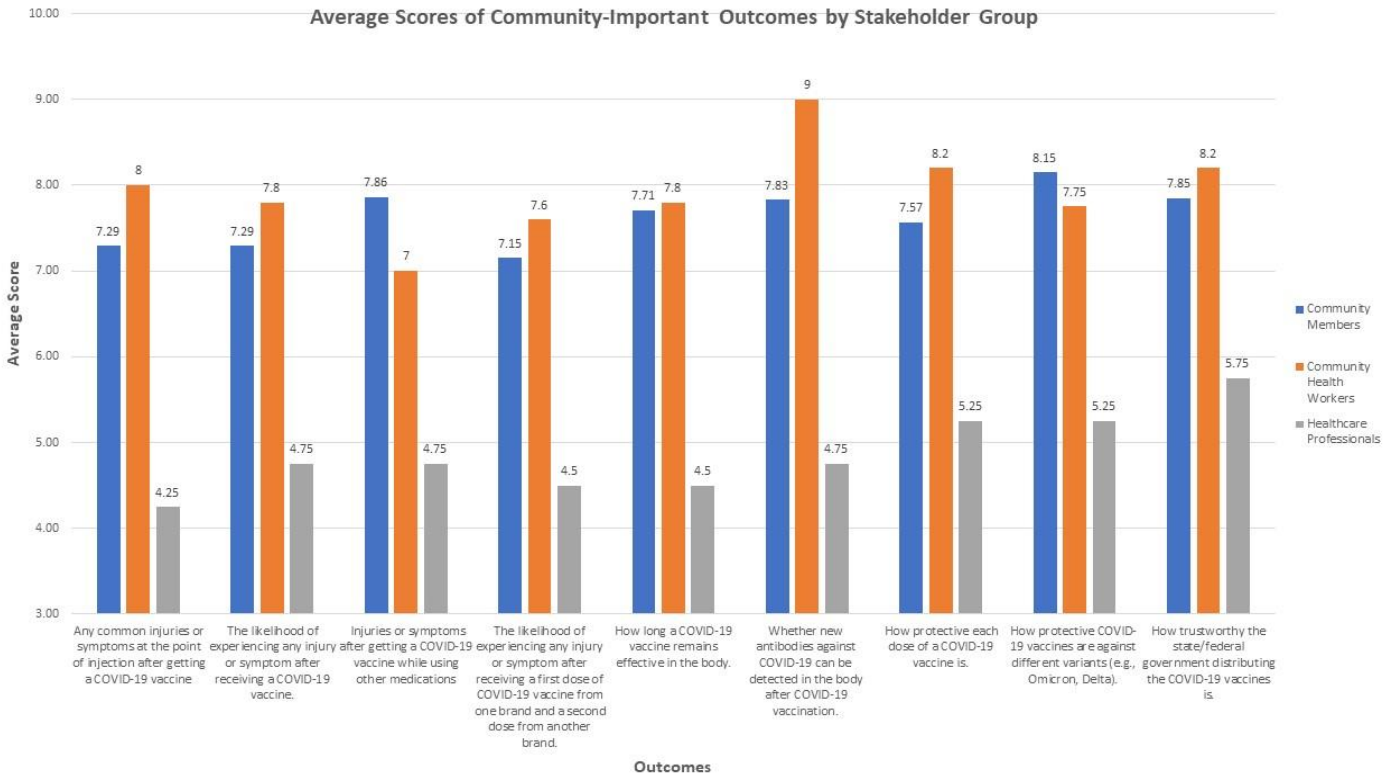


Figure 5.2. "Community-important outcomes" and respective average votes by stakeholder group

5.4.4 Consensus Meeting

The meeting lasted approximately two hours and 10 community members and six community health workers participated. During the NGT phase of the meeting, participants voted with a ≥70% majority needed to retain all finalized outcomes from the second-round survey. After discussions regarding the similarities and differences among outcomes, community members discussed grouping the outcomes into "domains" or categories. Three domains were decided upon: "Is the vaccine safe?," "Does the vaccine work in the body?" and "Does the vaccine work in the community?" Community members and community health workers did not vote to "rescue" any

excluded outcomes, but one participant nominated the following outcome to be included in the final core outcome set: “Impact of vaccines on other priority issues in the community.” After further discussion, this was broken down into two specific outcomes: (i) Impact of vaccines on socioeconomic status of the community; and (ii) Impact of COVID-19 vaccines on severity of chronic conditions. It was also suggested that an outcome related to “community perspectives post-COVID-19 vaccination”, which captured how vaccinated individuals in the community felt about their decision be included in the core outcome set. When each outcome was taken to a vote, community-based participants unanimously scored each with a score > 6. Additionally, participants proposed combining multiple outcomes into one: Outcomes of “experienced any common injuries or symptoms at the point of injection after getting a COVID-19 vaccine”; “experienced any common injuries or symptoms anywhere in the body after getting a COVID-19 vaccine”; “injuries or symptoms after getting a COVID-19 vaccine that were considered life threatening or placed an individual at immediate risk of death or disability”; and, “experienced any unexpected injuries or symptoms after getting a COVID-19 vaccine” were combined into one outcome: “any injury or symptom after getting a COVID-19 vaccine.” Participants also discussed categorizing final outcomes into “domains.” Community members discussed how to group the final outcomes together and collectively developed the final labels for the domains. Thus, the final COS included 19 outcomes across four “domains” (Table 5.5):

Table 5.5. Final COVID-19 Vaccine Domains and Core Outcome Set (COS)

Is the vaccine safe?
1. Any injuries or symptoms after getting a COVID-19 vaccination.
2. The likelihood of experiencing any injury or symptom after receiving a COVID-19 vaccine.
3. Any injuries or symptoms after getting a COVID-19 vaccine while using other medication.
4. Long-term side effects (more than one year post vaccination).
5. The likelihood of experiencing any injury or symptom after receiving a first dose of COVID-19 vaccine from one brand and a second dose from another brand.
6. Tolerance for any injuries or symptoms that occurred after getting a COVID-19 vaccine.
Does the vaccine work in the body?
7. Prevention of COVID-19 disease.
8. How long a COVID-19 vaccine remains effective in the body.
9. Detection of COVID-19 antibodies after COVID-19 vaccination.
10. Protective effect of each dose of a COVID-19 vaccine.
11. Protective effect of COVID-19 vaccines against different variants (e.g., Omicron, Delta).
Does the vaccine work in the community?
12. Trustworthiness of COVID-19 vaccine information.
13. Trustworthiness of the state/federal government.
14. Number of COVID-19 related deaths in the community.
15. Number of COVID-19 related hospitalizations in the community.
16. Number of COVID-19 cases in the community.
Outcomes Nominated During Consensus Meeting for Inclusion in COS
17. Impact of vaccines on socioeconomic status of the community.
18. Impact of vaccines on severity of chronic conditions in the community.
19. Community perspectives post-vaccination.

5.5 Discussion

Given the observed disparities in COVID-19 vaccine uptake among neighboring communities in Baltimore City, this study sought to identify which outcomes used in COVID-19 vaccine studies were most critical to Black individuals' decisions to get vaccinated. Many of the core outcomes identified under the "Is the vaccine safe?" and "Does the vaccine work in the body?" domains are commonly used in safety and efficacy studies in clinical trials (Anderson et al., 2020; Baden et al., 2021; Polack, Thomas, Kitchin, Absalon, Gurtman, Lockhart, Perez, Perez Marc, et al., 2020). In fact, in the Phase III trials assessing each of the approved COVID-19 vaccines in the

United States, adverse events and prevention of COVID-19 disease were reported as primary outcomes of interest (Skowronski & De Serres, 2021; Wang, 2021). Due to the urgent need for COVID-19 vaccine development and distribution, long-term side effects (effects taking place more than one-year post-vaccination) were not reported prior to distribution. While evidence from previous studies of similar vaccines informed clinical estimates of long-term effects (Philip R Krause & Marion F Gruber, 2020), follow-up data from clinical trials did not exceed one year. Studies using outcomes which assess the interaction of the vaccines with concomitant medications and the effects of mixing vaccines have been conducted, however, these were not primary outcomes for Phase III clinical trials and often focused on a specific drug (Desai et al., 2021; Tsourdi, Yu, Jan de Beur, & Drake, 2021). Similarly, while studies examining how long immunity to SARS-CoV-2 persists in the body and the protective effects of the vaccine against different COVID-19 variants have been conducted, these were again separate from the Phase III trials (Sewell, Agius, Kendrick, & Stewart, 2020; Tavilani, Abbasi, Ara, Darini, & Asefy, 2021). Furthermore, some COVID-19 variants emerged as dominant strains after vaccines were already developed, approved and distributed (e.g., Delta, Omicron), it is understandable that such outcomes were not assessed during Phase III trials. Dose effects and presence of antibodies to SARS-CoV-2 were assessed during several Phase II and Phase III clinical trials. Clinical trials frequently measure subsequent mortality, hospitalization, and cases as well, but only among the sample, not at a population-level.

Outcomes categorized under the domain "Does the vaccine work in the community?" including vaccine uptake and coverage, deaths, case rate, and hospitalizations post-vaccination are commonly used in studies measuring effectiveness of vaccine rollouts (Linn et al., 2010; B. P. Murthy et al., 2021; Schmid et al., 2017). However, measures of trust, socioeconomic impacts,

health impacts, and community perspectives are more commonly seen in vaccine hesitancy literature than as measures of equitable vaccination (Fisher et al., 2020; Khubchandani et al., 2021; MacDonald & Hesitancy, 2015). Interestingly, participants excluded measures of willingness to become vaccinated and vaccine uptake from the Delphi survey after round 1, suggesting that while vaccine uptake and coverage provide valuable information for public health researchers and practitioners, they may have less value to community members in their decision about whether to get vaccinated. More important to community members are knowing if information about vaccines can be trusted, if their community will benefit or be harmed socioeconomically from the vaccines, if any ongoing co-morbidities may be affected by the vaccines, and to gain insight on how their fellow community members felt post-vaccination. It is noteworthy that participants excluded outcomes related to access to vaccines, such as cost of the vaccines, transportation to the vaccine sites, and time off from work, after round 1 of the Delhi process. Together, these findings suggest that despite sufficient physical availability of vaccines throughout the city, community members experienced social barriers to access that may have contributed to disparities in uptake.

Review of the nine outcomes classified as "community-important outcomes" after the round 2 Delphi suggest that, on average, community members and community health workers placed greater importance on understanding specific safety concerns (e.g., injuries or symptoms occurring post-vaccination while taking other medications, injuries or symptoms occurring post-vaccination after mixing brands, pain at the injection site, likelihood of experiencing injuries or symptoms post-vaccination) and efficacy concerns (e.g., protective effect of COVID-19 vaccines against different COVID-19 variants, how long COVID-19 vaccines remain effective in the body, how protective each dose is) than health professionals. Trust in the state/federal government was also of greater critical concern for community members and community health workers than for

healthcare professionals. Interestingly, safety and efficacy outcomes used in all clinical trials already include many of the community-important outcomes identified in this study. As such, our results may indicate that greater emphasis should be placed on ensuring that these specific findings are disseminated more clearly to communities. Furthermore, although public trust in major information sources, including the state/federal government, is often measured in vaccine hesitancy surveys, the *trustworthiness* of the sources should be measured during rollout as well, according to criteria that are developed by the community themselves. In summary, core outcomes identified under the “Is the vaccine safe?” and "Does the vaccine work in my body?” domains are largely already included in COVID-19 vaccine studies. Other core outcomes, however, particularly those in the “Does the vaccine work in the community” domain and those identified during the consensus meeting pertaining to trustworthiness have not been thoroughly addressed in vaccine effectiveness studies.

