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EXPERT OPINION OF DRS. RANIT MISHORI AND BRIANNA DA SILVA BHATIA, PUBLIC HEALTH, AND MEDICAL EXPERTS, CONCERNING THE EFFECTIVENESS OF AND EQUITABLE ALLOCATION OF COVID-19 VACCINES, AND THE IMPORTANCE OF PUBLIC HEALTH CAMPAIGNS.

Ranit Mishori, MD, MHS, FAAFP, and Brianna da Silva Bhatia, MD, MPH, submit this expert opinion, which was requested by the Open Society Justice Initiative. It is our understanding that we were requested to render this opinion due to our longstanding expertise concerning the medical, public health, and human rights issues being considered. It is our further understanding that this opinion is meant to be used before the European Committee of Social Rights. We do note that it is outside of our expertise to provide an opinion on legal issues related to the claim.

This opinion has been prepared wholly independent of the Open Society Justice Initiative and we have received no remuneration and/or compensation of any kind for producing this expert opinion.
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I. Relevant Background and Qualifications

Dr. Ranit Mishori has the following professional background relevant to the issues of concern:

1. I am a senior medical advisor at Physicians for Human Rights (PHR). I am also a Professor of Family Medicine at the Georgetown University School of Medicine, and Vice President and Chief Public Health Officer at Georgetown University where I lead the university’s COVID-19 response and manage other public health challenges across all campuses. I established and lead the Public Health team that manages the response to COVID-19 and other infectious diseases and public health emergencies day-to-day. I oversee the university’s contact tracing and care navigator operations and provide technical expertise to all units and divisions in creating policies, establishing, and running protocols related to testing, vaccination, public health mitigation measures, community relations, strategic communications, and more.

2. Pre-pandemic I directed the Department of Family Medicine’s Global Health Initiatives and led Georgetown’s Practice-Based Research Network, among other leadership roles.

3. I have worked with PHR since 2006 as a consulting medical expert on asylum evaluations, torture, health worker training, mobile health, and sexual violence. As PHR’s Senior Medical Advisor, I am deeply engaged in programmatic work and organizational strategy related to COVID-19, health and detention, attacks on healthcare, torture, multi-sectoral training of healthcare workers globally, among others.

4. I am board certified in Family Medicine and did my residency training at the Georgetown University/Providence Hospital Family Medicine Residency program. I received my medical degree from Georgetown University School of Medicine and a Master’s Degree in International Health from the Johns Hopkins Bloomberg School of Public Health, in the Disease Control and Prevention Track (focusing on the science of how to halt the spread of
infectious disease). I am currently a candidate for an MSc/LLM in International Human Rights Law at Oxford University.

5. To ensure accurate public information about COVID-19, I have also served as a special advisor on COVID-19 coverage for a well-known US daily news program (the PBS NewsHour) and appeared as an expert on their news programming. I have also served as a special advisor for their institutional preparedness, news coverage and staff safety related to COVID-19.

6. I have written scientific and lay-media articles about the impact of COVID-19 on individuals, marginalized populations, the healthcare system, and have been interviewed in US media about COVID-19.

7. In addition, I have served as a COVID-19 expert consultant to multiple US and international legal partners working on COVID in detention and in the prison system; I have served as a member of the Covid-19 Crisis Action Group for OMCT (the World Organization Against Torture), co-authoring global correctional COVID-19 guidelines and testifying in front of the UN’s Committee Against Torture and other regional meetings about COVID-19 in correctional settings.

Dr. Brianna da Silva Bhatia has the following professional background relevant to the issues of concern:

8. I am a COVID-19 Health Strategist at Physicians for Human Rights (PHR). I am also Board Certified from the American Board of Internal Medicine, and a practicing physician. I completed my Internal Medicine residency training at Easton Hospital, an Academic Affiliate of Drexel University in Philadelphia, Pennsylvania. I received my medical degree from Aureus University School of Medicine. I have a Master of Public Health completed at the University of Washington School of Public Health, with an emphasis in Health Systems and Population Health.
9. As an attending physician, I have worked in the hospital, telemedicine, primary care, and administrative spaces. I have worked with rural, urban, vulnerable and underserved populations, including the elderly, homeless, formerly and currently incarcerated individuals, immigrants and refugees. Currently, I primarily work in the hospital where I treat many decompensated and new health conditions, respond to medical emergencies and end of life care. I regularly care for COVID-19 patients in the hospital.