The Delphi process has several inherent limitations. In this study, special weight was given to community member responses during the two rounds of the Delphi process as well as the consensus meeting, by including a greater sample size of stakeholders from the community member group than other groups. While similar methods have been employed in other studies using the Delphi process (Clearfield, Miller, et al., 2021), it is possible that a different sample of community members from other parts of Baltimore (i.e., individuals from high-income neighborhoods) would have affected the overall voting results in this particular stakeholder group.

Another inherent limitation in the Delphi process is differing perceptions or understandings of the Likert scale among stakeholder groups. Previous studies in COS development have found that nonexpert groups, such as community members or patients, generally feel inclined to rate all outcomes as critically important (Gargon, Williamson, & Young, 2017). This was observed during

our study as well, although participants were provided an orientation to the scoring method prior to survey completion.

To ensure that misunderstandings regarding the outcomes and the ratings did not take place, we also held a consensus meeting with nonexpert stakeholders including primarily community members and community health workers. To reduce the risk of power imbalances biasing discussion in the consensus meeting, we did not invite healthcare professionals to participate. Although this may have succeeded in preserving the voices of community members and community health workers, the fact that experts did not get final input into the COS suggests that some outcomes of importance to healthcare professionals may have been excluded. However, as the healthcare professionals stakeholder group is in a position of power, it is likely that such outcomes of interest can be included in future research regardless. Of importance, if experts were included, they may have dismissed nonexpert priorities in the final voting as outcomes would not have been able to achieve high consensus without their votes.

There were also inherent challenges with the conduct of in-person consensus meetings; there is typically a risk that in-person discussions may center the voices of some participants, while making others less inclined to be vocal (Clearfield, Miller, et al., 2021). To address, and minimize, these concerns, the sample was drawn from a support group in which all participants were already familiar with one another and regularly meet to share thoughts and opinions. Finally, the list of outcomes decided upon at the consensus meeting did not specify when or how outcomes should be measured. However, the domains determined at the consensus meeting point to measures of safety (i.e., “Is the vaccine safe?”), efficacy (i.e., “Does the vaccine work in the body?”) and implementation (i.e., “Does the vaccine work in the community?”). This may indicate the types of

studies to which each set of outcomes should be applied. For instance, outcomes listed under the "Is the vaccine safe?" domain should be used in clinical trials assessing safety.

Despite limitations in the Delphi process, studies have shown it to be a valid methodology in social science, particularly in its application of COS development (Landeta, 2006**)**. To uphold some principles of CBPR, this study centered and preserved the voice of the community throughout the Delphi process. In doing so, outcomes of importance to Black individuals living in low-income communities in Baltimore City were identified, highlighting two important needs. First, a need to better disseminate and communicate results of COVID-19 vaccine studies – specifically those relating to safety and efficacy trials - to members of these communities, utilizing sources the community deems trustworthy. Second, a need to broaden the scope with which we measure equitable access to vaccines. In this case, the absence of physical barriers to access in the final COS - such as cost and transportation- suggest that other, more nuanced, barriers to vaccine access may persist among predominantly Black, low-income communities in Baltimore City.

This study provides a framework with which researchers can begin to rethink measures of equity in vaccine distribution. While coverage and uptake are important indicators of equitable access, social causes of inequity are often overlooked. Our findings suggest that concerns related to institutional trust, economic and health impacts, community acceptance of the vaccines, and trustworthiness of vaccine information may all function as barriers to vaccine uptake that are not equally felt across the population. Public health researchers should apply these outcomes to evaluations of vaccine rollouts to measure equitable access to vaccination.

Regarding next steps, results will be reported back to the community members and develop appropriate instruments to measure these core outcomes. This is the first COVID-19 vaccine COS developed through engagement with low-income community members in Baltimore City. Use of

the COS in COVID-19 studies, particularly in those evaluating equitable access to vaccines, will ensure that evidence produced is of importance to community members in their decision-making process regarding vaccine uptake.

Chapter 6. Summary

This dissertation explores why disparities in COVID-19 vaccine uptake persist among neighboring communities in Baltimore City, Maryland and develops a COS for measuring safety, efficacy and implementation of COVID-19 vaccines. As this COS was developed in collaboration with African American/Black residents of a low-income community in Baltimore City with low rates of vaccine uptake, the findings of this dissertation can be used to enable equitable vaccine uptake among similar communities. Throughout this dissertation, key principles of CBPR were applied, including acknowledging the community as a unit of identity, empowering community members to engage in a power-sharing process that addresses social inequalities, and framing the local relevance of public health problems in the context of multiple determinants of health. In doing so, the voices of community members living in a neighborhood experiencing relatively lower levels of vaccine uptake were amplified, providing unique insight into the experiences and priorities of an understudied population. Ultimately, this dissertation developed the first COS for measuring equitable distribution of COVID-19 vaccines to date.

6.1 Summary of Major Findings

Chapter 3 describes a qualitative study that aimed to understand the process by which residents in a low-income, predominantly Black community decided whether to receive a COVID-19 vaccine. Most participants consistently reported satisfactory physical access to vaccines, favorably discussing their widespread availability. However, difficulties associated with accessing mobile clinics and taking time away from daily life activities to receive a COVID-19 vaccination and/or deal with any side effects, were still brought up by some participants. Importantly, through thematic network analysis, this study found that several themes including “physical access to

vaccines," "perceived importance of COVID-19 vaccination in relation to pre-existing needs," and "safety and efficacy of vaccines" were contextually related to the "Access to understandable, trustworthy information" theme. This underscores the importance of trust in decision making around vaccination uptake. The connection between trusted sources of information and environmental injustices, such as poverty and lack of community health workers, highlights the influence of historical, social, and contextual factors on vaccine uptake, particularly as it relates to equity; the systemic structures that give rise to disparities in such communities are associated with the lack of trust community members feel in available sources of information. The numerous connections between trusted sources of information and other emergent themes suggest that trust is an important factor in the decision-making process and plays an important role in equitable vaccine uptake. Similarly, it should be recognized that it is a privilege to be able to prioritize COVID-19 vaccination in relation to other needs and to address personal concerns regarding the safety and efficacy of the vaccines.

Chapter 4 described a systematic literature review that identified primary outcomes extracted from studies that evaluated the safety, efficacy, and effectiveness of COVID-19 vaccines in the United States and assessed the extent to which they aligned with patient-important outcomes (PIOs) derived from the 3C's Model of vaccine hesitancy. Effectiveness studies pertained to those evaluating the implementation of COVID-19 vaccines after actual rollout among an existing population. Among the fifty-six studies that met inclusion criteria for evaluating the safety, efficacy, and effectiveness of COVID-19 vaccines, only five patient-important outcomes (PIOs) aligned with extracted primary outcomes, suggesting that existing measures used in vaccine studies may not sufficiently address the concerns or priorities of those in need of the vaccines. Nine PIOs related to: 1) trust in the system and people who deliver vaccines 2) trust in the motivations behind

the policy makers in charge of rollout; 3) access to understandable information; 4) cost; 5) eligibility; 6) geographic availability; 7) ability to take time off from work; 8) appeal of immunization services; and, 9) physical availability of the vaccines did not align with any extracted primary outcomes from the included studies, suggesting that these outcomes are overlooked in current research practice. Given the high demand for rapid, ongoing research on the safety, efficacy and effectiveness of COVID-19 vaccines, as well as the increasing threat of novel emerging pathogens in a globalized world, this review provides an innovative method to incorporate PIOs in COVID-19 vaccine studies and highlights key gaps in the existing literature. Disseminating the results of safety, efficacy and effectiveness studies which address factors described in the 3C's Model of vaccine hesitancy could improve vaccine uptake, particularly among more hesitant populations.

The study described in Chapter 5 sought to develop a COS by identifying which outcomes used in COVID-19 vaccine studies were most critical to decisions to get vaccinated among key stakeholders including African American/Black community members from Baltimore City, local community health workers (CHWs), and healthcare professionals. Through application of a Delphi survey methodology, a final COS including 19 outcomes across four domains was developed. Many of the outcomes included in the final COS pertain to safety and efficacy of the vaccines. These are commonly used as primary outcomes in clinical trials. Outcomes related to vaccine implementation, i.e. vaccine uptake and coverage, deaths, case rate, and hospitalizations post-vaccination are included in the final COS and are commonly used in studies measuring effectiveness of vaccine rollouts. However, measures of trust, socioeconomic impacts, health impacts, and community perspectives are virtually never utilized as measures of equitable vaccination. Interestingly, participants excluded measures of willingness to become vaccinated

and vaccine uptake from the Delphi survey after round 1, suggesting that while vaccine uptake and coverage provide valuable information for public health researchers and practitioners, they may have less value to community members in their decision about whether to get vaccinated. More important to community members are knowing if information about vaccines can be trusted, if their community will benefit or be harmed socioeconomically from the vaccines, if any ongoing co-morbidities may be affected by the vaccines, and to gain insight on how their fellow community members felt post-vaccination. It is noteworthy that participants also excluded outcomes related to access to vaccines, such as cost of the vaccines, transportation to the vaccine sites, and time off from work, after round 1 of the Delhi process, suggesting that physical availability of vaccines throughout the city was not a major concern for community members; however, social barriers to access such as trust and socioeconomic impacts may have contributed to disparities in uptake.

6.2 Limitations

This dissertation, as in any study, had several limitations. First, since this research took place approximately one year after COVID-19 vaccines were first rolled out to the public in Baltimore, Maryland, participants were asked to retrospectively express their perspectives about the introduction of the vaccines, their decision-making processes, and their experiences with vaccine uptake. As such, this research must acknowledge the potential for recall bias in responses to semi-structured interviews and Delphi questionnaires. However, as vaccines continue to be rolled out and disparities in vaccine uptake continue to persist within this community, the experiences shared also provide information about the issues of vaccine rollout that are still in play. Second, since participants for the Delphi survey were recruited through existing social support groups at STAR, the participants had standing relationships with the CHWs, which likely contributed to the fact that most were vaccinated. This may have biased the final COS as it was

more heavily reliant on perspectives of vaccinated rather than unvaccinated community members. Another limitation is that this dissertation was conducted in a single community with its own contextual challenges and facilitators, making the results of this study not widely generalizable to the rest of the United States. However, there are many communities in the United States with similar demographics, health disparities, historical context and comparable vaccine uptake disparities, for which these results may apply.

While this dissertation applied vaccine hesitancy factors and constructs associated with the 3C's Model of vaccine hesitancy (i.e., using the 3C's model to inform the development of semi-structured Interview Guide in Chapter 3, application of 3C's model constructs as PIOs in Chapter 4) it must be acknowledged that other health behavior theories have been used to understand the mechanisms of health behavior change in the context of vaccine hesitancy as well, including the Health Belief Model, the Theory of Planned Behavior and the Theory of Reasoned Action (Gerend & Shepherd, 2012; Malosh et al., 2014; Mo & Lau, 2015). However, the 3C's model was selected for this dissertation because, as suggested by Quinn et. al (2016), it incorporates broader, more contextual factors than these other theoretical models, allowing for the assessment of a broader range of factors associated with vaccine hesitancy (Quinn et al., 2016). However, several theoretical constructs that correlate with vaccine uptake not explicitly addressed in the 3C's model, including knowledge (Lindley et al., 2016) attitudes (Harris et al., 2022; Lindley et al., 2016), cues to action (i.e., the specific stimuli necessary to trigger appropriate health behavior; (Mattson, 1999), and perceived self-efficacy (i.e., individuals that are confident in their capability to perform healthy behaviors are more likely than those who are not to fulfill that self-perception; (Bandura, 1977; Schmid et al., 2017). These may have been overlooked in this study and as a result, left out of the final COS.

The Delphi process described in Chapter 5 did not account for the fact that participants may have perceived the nine-point Likert scale differently, for instance, with some viewing it as a scale ranging from "not important" to "very important" and others from "least important" to "most important." Although participants were provided an orientation to the scoring method prior to survey completion, it is possible that respondents felt inclined to rate all outcomes as "critically important." To ensure that misunderstandings regarding the outcomes and the ratings did not take place, we also held a consensus meeting with nonexpert stakeholders, including primarily community members and community health workers. Healthcare professionals were not invited to participate in this consensus meeting out of concern that their presence could influence whether community members and CHWs felt empowered to speak up during the meeting. Although exclusion of the health professionals may have succeeded in preserving the voices of community members and community health workers, some outcomes of importance may have been excluded in the final COS. Of importance, if experts were included, they may have dismissed nonexpert priorities in the final voting as outcomes would not have been able to achieve high consensus without their votes.

Another limitation regarding the final COS is that it does not specify when or how outcomes should be measured in future research. However, the domains determined at the consensus meeting that point to measures of safety (i.e., "Is the vaccine safe?"), efficacy (i.e., "Does the vaccine work in the body?") and implementation (i.e., "Does the vaccine work in the community?"), suggest the types of studies to which each set of outcomes should be applied. For instance, outcomes listed under the "Is the vaccine safe?" domain should be used in clinical trials assessing safety.

6.3. Public Health Implications

The findings from this dissertation provide a framework with which public health researchers can begin to rethink measures of equity in vaccine uptake. While coverage and uptake are important indicators of equitable access, social causes of inequities are often overlooked, particularly among underserved communities such as Baltimore City, Maryland and other cities with similar socioeconomic and demographic profiles. These findings suggest that community-important concerns related to institutional trust, economic and health impacts, community acceptance of the vaccines, and trustworthiness of vaccine information may all function as barriers or facilitators to vaccine access that are not equally experienced across the general population.

Ahead of vaccine rollout in Baltimore City, the Baltimore City Health Department (BCHD) developed a detailed strategy to vaccinate residents against COVID-19 framed through the lens of health equity, "ensuring that every Baltimorean has a fair and just opportunity to get vaccinated."(Dzirasa, 2021) In this plan, the BCDH acknowledges that partners should "recognize the historical and current racism in Baltimore City, injustices within the healthcare system, and other issues that may contribute to vaccine deliberation among residents."(Dzirasa, 2021) Notably, the proposed evaluation of the BCHD strategy only includes outcome measures of vaccine coverage, stratified by race, ethnicity, age, gender and neighborhood. These outcomes were used to monitor and inform vaccine distribution and prioritization. No other discrete outcomes are proposed in this evaluation, highlighting a major gap in current public health practice. To accurately evaluate the degree of equity in a vaccine rollout program, BCHD and other health departments in similar contexts should incorporate a COS consisting of well defined, measurable outcomes relating to trust and other context-specific, psychosocial factors of vaccine uptake in their evaluations of vaccine implementation.

To this end, researchers must place a greater emphasis on understanding contextual factors prior to vaccine distribution Not all members of the public accept information equally, nor do they have equal levels of trust or health literacy. As such, underserved communities may fall through the cracks and not receive critical information in a form they are able to access or understand. Communities facing hardships such as poverty, addiction, or HIV, should be provided additional resources and services to ensure that vaccination is a realistic priority. Additionally, public health researchers should engage, partner and collaborate with communities of interest using methods of CBPR such that community members are empowered to voice their perspectives and experiences. The needs identified through CBPR authentically frame the issues and contexts in which they exist and should be incorporated in further studies evaluating vaccine rollout efforts. Public health practitioners should allocate more resources to disseminating information through partnerships with trusted sources including local leaders and community health workers. Such efforts have been shown to be cost-effective and sustainable (Ibe, 2021).

Throughout this dissertation, the importance of "trust" in the vaccine uptake decision-making process, and its deeply rooted connections to constructs of environmental injustice, access, and health communication, is repeatedly demonstrated. As findings from this research suggest, there is still much room for improvement in how we develop, implement, and evaluate interventions requiring community trust, such as vaccine rollouts. Employing more extensive research to understand community context, engaging and partnering with community members and community leaders using CBPR, and utilizing well-defined outcomes- as in the proposed COS-, with feasible, consistent units of measure (e.g., validated scales) will all contribute to this effort. But for these changes to be truly effective, a foundational shift in the way the US health

system funds, values, and supports community centers and community health workers must take place.

As defined by the American Public Health Association, a CHW is "a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served" (Ibe, 2021) This trust between community members and CHWs facilitates critical links to health and social services. Collaboration between healthcare professionals and CHWs has been shown to improve access to services and improve the cultural competence of service delivery (Brownstein et al., 2007; Krieger, Song, & Philby, 2015; Norris et al., 2006; Peretz et al., 2012). Similarly, research has shown that CHWs build capacity among communities, increase health knowledge through accessible community education, and increase self-agency among community members through outreach, informal counseling, social support, and advocacy activities (Freeman, 2016; Kangovi, Mitra, Grande, Long, & Asch, 2020; Peretz et al., 2012). As CHWs live and work in the same communities they serve, they should be empowered with sufficient resources to address the health disparities that result from social determinants of health on historically marginalized and underserved communities. Their shared experiences and values connect them to the communities in which they serve in a way that cannot be duplicated in other sectors of the healthcare system. However, for CHWs to operate at the capacity and frequency with which they are needed, particularly in times of crisis, such as the COVID-19 pandemic, long-term, sufficient funds are needed to support CHWs in their work.

6.4 Future Directions

Results of this dissertation will be shared with community members in a way that is accessible and meaningful to them. This will be done in collaboration with CHWs and through further partnership with STAR staff. Further research to develop appropriate instruments to

measure these core outcomes and then validate those instruments should also be conducted. As this is the first COVID-19 vaccine COS developed in collaboration with low-income community members in Baltimore City, it is important to consider the context in which it was developed and the impact of the COVID-19 pandemic on this particular community to better understand how similar communities could benefit from this COS. STAR, the faith-based community group that collaborated on this dissertation work, experienced several challenges during the pandemic: due to the lockdown policies implemented in Baltimore City in 2020, STAR was unable to hold social support groups, conduct informal counseling sessions, and interact with members of the community during much of the pandemic. While many in the country turned to online video conferencing apps platforms such as Zoom to continue in-person activities, many members of this community did not have the resources to do so. The experiences of loneliness, anxiety, depression, and isolation expressed by participants in Chapter 3 speak to the harms that inaccessible social support can yield. Due to the economic impacts of the pandemic at the state and federal level, many community groups including STAR that rely on grant funding for their operations have experienced negative consequences on their operations, staffing and/or services capabilities (Ibe, 2021).

Without a public health structure that incorporates and values CHWs, communities that rely on local organizations, such as STAR, continue to be disadvantaged, perpetuating the ongoing disparities of health, education, and income. In July 2022, Baltimore City Mayor Brandon M. Scott acknowledged the importance of community centers, awarding STAR and 119 other nonprofit organizations in the City COVID-19 relief grants of up to $50,000 (Lewis, 2022) While this is an important contribution to non-profits serving communities in the City, long-term funding mechanisms built into our healthcare system are needed to ensure that community groups are able

to sustainably operate. Unstable funding for such groups undermines the value of CHW's lived experiences. It is these lived experiences that enables them to support communities that have been systemically disenfranchised. As CHWs are central to any efforts to improve health outcomes and address SDOH, public health researchers, practitioners, and policy makers must work together to increase their funding and ensure their value is recognized within the healthcare system to establish health equity in Baltimore City. Partnership and collaboration with CHWs will be critical to optimal application of the COS in COVID-19 vaccine studies, particularly in those evaluating equitable access to vaccines. Incorporation of this COS and the COS development methods described in this dissertation in future COVID-19 vaccine studies will ensure that evidence produced is of importance to community members in their decision-making process regarding vaccine uptake. It is this relevance to community decision making that may be the key to improving vaccine uptake among underserved communities, promoting health while furthering social justice.

Appendices

Appendix A: Phase I - Recruitment Screening Questionnaire

Participants who are interested in participating in Phase I of this study will be directed to a link with a questionnaire designed in Qualtrics. The link will bring interested parties to a landing page that will provide more information and begin the screening process. The screening questionnaire will screen for individuals that meet the inclusion criteria. If inclusion criteria are met, participants will be contacted to schedule a semi-structured interview:

Landing page text: Thank you for your interest in learning more about this study! The purpose of this research is to better understand perceptions, beliefs, and experiences related to COVID-19 vaccination among low-income, minority communities in Baltimore City. We are recruiting participants to participate in a one-time, 30-minute interview. The interview will take place in-person or via Zoom, according to individual participant preference. All interviews will be conducted in accordance with CDC COVID-19 recommendations. This study is available to interested participants who are over 18 years of age that are living in Baltimore City. $40 gift cards will be provided to all participants. Participants will be accepted on a rolling basis until study completion. Study staff are available to answer your questions about this research study and can be contacted at (561) 809-5965.

If you would like to apply to participate in this study, please fill out the screening questionnaire here. This brief questionnaire will ask for demographic information (age, race/ethnicity, zip code, employment status, education, income) and for vaccination status.

Recruitment Screening Questionnaire:

1. First and Last Name:

2. Date of Birth:

3. Sex: M/F/Other

4. Age:
    a. 18-29
    b. 30-39
    c. 40-49
    d. 50-59
    e. 60-69
    f. 70+

5. Race:
    a. Asian or Pacific Islander
    b. Black or African American
    c. White
    d. Other or Unknown
6. Ethnicity
    a. Hispanic or Latino
    b. Mixed Ethnicity
    c. Not Hispanic/Latino
    d. Other or Unknown
7. Zip Code:
8. Household Income:
    a. __ <$25,000
    b. __$25,000-<$50,000
    c. __$50,000-<$75,000
    d. __$75,000-<$100,000
    e. __≥$100,000
9. Highest Education Level Achieved
    a. High school, no diploma
    b. High school Diploma
    c. 1 or more years of college, no degree
    d. Associates Degree
    e. Bachelor's Degree
    f. Graduate School Degree

Appendix B: Phase I - Recruitment Flyer

UNIVERSITY OF MARYLAND | SCHOOL OF PUBLIC HEALTH

PARTICIPANTS NEEDED:
COMMUNITY PERSPECTIVES ON COVID-19 VACCINES

- Participants 18 and older needed to better understand the perspectives and concerns related to COVID-19 vaccines.
- Study participants will participate in short, 30-minute interview with UMD researcher.
- $40 gift card, reimbursement for transportation, and food and beverages on day of interview will be supplied to participants.
- Interviews will take place at STAR office or via Zoom, depending on participant preference.