10. I also apply my public health knowledge in response to the COVID-19 pandemic. I have participated in testimony to the Oregon State Legislature and was an expert witness with the Office of Public Defense Services for Habeas Corpus Petitions, advocating for fair and equitable COVID-19 vaccinations and protections for vulnerable people. I also serve on the Bioethics Triage Team for my medical institution, where we have trained to respond to the stress on our healthcare system, in part due to the COVID-19 pandemic, and are responsible for the distribution of scarce healthcare and treatment resources.

II. Methodology

11. To prepare this report, we have reviewed the medical and scientific literature, as well as guidelines, standards, and expert opinions from globally recognized health authorities. This includes publications from academic centers, studies in prominent medical journals, randomized control and other clinical trial data, and public health guidance from local and international organizations. We have also utilized secondary sources of public health data from private and public organizations that are accessible to the public. Due to the limited amount of publicly and easily accessible COVID-19 data specific to Bulgaria, we also reviewed information obtained following a Freedom of Information request filed by the Bulgarian Helsinki Committee.¹

¹ Decision No. 32 / 12.12.2022 for providing access to public information, issued by Prof. Dr. Iva Hristova, PhD, Director of the National Centre for Infectious and Parasitic Diseases, pursuant to Art. 28(2), in conjunction with Art. 34 of the Access to Public Information Act (APIA)
III. Executive Summary

12. In March 2020, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), responsible for the infectious disease known as "COVID-19," was declared a global pandemic. At this time, more than 674,000,000 infections and more than 6,690,000 deaths have been reported worldwide. The impact of COVID-19 cannot be adequately measured by the number of infections or deaths alone. Between January 2020 and December 2021, 18 million more people died worldwide than what would have been expected ("excess deaths"), and their deaths are likely related to COVID-19 and its impact. Further, among people who recover from the acute phase of COVID-19, there is a growing body of evidence demonstrating that many people suffer prolonged symptoms or complications, often referred to as "Long COVID," which has and will continue to impact people's quality of life, healthcare utilization, and ability to work, among others.

13. SARS-CoV-2 is spread through direct person-to-person transmission via droplets and aerosolized particles. Asymptomatic spread of the virus has aided in the rapid spread of the disease. All people are susceptible to and capable of being infected with SARS-CoV-2. COVID-19 can become a very serious multi-system disease, which can lead to, among other things, respiratory, heart and kidney failure, blood clots, neurological complications, secondary infections, and death. Older people and people with chronic underlying conditions such as cancer, diabetes, heart disease, or chronic kidney disease, are at higher risk for severe COVID-19, hospitalization, and death.

14. Vaccines have been and remain one of the most important public health interventions. COVID-19 vaccines have proven to be safe, and an important and effective way to reduce severe COVID-19 and death. In the early days of the pandemic, before SARS-CoV-2 Omicron mutations emerged, the vaccines were very effective at reducing transmission and infection from SARS-CoV-2 and helped to control and reduce the spread of the virus. Importantly, evidence is mounting that COVID-19 vaccinations reduce the burden of "Long COVID." Based on best public health practices, lessons learned from previous health emergencies, and mounting information and data on COVID-19, virtually all global health organizations and experts recommended vaccines be prioritized, particularly for frontline
healthcare workers, vulnerable people, and populations at high risk for severe disease and death. Subsequently, most countries followed these evidence-based recommendations.

15. Guidelines for vaccine allocation and prioritization plans became available from different health authorities as early as 2020. Globally, best practices quickly centered on equitable access, and public health and human rights principles.

16. In 2020, when vaccines were not available, the average number of deaths from COVID-19 in Bulgaria was 123 per 100,000 population; the number of people who died in the 65-69, 70-74, and 75-79 age groups was double, triple, and nearly quadruple that of the average. The number of people who died in the 80+ age group was 561 per 100,000 people.

17. Bulgaria received its first shipment of vaccines December 26, 2020. Between December 2020 and the end of June 2021 Bulgaria received 2,838,420 doses of Comirnaty vaccine (also known as the Pfizer mRNA vaccine), 1,183,200 doses of Vaxzevria vaccine (also known as the AstraZeneca vaccine), 488,400 doses of the Spikevax vaccine (also known as the Moderna mRNA vaccine), and 152,500 doses of Janssen (also known as Jcovden or the J&J vaccine). All were considered highly safe and effective at the time, with protection against transmission, hospitalization, severe or critical disease, and death, with little or no difference in serious adverse events, compared to placebo.