SIGN UP NOW: xxx.com
CALL 561-809-5065

Appendix C: Phase I - Semi-Structured Interview Questionnaire

Guided by the WHO Strategic Advisory Group on Experts (SAGE) Working Group on Vaccine Hesitancy's Complacency, Convenience and Confidence (3 C's) Model of Vaccine Hesitancy [1] the questions in this interview guide correspond to the three paradigms which encompass potential barriers and facilitators of COVID-19 vaccination.

WHO 3 C's Model Paradigm	**Definition**	**Semi-Structured Questions***
Convenience	The extent to which factors of physical availability, affordability and willingness-to-pay, accessibility, ability to understand (language and health literacy) and appeal of immunization services affect uptake.	*1. Can you tell me a bit about what your daily life/routine was like before the pandemic?* *2. During that time, prior to the pandemic, what were some of the typical concerns among people in your community?* *3. When the vaccines first became available earlier this year, how easy was it for people in your community to get fully vaccinated?* 4. *Are you aware of anyone in your community who has been vaccinated for COVID-19? To the best of your knowledge, can you tell me a bit about their experience?* *5. Generally, how easy is it for people in your community to get vaccinated today?* *6. To the best of your knowledge, how eager are people in your community to get the vaccine? (probe: In your experience, what are some reasons?)* *7. Generally, how eager are people in your community to get a COVID-19 booster? (probe: In your experience, what are some reasons?)* *8. Do you know of any challenges people have faced in getting a COVID-19 vaccine?* *9. Do you know of any challenges people have faced in getting a COVID-19 booster, specifically?*
Complacency	Extent to which perceived risks of vaccine-preventable disease are low and vaccination is not deemed a necessary preventive action. Complacency about a particular vaccine is influenced by many factors, including other life/health responsibilities that may be perceived as more important at that point in time.	1. *How did the COVID-19 pandemic affect your daily life/tasks? (probe: going to work, church, visiting family)* 2. *Do you know of anyone in your community whose job has been affected by the COVID-19 pandemic? Can you tell me a bit about what happened?* *3. In your opinion, how big of a threat do people in your community perceive COVID-19 to be?* *4. Are there other problems in your community that you feel are more important or urgent than COVID-19?*

		5. *Are you aware of anyone in your community who has ever gotten COVID-19? If so, can you tell me a bit about how they responded to it? (probe: did they stay at home, seek treatment)* 6. *Based on your own experience, how important did people in the community feel getting vaccinated against COVID-19 was when the vaccines first became available earlier this year?* 7. *Based on your own experience, how important do people in your community feel getting a booster shot is?* 8. *In your opinion, how concerned are people in your community about getting new variants of COVID-19 such as Omicron and Delta?*
Confidence	Participant trust in: (i) the effectiveness and safety of vaccines; (ii) the system that delivers them, including the reliability and competence of the health services and health professionals and (iii) the motivations of policy-makers who decide on the needed vaccines.	1. *Generally, how do you think people in your community feel about COVID-19 vaccines?* 2. *Based on your own experience, where do most people in your community go to get trusted information about healthcare in general? Can you explain why?* 3. *Based on your own experience, where do most people in your community go to get trusted information about COVID-19 vaccines specifically? Can you explain why?* 4. *Generally, do people in your community trust the COVID-19 vaccine? Why or why not?* 5. *How do most people in your community feel about wearing masks when around others?* 6. *Generally, how safe do people in your community feel COVID-19 vaccines are?* 7. *In your opinion, how do people in your community feel about the differences between the three COVID-19 vaccines currently offered (Moderna, Pfizer, J&J)?* 8. *In your opinion, how confident are people in your community about the effectiveness of COVID-19 booster shots?* 9. *Do you have any suggestions for policy makers as they advocate for vaccination in your community?* 10. *Do you have any suggestions for healthcare professionals promoting vaccination in your community?* 11. *What are some concerns that people in your community may have with the COVID-19 vaccines?*

Appendix D: Baltimore City community statistical area demographic characteristics by percent COVID-19 vaccine coverage

Community statistical area demographic characteristics by % COVID-19 vaccine coverage

Community Statistical Area	Population	% Black	% White	% Asian	% Other	% Multiple Race	Median Household Income
Less than or equal to 30% Coverage							
Cherry Hill	8541	90.3	5.1	1.0	1.1	2.5	$22,659
Brooklyn/Curtis Bay/Hawkins Point	14626	37.7	48.4	1.4	8.2	4.3	$35,862
Dickeyville/Franklintown	3771	80.5	9.2	1.8	1.2	7.2	$32,768
Average		**69.5**	**20.9**	**1.4**	**3.5**	**4.7**	**$30,429.50**
31% to 50% Coverage							
Allendale/Irvington/S. Hilton	16080	87.6	9.2	0.4	0.1	2.7	$35,958
Clifton-Berea	8413	94.9	3.3	0.1	0.9	0.8	$25,738
Belair-Edison	16250	88.8	9.3	0.5	0.3	1.1	$38,906
Dorchester/Ashburton	11759	93.1	3.3	0.3	0.5	2.8	$36,870
Edmondson Village	8568	97.5	1.1	0.0	1.0	0.5	$36,648
Forest Park/Walbrook	9102	95.2	2.9	0.1	0.2	1.6	$37,161
Greater Mondawmin	9284	94.5	2.0	0.3	0.3	2.9	$38,655
Greater Rosemont	15631	98.6	0.5	0.2	0.3	0.4	$30,865
Greenmount East	7691	96.6	2.9	0.0	0.2	0.3	$23,277
Harford/Echodale	16186	54.4	41.4	0.6	2.3	1.2	$54,086
Howard Park/West Arlington	10553	94.1	3.9	0.1	0.5	1.3	$39,468
Madison/East End	7204	89.9	5.2	0.1	4.1	0.6	$27,454
Midway/Coldstream	9356	95.1	2.3	0.4	0.9	1.3	$34,523
Northwood	16949	86.5	8.9	1.0	0.5	3.1	$58,266
Penn North/Reservoir Hill	10576	85.0	10.9	0.3	2.2	1.6	$33,264
Pimlico/Arlington/Hilltop	11686	96.3	1.8	0.3	0.6	1.0	$32,410
Poppleton/The Terraces/Hollins Market	4916	79.4	17.2	1.4	0.3	1.6	$17,228
Sandtown-Winchester/Harlem Park	15518	96.7	0.8	0.4	1.3	0.8	$24,374
Southern Park Heights	14931	94.5	3.9	0.4	0.7	0.6	$26,015
Southwest Baltimore	17137	74.3	17.4	1.3	2.5	4.5	$24,946
Upton/Druid Heights	10071	93.3	3.7	1.5	0.3	1.2	$15,950
Westport/Mount Winans/Lakeland	6966	71.8	24.2	2.2	0.8	0.9	$41,368
Baltimore City	622454	62.8	30.3	2.6	2.0	2.3	$41,819
Average		**87.9**	**9.0**	**0.6**	**1.0**	**1.5**	**$33,706.40**
50% to 80% Coverage							
Beechfield/Ten Hills/West Hills	13352	78.5	16.4	0.8	1.0	3.2	$52,623
Glen-Fallstaff	17298	61.8	30.3	2.1	3.8	2.0	$39,694
Cedonia/Frankford	23701	76.3	14.4	4.7	2.2	2.3	$39,306
Chinquapin Park/Belvedere	8321	70.0	24.7	0.9	0.2	4.2	$44,253
Claremont/Armistead	8332	57.1	34.8	1.0	4.2	2.9	$34,034
Cross-Country/Cheswolde	14016	19.3	72.9	6.4	0.9	0.6	$54,868
Greater Charles Village/Barclay	16556	32.4	48.6	13.9	1.4	3.8	$30,845
Greater Govans	10762	90.4	6.4	0.2	0.3	2.6	$36,531
Hamilton	13487	63.7	31.5	1.1	0.5	3.2	$63,986
Harbor East/Little Italy	5658	58.5	33.1	4.8	2.8	0.8	$36,579
Lauraville	12247	56.5	36.2	2.5	2.2	2.6	$66,196
Loch Raven	17221	90.5	6.6	1.2	1.1	0.5	$47,992
Medfield/Hampden/Woodberry/Remington	17486	10.9	78.2	7.0	1.1	2.9	$58,210
Midtown	15521	30.3	54.4	8.6	2.8	3.8	$38,867
Morrell Park/Violetville	7836	18.3	74.2	2.1	1.7	3.7	$38,210
North Baltimore/Guilford/Homeland	17389	16.0	70.1	7.8	1.4	4.7	$81,451
Oldtown/Middle East	9285	88.4	8.1	2.1	1.0	0.4	$14,105
Orangeville/East Highlandtown	10280	15.1	63.9	1.9	15.1	3.9	$40,431

Patterson Park North & East	14478	37.8	54.1	0.9	4.2	3.0	$56,652
Southeastern	5583	27.5	55.2	1.9	12.6	2.7	$32,102
The Waverlies	7796	76.4	16.5	2.3	3.2	1.7	$32,652
Washington Village/Pigtown	5345	54.2	39.6	2.6	0.2	3.4	$48,175
Average		**51.4**	**39.6**	**3.5**	**2.9**	**2.7**	**$44,898.16**
Greater than or equal to 81% Coverage							
Mount Washington/Coldspring	5134	25.5	65.8	6.7	0.8	1.1	$76,263
Highlandtown	7309	12.4	80.1	1.5	3.8	2.2	$71,660
South Baltimore	7097	2.5	89.7	3.4	2.1	2.3	$88,487
Inner Harbor/Federal Hill	13332	13.0	79.2	4.8	0.7	2.3	$88,854
Canton	7968	2.5	90.1	3.8	1.9	1.7	$91,736
Greater Roland Park/Poplar Hill	7620	6.9	82.6	7.0	0.7	2.9	$104,482
Downtown/Seton Hill	5913	32.3	49.3	12.0	3.3	3.1	$44,819
Fells Point	9534	5.6	80.5	4.6	6.7	2.5	$77,433
Average		**12.6**	**77.2**	**5.5**	**2.5**	**2.3**	**$80,466.80**

Appendix E: Saturation Matrix

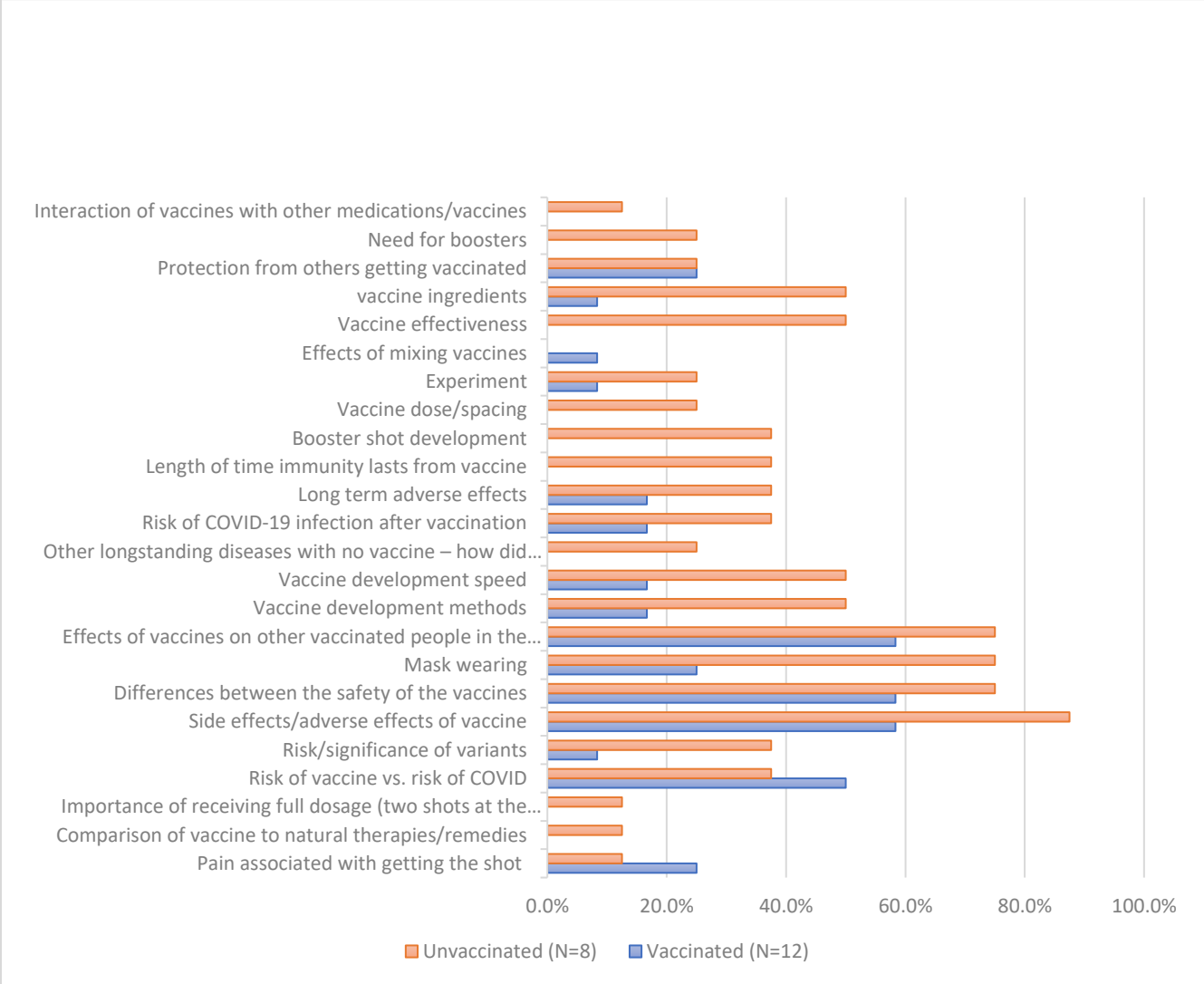
Codes	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Pain associated with getting the shot	x	x			x										x					
Comparison of vaccine to natural therapies/remedies	x																			
Importance of receiving full dosage (two shots at the correct interval)	x																			
Availability of the vaccines	x	x	x		x	x	x					x								
Risk of vaccine vs risk of COVID	x		x	x	x		x	x				x		x			x	x		
Loss of job due to pandemic	x	x		x												x				
Long lines	x																			
Trust in local healthcare providers	x	x			x						x	x	x	x	x			x		
Risk/significance of variants	x	x	x	x												x				
Side effects/adverse effects of vaccine	x		x	x	x	x	x	x	x	x		x		x	x	x	x	x		x
Differences between the safety of the vaccines	x	x	x	x			x	x	x		x	x	x	x		x	x			
Mask wearing	x		x	x	x			x					x	x			x	x		
Effects of vaccines on other vaccinated people in the community	x	x	x	x	x	x			x	x	x		x	x			x			x
Ease of access to vaccine	x	x	x	x	x	x	x		x			x	x			x	x			x
Youth/young people don't get vaccine		x	x		x							x			x		x			x
Trust in local news		x			x	x			X								x			
Trust in government sources		x	x			x	x		x				x	x	x					
Google, YouTube				x	x		x					x			x	x				x
Vaccine development methods		x		x						x	x			x				x		
Vaccine development speed		x	x	x						x	x									x
Other longstanding diseases with no vaccine – how did covid come so quick?														x						x
Personal experience with COVID-19			x	x	x				x	x	x	x	x	x	x					
Long term adverse effects			x	x				x					x			x				
What we don't know			x	x										x						x
Risk of COVID-19 infection after vaccination			x	x										x				x		
Mandates or incentives to get vaccinated			x	x	x						x	x					x			x

Mental health impacts of pandemic			x											x						x
Length of time immunity lasts from vaccine			x	x							x									
Booster shot development			x	x							x									
Vaccine dose/spacing			x								x									
Experiment			x							x				x						
Effects of mixing vaccines			x																	
Societal pressure				x								x								
Negative impacts on life because of pandemic				x												x				
Time away from work due to vaccine side effects				x														x		
Vaccine effectiveness				x				x			x			x						
Racism				x																
Ensuring access to second shot/booster				x		x														
Microchip/gov tracking/conspiracy theories					x									x						
Other priorities			x	x			x					x		x		x				x
Vaccine ingredients								x						x		x		x		x
Protection from others getting vaccinated					x			x		x	x	x								
Transportation to vaccination site	x								x							x	x			
Need for booster(s)				x							x									
Money trail/Big pharma											x									x
Drug addiction												x		x				x		x
Literacy												x					x			
Trusting family												x		x						
Stigma												x					x			
Cost of seeing a healthcare provider													x					x		
Threat of COVID-19														x	X		x			
HIV/AIDS														x						x
Frequency of doctor visits																		x		
Housing																x				
Availability of Mobile Clinics																x	x			
Interaction of vaccine with other medications/vaccines																				x
Crime																				x

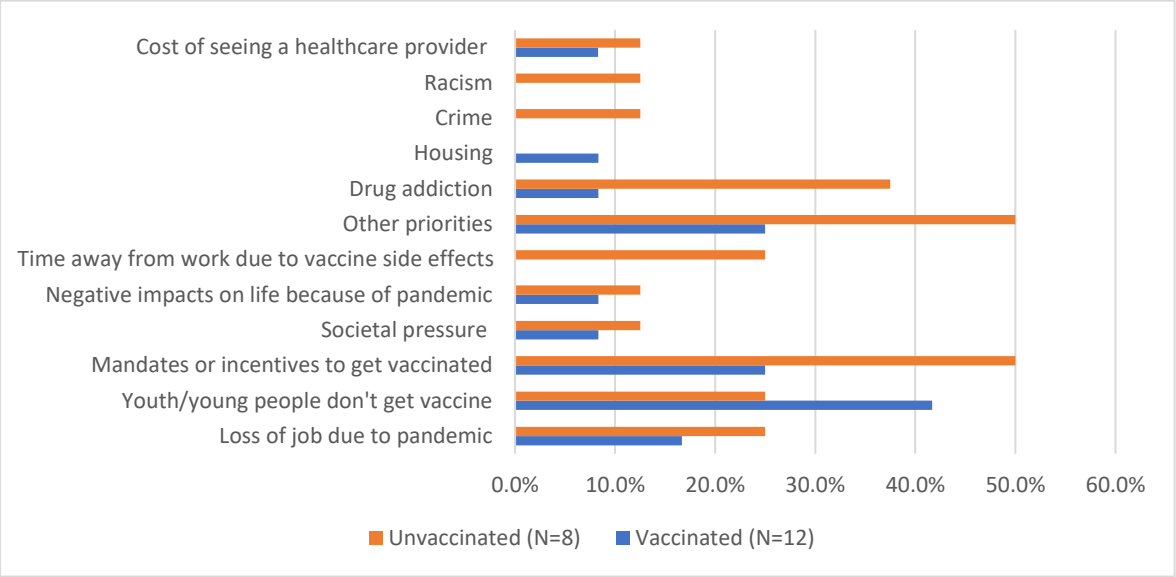
*Green columns correspond with fully vaccinated participants, red columns correspond with unvaccinated participants, yellow columns correspond with partially vaccinated participants.

Appendix F: Bar chart representations of subgroup analyses of thematic analysis

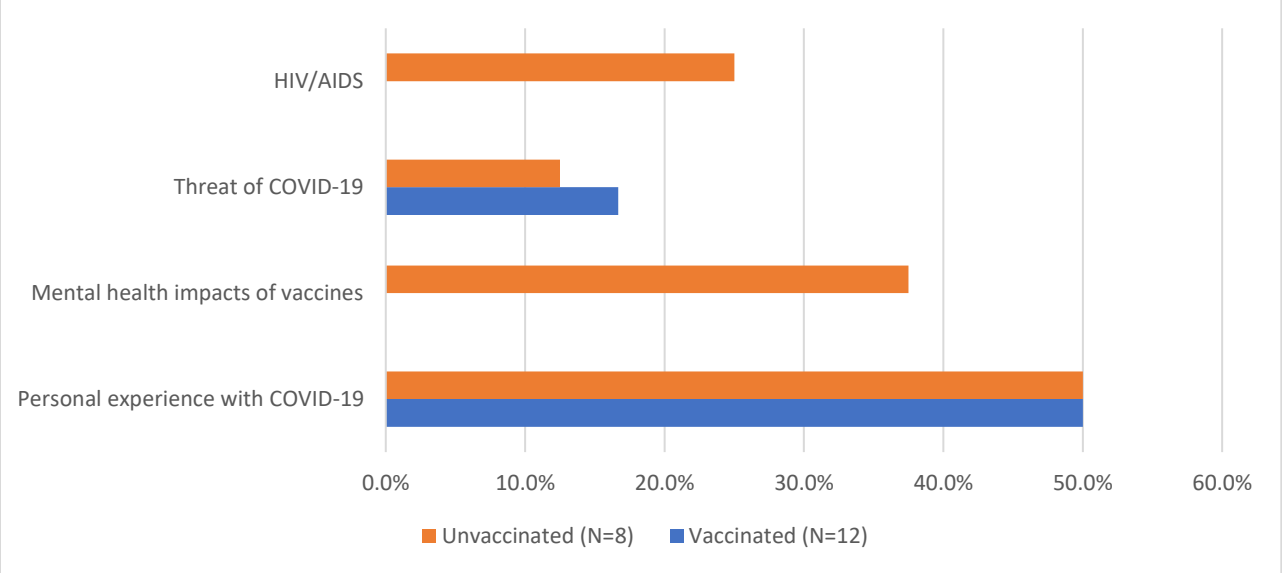
Appendix F(i): Proportion of vaccinated/unvaccinated respondents addressing each code pertaining to Theme I: Safety and Efficacy of Vaccines during interviews