18. Between December 2020 and the end of June 2021 Bulgaria, compared to the European Union, had the highest COVID-19 case fatality rate (defined as the proportion of COVID-19 deaths among identified cases, or the number of people who died from COVID-19 divided by the number of people diagnosed with COVID-19, during a specified time period), the 3rd highest number of confirmed COVID-19 deaths (death attributed to COVID-19 in a person with confirmed SARS-CoV-2), and the lowest amount of COVID-19 vaccine doses administered.

19. The severe impact of the COVID-19 pandemic in Bulgaria is related to low vaccination uptake. Across the world, the downward trend of death rates has correlated with scientific
progress, such as the roll out of therapeutics and interventions, namely COVID-19 vaccines and the progressive uptake of them. It is impossible to ignore the correlation between negative outcomes and vaccination rates in Bulgaria. When compared to Eastern Europe, the European Union, other continents, and the world as a whole, Bulgaria has the highest COVID-19 deaths per million people, the highest case fatality rate, the lowest or near lowest amount of COVID-19 vaccines administered per 100 people, and the lowest or near lowest share of people fully vaccinated. It is not a coincidence that deaths and case fatality rates were reduced in most parts of the world as vaccination uptake increased.

20. By the end of June 2021, the cumulative uptake of a complete COVID-19 vaccine series (2 doses, "fully vaccinated") in Bulgaria was: 32% of people in long-term care facilities, 20.8% of healthcare workers, and 20.3% of people aged 60 years and older. Within the WHO European region, the cumulative median uptake of a complete COVID-19 vaccine series was: 67.6% of people in long-term care facilities, 62.3% of healthcare workers, and 59.7% of people aged 60 years and older. Compared to the European Union, Bulgaria had the lowest number of people fully vaccinated (2 doses) at 11.88% of the population, and one of the highest excess mortality rates (the number of deaths during the COVID-19 pandemic compared to the deaths that would have expected had the pandemic not occurred; provides information on the burden of death potentially related to the pandemic by including direct and indirect deaths).

21. As of December 2022, and among adults aged 60 years and older, Bulgaria has the lowest primary series completion compared to the European Union, at 38.4%. Completion of a primary series among adults aged 60 years and older is above 90% for more than half of EU countries.

22. As of January 10, 2023, there have been 1,293,491 confirmed SARS-CoV-2 infections, and 38,127 deaths in Bulgaria. Characteristics are available for 36,700 deaths: People above the age of 65 years accounted for 76.7% of all deaths in Bulgaria, and males between the ages of 65-74 years of age accounted for most of those deaths.
23. Further, effective health communication campaigns are necessary to educate, gain the public's trust, and overcome health mis/disinformation and scientific distrust. Health communication has helped to promote social cooperation for the special protections necessary for elderly people and those with multiple medical conditions and/or social risk factors which place them at increased risk for severe COVID-19 and death.

IV. COVID-19 and Vulnerable Groups

A. What is COVID-19 and How Is It Spread?

24. In December 2019 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was detected in Wuhan, China. SARS-CoV-2 causes the infectious disease known as "COVID-19."²

25. SARS-CoV-2 spread rapidly and on January 23, 2020, the World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern. They advised that every country in the world should "place particular emphasis on reducing human infection, prevention of secondary transmission and international spread..."³ By March 2020, SARS-CoV-2 was declared a pandemic.⁴

26. COVID-19 has arguably become one of the deadliest and most catastrophic events in our lifetimes. Since testing became available, more than 660,100,000 infections and more than 6,600,000 deaths have been reported worldwide.⁵ True counts are likely even higher due to

the burden of undetected or asymptomatic illness, lack of testing supplies and access, and
more recently, a reduction in testing for and monitoring of COVID-19.

27. SARS-CoV-2 is spread through direct person-to-person respiratory transmission. It occurs
mainly through close contact (within approximately six feet or two meters) via respiratory
droplets such as when a person sneezes, coughs, or talks. SARS-CoV-2 can also be
"airborne" or spread longer distances through very tiny particles that remain in the air,
particularly in enclosed and poorly ventilated spaces. Infection may also occur if a
person touches a contaminated surface and then touches their face, eyes or nose. People can
transmit the virus before they start to show symptoms and are most contagious within the
first 5 to 10 days of infection; data suggests that the time period for spreading the disease is
variant dependent. People with asymptomatic infections still spread SARS-CoV-2.