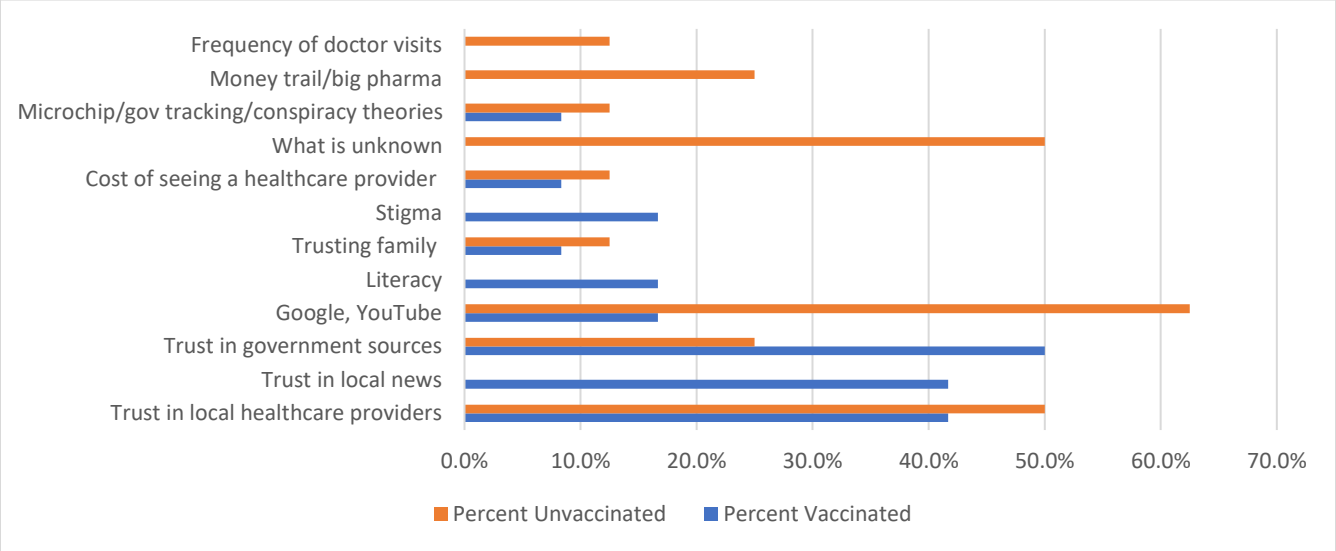
Appendix F(ii): Proportion of vaccinated/unvaccinated respondents addressing each code pertaining to Theme II, Subtheme a: Persistent Environmental Injustices during interviews



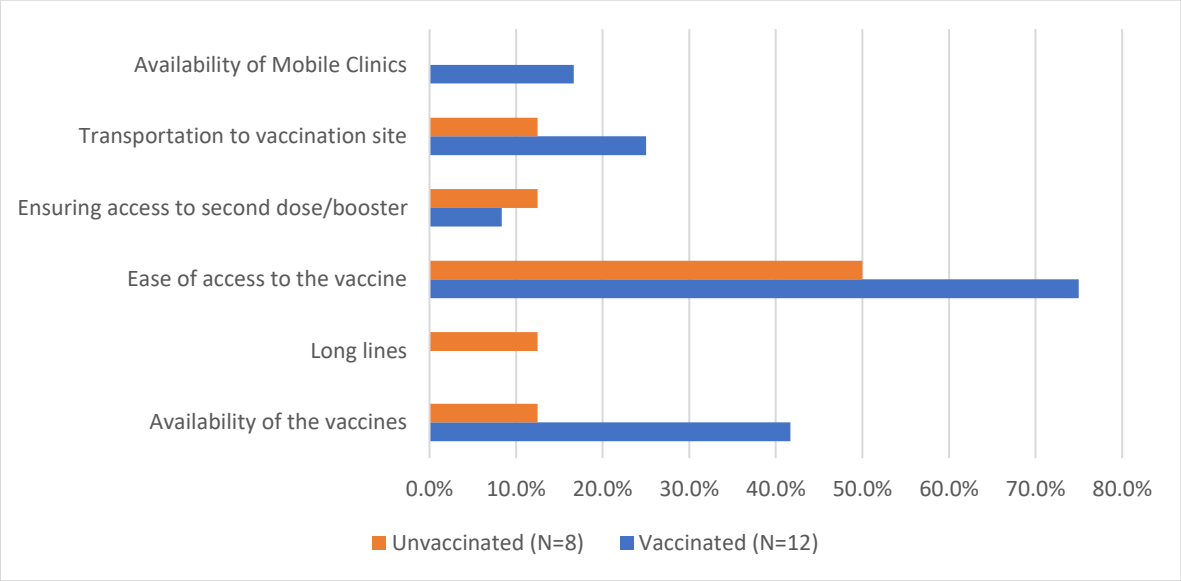
Appendix F(iii): Proportion of vaccinated/unvaccinated respondents addressing each code pertaining to Theme II, Subtheme b: Pre-existing health needs during interviews



Appendix F (iv:) Proportion of vaccinated/unvaccinated respondents addressing each code pertaining to Theme III, Access to understandable, trustworthy information



Appendix F (v): Proportion of vaccinated/unvaccinated respondents addressing each code pertaining to Theme IV, Physical access to vaccines



Appendix G – Table of Included Studies, Race/Ethnicity of Sample (if reported), primary outcome(s) and description of primary outcome(s)

Number	Type of Study	Author, Year of Publication	Race/Ethnicity Makeup of Participants	Primary Outcome(s) Reported	Description of Primary Outcome(s)
1	Efficacy/Phase III clinical trial	Thomas et al., 2021	Not reported	Adverse events /Reactogenicity	Adverse Events are unfavorable changes in health, including abnormal laboratory findings, that occur in trial participants during the clinical trial or within a specified period following the trial such as pain at injection site, fatigue
				Prevention of death post-vaccination	Deaths associated with vaccination
2	Efficacy/Phase III clinical trial (protocol)	Janssen Vaccines & Prevention B.V, 2020	N/A	Molecularly Confirmed Moderate to Severe/Critical COVID-19 post-vaccination	Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of signs and symptoms or severe COVID-19 defined in Food and Drug Administration (FDA) guidance.
3	Efficacy/Phase III clinical trial (protocol)	Moderna, 2020	N/A	Time to first Occurrence of COVID-19 post-vaccination	Participants with first Occurrence of COVID-19 Starting 14 Days after Second Dose of mRNA-1273 Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)
				Medically Attended AEs (MAAEs) Leading to Withdrawal	Number of participants with AEs or MAEs Leading to Withdrawal. MAEs were defined as adverse events with medically-attended visits that were not routine visits for physical examination or vaccination, such as visits for hospitalization, an emergency room visit, or

					an otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason.
				Participants with Solicited Local and Systemic Adverse Reactions (ARs)	Any solicited, untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related (FDA 21 CFR 312.32(a))
				Unsolicited AEs (UAEs)	Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related that is volunteered or noted in an unsolicited manner (FDA 21 CFR 312.32(a))
				Serious AEs (SAEs)	Any injury or symptom that occurs after getting a vaccination that is considered life threatening or places an individual at immediate risk of death or disability (FDA 21 CFR 312.32(a))
4	Efficacy/Phase III clinical trial (protocol)	Biontech RNA Pharmaceuticals GmbH	N/A	Adverse Events/Reactogenicity	Measures of AEs including ARs, UAEs, and SAEs.
				Tolerability	**The degree to which overt adverse effects can be tolerated by the subject (International Conference on Harmonization)**
				Immunogenicity	Biomaterial being detected by the body's immune system as a foreign object (Downes and Mishra, 2011). https://www.sciencedirect.com/topics/medicine-and-dentistry/immunogenicity
5	Expanded/Phase II clinical trial	Jackson et al, 2020	N=45; 2% American Indian or Alaska Native; 2% Asian; 4% Black; 89% White; 2% Unknown; 13% Hispanic or Latino	Immunogenicity	Dose-dependent immune response. T-cell responses against the spike protein for 25-µg and 100-µg dose groups
				Adverse Events/Reactogenicity	Measures of AEs including ARs, UAEs, and SAEs.
6	Expanded/Phase II clinical trial (protocol)	National Institute of Allergy and Infectious Diseases (NIAID)	N/A	Adverse Events/Reactogenicity	Measures of AEs including ARs, UAEs, and SAEs.

7	Efficacy/Phase III clinical trial	Thomas SJ et al., 2021	Total N = 44,047; 82% White; 9.6% Black or African American; 1.0% American Indian or Alaskan Native; 4.3% Asian; 0.2% Native Hawaiian or other Pacific Islander; 2.5% Multiracial; 0.5% Not Reported; 25.9% Hispanic or Latinx	Infection with SARS-CoV2 post-vaccination	Participants were monitored for potential COVID-19 throughout the trial and tested for SARS-CoV-2 if they developed symptoms potentially indicative of COVID-19. BNT162b2 efficacy against confirmed COVID-19 with an onset of 7 or more days after the second vaccine dose was summarized in participants
				Adverse Events	Measures of AEs including ARs, UAEs, and SAEs.
8	Efficacy/Phase III clinical trial	Baden LR et al., 2021	N=30,351; 79.2% White; 10.2% Black or African American; 4.6% Asian; 0.8% American Indian or Alaska Native; 0.2% Native Hawaiian or Other Pacific Islander; 2.1% Multiracial; 2.1% other; 0.9% Unknown/Not reported; 20.5%	Time to first occurrence of symptomatic Covid-19	Onset of symptomatic COVID-19 at least 14 days after the second injection in the per-protocol population, among participants who were seronegative at baseline

			Hispanic or Latino; 78.5% Not Hispanic or Latino		
9	Efficacy/Phase III clinical trial	El Sahly HM, et al., 2021	Total N = 28,451; 79.7% White; 9.6% Black; 4.7% Asian; 0.8% American Indian or Alaska Native; 0.2% Native Hawaiian or Pacific Islander; 19.7% Hispanic or Latinx; 79.3% Non-Hispanic or Lanix	Time to first occurrence of symptomatic Covid-19	Prevention of Covid-19 illness with onset at least 14 days after the second injection in participants who had not previously been infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
10	Efficacy/Phase III clinical trial	Sadoff J et al., 2022	Total N = 43,788 58.7% White; 19.4% Black or African American; 9.5% American Indian or Alaskan Native; 3.3% Asian; 0.2% Native Hawaiian or Pacific Islander; 5.6% Multiracial; 3.3% Not reported, unknown	Time to first occurrence of moderate to severe–critical Covid-19	Disease onset at least 14 days after administration and at least 28 days after administration in the per-protocol population
11	Efficacy/Phase III clinical trial	Gilbert P B, et al., 2021	Total N=1,147; 72.7% White; 18.0% Black or African American; 2.7% Asian; 1.7%	Time to first occurrence of symptomatic Covid-19	First occurrence of acute symptomatic COVID-19 with virologicallyconfirmed SARS-CoV-2 infection in participants with no evidence of previous SARS-CoV-2 infection.

			American Indian or Alaska Native; 0.4% Native Hawaiian or Other Pacific Islander; 1.4% Multiracial; 2.4% Other; 0.8% Not reported or unknown; 31.9% Hispanic or Latino; 67.8% Not Hispanic or Latino		
12	Efficacy/Phase III clinical trial	Achiron A et al., 2022	Not reported	Immunogenicity	Humoral and memory cellular immune responses were assessed within 1 and 3 months following the third Pfzer BNT162b2 vaccine dose and compared between the groups
13	Efficacy/Phase III clinical trial	Sablerolles R, et al., 2021	Not reported	Immunogenicity	level of Spike protein-specific binding antibodies
14	Safety/Phase I clinical trial	Mateus J et al., 2021	Not reported	Immunogenicity	Immune memory over7 months after vaccination
15	Expanded/Phase I/II clinical trial	Mulligan MJ, et al., 2020	Total N=45; 82.2% White; 2.2% Black or African American; 15.6% Asian; 4.4% Hispanic/Latino; 93.3% Non-Hispanic/non-Latino	Adverse Events/Reactogenicity	the proportion of participants who reported solicited local reactions, systemic events and use of antipyretic and/or pain medication within 7 days after vaccination, adverse events and serious adverse events (available up to around 45 days after dose 1), and the proportion of participants with clinical laboratory abnormalities 1 and 7 days after vaccination
16	Efficacy/Phase III clinical trial	Moreira ED et al., 2022	Total N=10,125; 79.0% White; 9.2% Black; 1.7% American Indian or Alaska Native; 5.5% Asian; 0.2%	Laboratory confirmed Covid-19	The primary efficacy end point was the effectiveness of the BNT162b2 vaccine against laboratory confirmed Covid-19 beginning at least 7 days after the administration of dose 3.

			Native Hawaiian or other Pacific Islander; 4.0% Multiracial; 0.4% Other or not reported; 14.9% Hispanic or Latinx; 84.9$ Non-Hispanic or non-Latinx		
17	Efficacy/Phase III clinical trial	Sadoff J et al., 2021	Total N = 43,783 58.7% White; 19.4% Black or African American; 9.5% American Indian or Alaskan Native; 3.3% Asian; 0.2% Native Hawaiian or Pacific Islander; 5.6% Multiracial; 3.3% Not reported, unknown	Time to first occurrence of moderate to severe–critical Covid-19	Disease onset at least 14 days after administration and at least 28 days after administration in the per-protocol population
18	Expanded/Phase II clinical trial	Polack FP et al., 2020	Total N = 37,706; 82.9% White; 9.3% Black or African American; 4.3% Asian; 0.5% Native American	Prevention of confirmed Covid-19 infection	with onset at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose

			or Alaska Native; 0.2% Native Hawaiian or other Pacific Islander; 2.3% Multiracial; 0.6% Not reported; 28% Hispanic or Latinx	Prevention of confirmed participants with and participants without evidence of prior infection	Confirmed Covid-19 was defined according to the Food and Drug Administration (FDA) criteria as the presence of 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, combined with a respiratory specimen obtained during the symptomatic period or within 4 days before or after it that was positive for SARS-CoV-2 by nucleic acid amplification–based testing, either at the central laboratory or at a local testing facility (using a protocol-defined acceptable test)
19	Expanded/Phase II clinical trial (Protocol)	Thomas SJ et al., 2021	Total N = 44,047; 82% White; 9.6% Black or African American; 1.0% American Indian or Alaskan Native; 4.3% Asian; 0.2% Native Hawaiian or other Pacific Islander; 2.5% Multiracial; 0.5% Not Reported; 25.9% Hispanic or Latinx	Cases of COVID-19	Accrued cases of laboratory-confirmed Covid-19 with an onset of 7 days or more after the second dose was assessed in participants without serologic or virologic evidence of SARS-CoV-2 infection within 7 days after the second dose and in participants with or without evidence of previous infection Covid-19 that could be evaluated (data cutoff date, November 14, 2020)
				Solicited Adverse Events	solicited, prespecified local reactions, systemic events, and antipyretic or pain medication use during the first 7 days after receipt of each vaccine or placebo dose, which were recorded in an electronic diary
				Unsolicited Adverse Events	unsolicited adverse events after receipt of the first dose through 1 month after the second dose
				Serious Adverse Events	serious adverse events after receipt of the first dose through 1 and 6 months after the second dose.
20	Expanded/Phase II clinical trial	Izikson R et al., 2022	N =104; 98% White; 0% Black or African American; 2%	unsolicited systemic adverse events	occurring within 30 min after vaccine injection and adverse reactions up to 21 days after injection

			Native Hawaiian or other Pacific Islander; 0% Asian; 0% Multpile race; 2% Hispanic or Latino; 96% Not Hispanic or Latino	solicited injection site and systemic reactions	occurring within 30 min after vaccine injection and adverse reactions up to 21 days after injection
				Medically attended adverse events	a new onset or a worsening of a condition that prompts the participant or participant's parent/legally acceptable representative to seek unplanned medical advice at a physician's office or Emergency Department. Physician contact made over the phone or by email will be considered a physician office visit for the purpose of MAAE collection. This includes medical advice seeking during the study visit or routine medical care. This definition excludes pediatric check-ups, follow-up visits of chronic conditions with an onset prior to entry in the study, and solicited reactions
				Immunogenicity	Haemagglutination inhibition antibody response
21	Safety/Phase I clinical trial	Anderson EJ et al., 2020	N = 40; 98% White; 2% Asian; 2% Hispanic/Latino	Reactogenicity/Adverse Events	Includes serious adverse events, local and systemic reactogenicity events, and unsolicited adverse events.
				Dose-dependent response	Binding IgG responses for all the participants were assigned sequentially to receive two doses of either 25 µg or 100 µg of vaccine administered 28 days apart.

22	Safety/Phase I clinical trial (protocol)	National Institute of Allergy and Infectious Diseases, 2020	N/A	Reactogenicity/Adverse Events	Frequency of any adverse events including medically-attended adverse events, new-onset chronic medical conditions, frequency of any protocol specified adverse events of special interest, any serious adverse events, any unsolicited adverse events and grade of solicited local and systemic adverse events.
23	Expanded/Phase II clinical trial (protocol)	Sanofi Pasteur, a Sanofi Company, 2021	N/A	Reactogenicity/Adverse Events	Includes number of participants with serious adverse events, adverse events of special interest, and medically attended adverse events
				Immunogenicity	Antibody titers measured by hemagglutination inhibition before and after vaccination, number of participants with seroconversion.
24	Efficacy/Phase III (protocol)	BioNTtech SE, 2020	N/A	Reactogenicity/Adverse Events	Includes number of participants with serious adverse events, adverse events of special interest, and medically attended adverse events
				Immunogenicity	Neutralizing titers after a third dose of NBT162b2 at 30 ug compared to after 2 doses of BNT162b2, ,in the same individuals.
25	Effectiveness Evaluation	Acharya and Dhakal, 2021	N=403,714; 73.6% White; 14.7% Black; 3.6% Asian; 8.1% Other races; 20.3% Hispanic	Vaccination Uptake	binary indicator of self-reported vaccination status, state-level daily new first vaccine dose administered per 100 000 people
26	Effectiveness Evaluation	Agarwal, et al., 2021	Not reported	Disparities in vaccine uptake	Factors including social determinants of health associated with racial disparities in COVID-19 vaccinations at the country level.
27	Effectiveness Evaluation	Bajema et al., 2021	N=1,175; 40.4% White; 48.9% Black; 7.9% Hispanic; 2.8% Other race, non-Hispanic	COVID-19 related Hospitalizations	Vaccine effectiveness in preventing COVID-19–related hospitalization
28	Effectiveness Evaluation	Berk J et al., 2021	Not reported	Vaccine uptake	Feasibility and efficiency of vaccine implementation in a carceral setting with education and communication strategies used to mitigate vaccine refusals.
29	Effectiveness Evaluation	Berry SD, et al., 2022	N=7496; 70% White; 26.3%	Vaccine uptake	The proportion of residents (from electronic medical records) and staff (from facility logs) who received a

			Black; 3.1% Latino		COVID-19 vaccine (any), examined as 2 separate outcomes
30	Effectiveness Evaluation	Blaiszik B, et al, 2021	Not reported	test-diagnosed infection	Local COVID-19 vaccine effectiveness using RT-PCR COVID-19 test data broken out by vaccination status from select localities in the U.S.A.
31	Effectiveness Evaluation	Brunelli SM, et al., 2021	N=2659; White 34.6%; 32.8%; 20.6% Hispanic; 3.6% Asian; 8.4% Other/unknown	test-diagnosed infection	Polymerase chain reaction (PCR)–confirmed clinical diagnosis of COVID-19
32	Effectiveness Evaluation	Cheng Z, Li Y, 2022	N=9606; 76.18% White non-Hispanic; 9.45% Black non-Hispanic; 8.3% Hispanic; 6.0% Other race	Disparities in vaccine uptake	The outcome variable of interest was the beneficiaries'COVID-19 vaccination status, which is captured by the question “since the date of COVID-19 vaccine availability, have you had a coronavirus vaccination?”
33	Effectiveness Evaluation	Donadio G, et al., 2021	Not reported; county level data	Vaccination Rate	County-level vaccination rates
				covd-incidence	COVID-19 incidence changes
34	Effectiveness Evaluation	Ehde DM, et al., 2021	N=359; 92.5% White; 3.1% More than one race; 1.7% Black/African American; 0.6% American Indian/ Alaska Native; 0.3% Asian	Vaccine Intention	Participants’ intentions to obtain a COVID-19 vaccination in two ways: asked to indicate their intent to get vaccinated when the vaccine was made available to them. Possible responses included “yes,” “no,” “undecided,” “I have already received one dose of the vaccine,” and “I have already received two doses of the vaccine. Vaccine willingness was also assessed using a 5-point scale (1 = not at all willing, 2 = a little willing, 3 = moderately willing, 4 = very willing, and 5 = extremely willing)
				Perceived risk of COVID-19 infection	Perceived risk for contracting COVID-19 was assessed using a 5-point scale (0 = no risk at all, 1 = a small risk, 2 = a moderate risk, 3 = a high risk, 4 = an extreme risk).
				Trust in information sources	Participants rated the extent to which they trust the information sources (1 = do not trust at all to 4 = totally trust).

				Perceived concern in the COVID-19 vaccine	Self-reported concerns about the vaccine assessed as "not a concern," a "minor concern," or a "major concern."
35	Effectiveness Evaluation	Gharpure R, et al., 2021	Not reported	Disparities in vaccine uptake	Assess vaccine uptake in these communities and identify characteristics that might impact uptake. e calculated the cumulative number of first and second doses of vaccine administered to residents and staff members at each clinic and normalized by the reported total bed capacity per community (presented as number vaccinated per 100 reported beds for assisted living communities and per 10 reported beds for residential care communities to account for differences in average community size
36	Effectiveness Evaluation	Greene SK, et al., 2021	Not reported	Hospitalizations	e calculated the rate ratio (RR) and 95% confidence interval (CI) for the interaction between implementation period (pre or post) and age-based eligibility (45–64 or 65–84 years). Analyses were stratified by race/ethnicity and borough of residence.
				Death	Same analyses of rate ratios as described above.
37	Effectiveness Evaluation	Hagan LM, et al., 2021	N=126,413; 31.4% White; 25.3% Hispanic; 39.3% Black; 1.4% Asian; 2.5% American Indian/Alaskan Native	Vaccine coverage	Vaccination coverage were calculated for the BOP incarcerated population using data from the BOP electronic medical record. Coverage among staff was calculated using data from the Centers for Disease Control and Prevention Vaccination Administration Management System Vaccination coverage were calculated for the BOP incarcerated population using data from the BOP electronic medical record. Coverage among staff was calculated using data from the Centers for Disease Control and Prevention Vaccination Administration Management System.
38	Effectiveness Evaluation	Hao and Shao, 2022	Not reported	Vaccine uptake	One question of the survey asks respondents whether they have gotten vaccinated for the coronavirus. Answers to this question are