28. All people are susceptible to and capable of being infected with SARS-CoV-2, particularly
if not practicing preventative measures (e.g. masking, distancing, isolation). There is a
spectrum of severity, with most people having mild disease. Mild symptoms may include
cough, fever, taste changes, runny nose, sore throat, among others. However, COVID-19
can become a very serious multi-system disease, which can lead to, among other things,
respiratory, heart and kidney failure, blood clots, neurological complications, secondary
infections, and death. Older patients and patients with chronic underlying conditions are at
a particularly high risk of severe disease and complications. Certain risk factors or medical

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conditions, such as older age, cancer, diabetes, or chronic kidney disease, make people at higher risk for severe COVID-19. Reinfection is possible, and with SARS-CoV-2 viral mutations creating variants that are more immune evasive, previous infection may be less protective from future re-infection.

29. Importantly, among people who recover from the acute phase of COVID-19, there is a growing body of evidence demonstrating that many suffer prolonged symptoms or complications, often referred to as "Long COVID." Long COVID includes a broad range of symptoms, such as fatigue, shortness of breath, chest pain, cough, dizziness, or psychological and cognitive changes that develop during or after COVID-19, and continue for at least 2 months.

30. Early in the pandemic there were no or very limited treatment options, thus making prevention and mitigation efforts the most powerful tools to keep communities safe. Efforts to limit, slow or reduce the spread of SARS-CoV-2 were and remain important mitigating strategies. This includes upgrading indoor ventilation, isolation of those infected, disinfection of shared materials, wearing a mask, avoiding poorly ventilated spaces, and indoor spaces. One of the most important measures of protection is vaccination, although the best protection is afforded by a layered approach and the incorporation of multiple interventions and strategies at the same time.

B. Older People Are Among the Most Vulnerable

31. In 2020, a significant amount of research emerged and readily identified vulnerable groups of people who were at risk for more severe COVID-19 disease, hospitalization, and/or death. This research, along with the guidelines of health organizations, more than established the need for prioritization and special protections among vulnerable Bulgarians. For example, data supported the following as risk factors for severe COVID-19 (non-exhaustive list):
A. Older age (typically ages 60-65 years and older)\textsuperscript{14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27}

- For example, individuals aged less than 65 years account for 4.5–11.2% of all COVID-19 deaths in European countries and Canada.\textsuperscript{28}

B. Male Gender\textsuperscript{29, 30, 31, 32, 33, 34, 35, 36, 37, 38}

C. Comorbid conditions:

\textsuperscript{16} Tao Chen et al, “Clinical characteristics of 113 deceased patients with coronavirus disease 2019: retrospective study,” \textit{BMJ} 368, 1091(March 2020):. doi:10.1136/bmj.m1091
\textsuperscript{21} Biagio Cangiano et al, “Mortality in an Italian nursing home during COVID-19 pandemic: correlation with gender, age, ADL, vitamin D supplementation, and limitations of the diagnostic tests,” \textit{Aging} 12, no. 24 (December 2020):24522-24534. doi:10.18632/aging.202307
\textsuperscript{23} Mark Joy et al, "Excess mortality in the first COVID pandemic peak: cross-sectional analyses of the impact of age, sex, ethnicity, household size, and long-term conditions in people of known SARS-CoV-2 status in England," \textit{Br J Gen Pract} 70, no. 701 (November 2020):e890-e898. doi:10.3399/bjgp20X713393
\textsuperscript{28} Ioannidis, "Population-level COVID-19," 109890.
\textsuperscript{29} Zhou, "Clinical course and risk factors," 1054-1062.
\textsuperscript{30} Nascimento, "Novel Coronavirus Infection," 941.
\textsuperscript{32} Williamson, "Factors associated with COVID-19," 430-436.
\textsuperscript{33} Michelozzi, "Mortality impacts coronavirus," 2000620.
\textsuperscript{34} Mohamed, "Sex Differences in Mortality," 2110-2124.
\textsuperscript{36} Petrelli, "Factors associated hospital admission," 1966.
Cardiovascular Disease 39, 40, 41, 42, 43, 44, 45, 46, 47
  
  ○ For example, the American College of Cardiology released a COVID-19 Clinical Guidance Bulletin and reported that case fatality rates for patients with cardiovascular disease and hypertension were 10.5% and 6.0%, respectively. 48

- Diabetes 49, 50, 51, 52, 53
- Chronic lung disease 54, 55, 56, 57
- Obesity 58, 59, 60
- Cancer 61, 62, 63, 64, 65
- Chronic kidney disease 66, 67, 68

43 Chen, "Clinical characteristics deceased patients," 1091.
47 Songjiang Huang et al, "COVID-19 patients with hypertension have more severe disease: a multicenter retrospective observational study," Hypertens Res 43, no. 8 (June 2020):824-831. doi:10.1038/s41440-020-0485-2
52 Parohan, "Risk factors for mortality," 1416-1424.
64 Bellan, "Fatality rate predictors mortality," 20731.
- Liver Disease
- Neurological diseases such as stroke or dementia
- Immunosuppression
- Learning disability
- Socioeconomic factors, such as residence in a low-income area or communal living

32. In 2021, research continued to accumulate and readily identified vulnerable groups of people who were at risk for more severe COVID-19 disease, hospitalization, and/or death. For example, data supported the following as risk factors for severe COVID-19 (non-exhaustive list):

A. **Older Age**

B. **Male Gender**

C. **Comorbid conditions:**
- Cardiovascular Disease\cite{84,85,86}
- Diabetes\cite{87,88}
- Chronic Lung Disease\cite{89,90}
- Obesity\cite{91}
- Cancer\cite{92,93,94}
- Chronic renal failure\cite{95}

33. As we enter the 4th year of the pandemic, the evidence has not changed; data from around the world only continues to strengthen and support initial public health recommendations.

34. The most significant risk factor for severe disease or death from COVID-19 is age. Older patients have higher mortality rates compared to the younger population. For example, cumulative deaths in the United States have primarily been in the older population: people aged 65-74 years, 75-84 years, and 85+ years account for 9.6%, 4.9% and 2% of the population, but accounted for 22.4%, 26%, and 26.9% of COVID-19 deaths, respectively.\cite{96}

\begin{enumerate}
\item \cite{84,85,86}
\item \cite{87,88}
\item \cite{89,90}
\item \cite{91}
\item \cite{92,93,94}
\item \cite{95}
\item Roohallah Alizadehsani, "Risk factors prediction, mortality," 2307-2320.
\item Aksel, "Early predictors of mortality," 290-296.
\item Alharthy, "Clinical Characteristics Predictors Mortality," 98-104.
\item Aksel, "Early predictors mortality," 290-296.
\item Bhaskaran, "Factors associated with deaths," 100109.
\item Alizadehsani, "Risk factors prediction, mortality," 2307-2320.
\item Aksel, "Early predictors of mortality," 290-296.
\item Ibid
\end{enumerate}
35. High risk comorbid conditions include obesity, dementia, diabetes, tobacco use, hyperlipidemia, cardiovascular disease, cancer, chronic kidney disease, chronic liver disease, stroke, and organ transplant recipients, among others.\textsuperscript{97, 98, 99, 100, 101, 102, 103}

36. It is important to note that Bulgaria has a large share of people aged 65 years and above (nearly 21% of the population).\textsuperscript{104}

37. Newer cases of individuals with severe disease and death can be attributed to the emergence of new variants and sub lineages of SARS-CoV-2 rendering the virus more transmissible, immune evasive, resistance to treatments, and other factors such as relatively low primary vaccine or booster uptake, and waning vaccine immunity. Together this delineates the importance of not only primary series vaccination, but staying up to date with booster doses, especially in high-risk populations.

C. SARS-CoV-2 Variants

38. The nomenclature system of SARS-CoV-2 for non-scientific audiences uses letters of the Greek Alphabet, such as Alpha and Beta.\textsuperscript{105} More specific and scientific nomenclature systems, such as the Pango, GISAID, and Nextstrain, are typically used by researchers.


public health agencies and in academia.\textsuperscript{106,107} For the rest of this section, Pango or Greek Alphabet nomenclature will be used.