					coded in a binary way as yes (1) and no (0).
39	Effectiveness Evaluation	Hughes MM, et al., 2021	Not reported	Vaccine coverage	Percentage of residents who received at least one COVID-19 vaccine dose
				Disparities in vaccine uptake	95% confidence intervals (CIs) within SVI tertiles were calculated for each of the 20 SVI metrics for the national analyses
40	Effectiveness Evaluation	Li Y et al., 2021	Not reported	Case growth rate	spread of COVID-19 shortly after the first shots were given
41	Effectiveness Evaluation	Marquez C, et al., 2021	N= 20,792; 70.5% Latinx; 14.1% White; 7.7% Asian, 2.4% Black,	Accessibility of vaccine	Measures of effectiveness associated with the multicomponent implementation strategy used indicators of behavior change, including the proportion of clients who said that they were able to get vaccinated more quickly had the neighborhood site not existed
				Social support/recommendation for vaccination uptake	The proportion of clients who stated that they were more likely to reach out to and recommend vaccination to their unvaccinated friends, family members and coworkers after their experiences at the UeS neighborhood vaccination site.
				Vaccination uptake/coverage	We also evaluated the proportion of clients at the neighborhood vaccination site who completed their second vaccine dose
42	Effectiveness Evaluation	McLaughlin JM et al, 2022	Not reported	COVID-19 cases	County-level cumulative numbers of reported and confirmed COVID-19 cases and CO
				COVID-19 related death	County-level cumulative numbers of COVID-19-related deaths
43	Effectiveness Evaluation	McNamara et al., 2022	Not reported	Cases, emergency	Probable and laboratory-confirmed COVID-19 cases
				Emergency department visits	Emergency department visits with a COVID-19 discharge diagnosis
				Hospital admissions	Hospital admissions for laboratory-confirmed COVID-19

				Deaths	COVID-19 deaths are those with confirmed or presumed COVID-19 reported
44	Effectiveness Evaluation	Moline, Whitaker	Not reported	Hospitalization	n laboratory-confirmed COVID-19–associated hospitalizations
45	Effectiveness Evaluation	Nanduri S, et al., 2021	Not reported	COVID-19 infection	Aggregate weekly numbers of new laboratory-confirmed SARS-CoV-2 infections among residents, by vaccination status
46	Effectiveness Evaluation	Puranik A, et al., 2021	Not reported	Vaccination rate	county-level vaccination rates
				COVID-19 incidence rate	corresponding COVID-19 incidence rates
47	Effectiveness Evaluation	Ritter AZ et al., 2021	Not reported	vaccine uptake	Implementation of activities to increase vaccination uptake, and vaccination rate outcomes
48	Effectiveness Evaluation	Roghani A et al., 2021	Not reported	Vaccine uptake	50 states in the United States that have cumulative vaccination data available up to April 2021
49	Effectiveness Evaluation	Rosenberg et al., 2022	Not reported	Cases	laboratory-confirmed Covid-19
				Hospitalizations	hospitalization with Covid-19 (i.e., Covid-19 diagnosed at or after admission)
50	Effectiveness Evaluation	Sehgal, 2021	Not reported	Vaccine uptake	Changes in vaccination rates
51	Effectiveness Evaluation	Tartof et al., 2022	Total 3,133,075; Asian 11.1%; Black 8.1%; Hispanic 39.4%; Other 2.3%; Pacific Islander 0.7%; White 33.1%	COVID-19 infection,	SARS-CoV-2 infections (without hospital admission)
				Hospitalization	COVID-19-related hospital admission
52	Effectiveness Evaluation	Thirumurthy et al, 2022	Not reported	Vaccination rates	daily vaccine doses administered in each state
53	Effectiveness Evaluation	Wang H et al., 2021	Not reported	Vaccination uptake	Vaccination rates at the town level in Connecticut during the second phase of the vaccine distribution plan when individuals aged 65 and over were eligible
54	Effectiveness Evaluation	Wang, Wang, Hu, Zhou, 2021	Not reported	COVID-19 infection rate	weekly growth rate of COVID-19 confirmed cases
				Vaccination coverage	The coverage rate of at least one dose among the general population

55	Effectiveness Evaluation	Wright BJ, et al., 2022	N=9667; 65.0% White; 16.9% Latino/Latina; 3.8% Black; 3.5% Asian; 10.9% Other	Hospitalization due to severe COVID-19	Patients were considered to have severe COVID-19 if they were admitted to the hospital, had a final coded diagnosis of COVID-19 (according to International Classification of Diseases Tenth Revision code U07.1) or a positive nucleic acid amplification test for symptomatic SARS-CoV-2 during their hospitalisation, and were treated with remdesivir or dexamethasone during hospitalisation.
56	Effectiveness Evaluation	Young-Xu Y, et al., 2021	N=6,647,733; 461,645 Hispanic; 16.6% Black; 4,361,621; 381, 648 Other	COVID-19 infection	positive SARS-CoV-2 test result

Appendix H: Core Outcome Set Survey – Round 1

Instructions: Thank you for your participation in this study. We want to know which outcomes related to COVID-19 vaccination are most important to you. For each outcome below, please mark the box that best describes how important that outcome is to you when deciding whether to get a COVID-19 vaccine. You can rate each outcome using a scale that ranges from 1 to 9, with 1 =not important at all and 9=most critical. If you are not sure what to rate a given outcome, please mark "Not sure."

****NOTE: Examples are provided for some outcomes. These examples do NOT pertain to COVID-19 vaccines specifically)**

Outcomes	Not important			Important but not critical			Critical			Not sure
In your opinion, when deciding whether to get the COVID-19 vaccine, how important is it for you to know…	1	2	3	4	5	6	7	8	9	
1. If participants in COVID-19 vaccine studies experienced any common injuries or symptoms at the point of injection after getting a COVID-19 vaccine. (*Examples: Pain, tenderness, redness, swelling, bruising)*										
2. If participants in COVID-19 vaccine studies experienced any common injuries or symptoms anywhere in the body after getting a COVID-19 vaccine. (*Examples: Nausea, vomiting, diarrhea, headache, fatigue, chills, fever)*										
3. If participants in COVID-19 vaccine studies experienced any unexpected injuries or symptoms after getting a COVID-19 vaccine. *(Example: Allergies to vaccine ingredients)*										
4. If participants in COVID-19 studies experienced any injuries or symptoms after getting a COVID-19 vaccine that were considered life threatening or placed an individual at immediate risk of death or disability. 5. (*Example: death, stroke, coma, hospitalization)*										
6. The severity of any injury or symptom that participants in COVID-19 vaccine studies experienced after receiving a COVID-19 vaccine. *(Example: no pain, mild pain, moderate pain, severe pain)*										
7. The relationship between the amount of vaccine (dose) and effects in the body. (*Example: lower dose, fewer injuries; higher dose, more injuries)*										
8. How well participants in COVID-19 vaccine studies tolerated any injury or symptoms that occurred after getting a COVID-19 vaccine. (*Examples: symptoms did not affect daily lifestyle, symptoms greatly impacted daily lifestyle)*										
9. The likelihood of experiencing any injury or symptom after receiving a COVID-19 vaccine. *(Example: There is a __% chance that individuals will experience some injury or symptom after receiving a COVID-19 vaccine)*										
10. If participants in COVID-19 vaccine studies experienced any injuries or symptoms after getting a COVID-19 vaccine while using other medications. *(Example: Reaction of prescription medication and COVID-19 vaccine)*										
11. Of any long-term side effects (injuries or symptoms) that participants of COVID-19 vaccine studies may have experienced. (*Example: conditions of the lungs or heart or any other organ which persist over one year after COVID-19 vaccination)*										
12. The likelihood of experiencing any injury or symptom after receiving a first dose of COVID-19 vaccine from one brand and a second dose from another brand. (*Example: __% of participants who received a Moderna vaccine followed by a Pfizer vaccine experienced injury or symptoms)*										

Outcomes	Not important			Important but not critical			Critical			Not sure
In your opinion, when deciding whether to get the COVID-19 vaccine, how important is it for you to know…	1	2	3	4	5	6	7	8	9	
1. The ability of the COVID-19 vaccine to produce an immune response in the body (*Example: Increased antibody concentration in blood after vaccination)*										
2. Whether the COVID-19 vaccine prevents people from contracting COVID-19 disease (*Examples: __% preventative of severe-critical COVID-19 disease, __% preventative of mild-moderate COVID-19 disease, __% preventative of asymptomatic COVID-19 disease)*										
3. How long a COVID-19 vaccine remains effective in the body (*Example: The COVID-19 vaccine remains effective for ___ months)*										
4. Whether new antibodies against COVID-19 can be detected in the body after COVID-19 vaccination. (*Example*: *COVID-19 vaccine produced sufficient new antibodies to fight infection*).										
5. Whether or not the COVID-19 vaccine prevents COVID-19 disease better than other existing vaccines *(Example: Comparing how the COVID-19 vaccine prevents COVID-19 disease to how the flu vaccine prevents COVID-19 disease)*										
6. Whether or not the COVID-19 vaccine prevents COVID-19 disease better than other natural treatments (*Example: Comparing how the COVID-19 prevents COVID-19 disease to how vitamin supplements prevent COVID-19 disease*)										
7. How protective each dose of a COVID-19 vaccine is. *(Example: one dose is __% protective against COVID-19, two doses are ___% protective against COVID-19 disease)*										
8. How protective COVID-19 vaccines are against different variants (e.g., Omicron, Delta) *(Example: COVID-19 vaccines are ___% protective against Omicron variant)*										

Outcomes	Not important			Important but not critical			Critical			Not sure
In your opinion, when deciding whether to get the COVID-19 vaccine, how important is it for you to know…	1	2	3	4	5	6	7	8	9	
1. The proportion of people in your community who are NOT willing to get a COVID-19 vaccine.										
2. The proportion of people in your community who are willing to get a COVID-19 vaccine.										
3. The proportion of people in your community who choose to wear masks in indoor spaces or when within 6 feet of other people.										
4. How to hold vaccine producers accountable for any injury or symptoms occurring after receiving a COVID-19 vaccine. *(Example: People who choose to get a COVID-19 vaccine are provided with information regarding how to hold pharmaceutical companies accountable)*										
5. Whether high-risk groups, such as the homeless, those dealing with addiction, and those with existing illnesses, are offered specialized opportunities to get the COVID-19 vaccine. (*Examples: Mobile Health Clinics, free shuttle/transportation to vaccination sites)*										
6. How reliable local social worker and community health workers are in regularly visiting with hard-to-reach groups *(Example: If community health workers in a mobile clinic say they will come to a neighborhood the following week, they follow through)*										
7. The cost of receiving the COVID-19 vaccine from a trusted health provider.										
8. The cost of transportation to get to the vaccine site.										
9. The number of days individuals should plan to take off from work after receiving a COVID-19 vaccine.										
10. How trustworthy the healthcare provider administering the COVID-19 vaccine is.										
11. How trustworthy the information being shared about COVID-19 vaccines is.										
12. The number of people in your community experiencing hospitalization and death from COVID-19 each week.										
13. Where to find information about the COVID-19 vaccines that is clear, understandable, and transparent.										
14. How trustworthy the state/federal government distributing the COVID-19 vaccines is.										
15. The number of people in your community that receive a COVID-19 vaccine each week during vaccine rollout.										

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