39. Very briefly, if SARS-CoV-2 were a tree, each main limb may be called a lineage. Lineages represent shared ancestry. Sometimes, a lineage or group of lineages, may be designated as a variant due to shared attributes or characteristics, and essentially represents a viral genetic code with one or more mutations.\textsuperscript{108} When a limb grows a new branch, it will be called a sublineage. For example: the public may think of Omicron (B.1.1.529) as one entity. However, Omicron has multiple lineages (such as BA.1, BA.2, BA.3, BA.4, BA.5), and these lineages have descendant lineages or sublineages (such as BQ.1.1, BQ.1, BF.7), or descendant recombinant lineages (such as XBB).\textsuperscript{109,110}

40. A SARS-CoV-2 variant that has increased transmissibility, increased virulence, a change in clinical disease presentation, or has demonstrated a decrease in response to interventions, diagnostics, or therapeutics is called a Variant of Concern (VOC).\textsuperscript{111}

41. Very briefly, mutations in the genetic material of the virus and/or the mixing of genetic code ("recombination") has resulted in new variants. These new lineages and sublineages impact transmission, severity, the resistance to natural or vaccine-induced immunity ("immune evasion"), and the success of available diagnostics or treatments.

42. In December 2020, the Alpha variant (B.1.17) was designated a VOC by the WHO.\textsuperscript{112} By early 2021 the Alpha variant quickly spread throughout the world and became the first highly publicized variant. The Alpha variant was believed to be 30-50% more contagious

\textsuperscript{111} World Health Organization, "Tracking SARS-CoV-2 variants"
\textsuperscript{112} Ibid
\textsuperscript{112} Ibid
than the original SARS-CoV-2 strain due to mutations in the spike protein, as well as causing more severe disease and death.\textsuperscript{113, 114}

43. The Alpha variant accounted for the majority of sequences in Bulgaria between January 2021 and July 2021.\textsuperscript{115, 116}

44. In May 2021, the WHO labeled the Delta variant (B.1.617.2) a VOC.\textsuperscript{117} Delta quickly spread worldwide and remained globally dominant between approximately July 2021 through December 2021.\textsuperscript{118, 119} It was estimated to be 80-90\% more transmissible than the Alpha variant, and more severe, especially for unvaccinated people.\textsuperscript{120}

45. The Delta variant was dominant in Bulgaria between approximately July 2021 and January 2022.\textsuperscript{121, 122}

46. Between the Alpha and Delta variants, the Beta and Gamma variants were labeled VOCs. They did not spread as aggressively, caused a far less global disease burden, were quickly overtaken by Delta, and were not as well known to the public.

47. In November 2021, the Omicron variant (B.1.1529) was designated a VOC.\textsuperscript{123} Within a few months Omicron spread worldwide. By the first week of January 2022, Omicron already accounted for 58\% of reported sequences globally.\textsuperscript{124} By January 25\textsuperscript{th}, Omicron accounted

\textsuperscript{115} Our World in Data, "Sequences by Variant"
\textsuperscript{117} World Health Organization, "Tracking SARS-CoV-2 variants"
\textsuperscript{118} Our World in Data, "Sequences by Variant"
\textsuperscript{120} Katella and Grubaugh, "Coronavirus Variants".
\textsuperscript{121} CoVariants, "Overview Variants/Mutations"
\textsuperscript{122} Our World in Data, "Sequences by Variant"
\textsuperscript{123} World Health Organization, "Tracking SARS-CoV-2 variants"
for over 98% of reported sequences globally.\textsuperscript{125} Epidemiological trends suggested that Omicron was less severe than the Delta variant, but demonstrated that Omicron had a much higher growth advantage resulting in increased and easier transmission than previous VOCs, even in the face of vaccination or previous infection, largely due to the immune evasion.\textsuperscript{126, 127} The Omicron variant has been characterized by multiple subvariants/sublineages with new genetic mutations.\textsuperscript{128, 129}


V. Effectiveness and Fair Allocation of Covid-19 Vaccines

A. Vaccines Are Safe and Effective, Particularly For People Aged 65 Years and Older People

49. Vaccines have been and remain one of the most important public health interventions contributing to human health and safety. As explained below, it has been scientifically shown that most approved COVID-19 vaccines are highly effective in preventing death and serious disease, and, prior to the emergence of new variants with immune-evasive mutations, worked well at reducing transmission and infection.

50. The Alpha variant was dominant both in Bulgaria and the world in the first half of 2021. The Alpha variant was associated with higher transmissibility, more severe disease, and a


\textsuperscript{126} Ibid


\textsuperscript{129} World Health Organization, "Tracking SARS-CoV-2 variants"
higher burden of death compared to the original "wild-type" virus\textsuperscript{130,131,132,133,134,135,136,137,138,139}.

51. Vaccine data during the Alpha variant predominance demonstrated the efficacy of available COVID-19 vaccines against the Alpha variant. For example:

- Data from over 23,000 people demonstrated that the Pfizer-BioNTech (BNT162b2) vaccine (1 and 2 doses) prevented both symptomatic and asymptomatic infection.\textsuperscript{140}

- Data collected from 383,812 individuals found that vaccination with the AstraZeneca COVID-19 Vaccine (ChAdOx1) or Pfizer-BioNTech vaccine (BNT162b2) reduced SARS-CoV-2 infections after only 1 dose, and greater reductions were observed after a second dose. The largest reductions were observed for symptomatic infections and/or infections with a higher viral load detected on nose or throat swabs. There was no significant difference between the BNT162b2 and ChAdOx1 vaccines.\textsuperscript{141}


\textsuperscript{136} Raju Mukherjee and Rohit Saradkekar, "Why are some coronavirus variants more infectious?," \textit{J Biosci} 46, no.4 (2021). doi: 10.1007/s12038-021-00221-y

\textsuperscript{137} Matteo Vassallo et al, "Patients Admitted for Variant Alpha COVID-19 Have Poorer Outcomes than Those Infected with the Old Strain.," \textit{J Clin Med} 10, no.16 (August 2021):3550. doi: 10.3390/jcm10163550


\textsuperscript{140} Emma Pritchard et al, "Impact of vaccination on new SARS-CoV-2 infections in the United Kingdom," \textit{Nature} 27, no.8 (August 2021):1370-1378. doi: 10.1038/s41591-021-01410-w
- Data from an outbreak in a correctional facility (high risk setting due to close proximity of people) demonstrated that the Moderna vaccine had an 87.1% vaccine effectiveness.\textsuperscript{142}

- In an evaluation at 21 hospitals in 18 states (United States), Pfizer-BioNTech or Moderna vaccine effectiveness against COVID-19-associated hospitalizations was 86% overall and 90% among adults without immunocompromising conditions. VE against COVID-19- associated hospitalization was 86% 2-12 weeks and 84% 13-24 weeks from receipt of the second vaccine dose.\textsuperscript{143}

52. The Delta variant was dominant both in Bulgaria and the world in the latter half of 2021. The Delta era was associated with increased infectivity, more severe disease, and reduced efficacy of vaccinations with greater breakthrough infections due to "immune escape." \textsuperscript{144}

53. Vaccine data during the Delta variant predominance demonstrated the efficacy of available COVID-19 vaccines against the Delta variant. For example:

\textsuperscript{142} Rachel Silverman et al, "Vaccine Effectiveness During Outbreak of COVID-19 Alpha (B.1.1.7) Variant in Men's Correctional Facility, United States," Emerg Infect Dis 28, no.7 (July 2022):1313-1320. doi: 10.3201/eid2807.220091
\textsuperscript{144} Koen Pouwels et al, "Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK," Nature 27 (October 2021):2127-2135. https://doi.org/10.1038/s41591-021-01548-7
\textsuperscript{146} Lin, "Disease Severity/ Clinical Outcomes"
\textsuperscript{147} Geddes, "Alpha to Omicron variants"
\textsuperscript{150} Camino Trobajo-Sammartin et al, "Differences in Transmission between SARS-CoV-2 Alpha (B.1.1.7) and Delta (B.1.617.2) Variants," Microbiol Spectr 10, no. 2 (April 2022). 10.1128/spectrum.0008-22
\textsuperscript{152} Kerstin Klasen et al, "COVID-19 due to the B.1.617.2 (Delta) variant compared to B.1.1.7 (Alpha) variant of SARS-CoV-2: a prospective observational cohort study," Sci Rep, no.1 (June 2022):10904. doi: 10.1038/s41598-022-14016-0
\textsuperscript{154} Mukherjee and Sutardekar, "Why are variants"
\textsuperscript{155} Sebczak and Pawlczak, "COVID-19 mortality Eastern European"
- Modeled data from a population of 2,691,418 people found that the effectiveness against infection for one dose of Oxford-AstraZeneca was 38.5% for and 19.5% for one dose of Pfizer-BioNTech vaccines. For two doses, an effectiveness against infection was 64.0% for Oxford-AstraZeneca and 83.9% for Pfizer-BioNTech.\(^{156}\)

- Data from 358,983 people demonstrated that two Pfizer-BioNTech vaccinations resulted in greater protection than two doses of Oxford-AstraZeneca. Either vaccination still reduced new infections, but the effectiveness and attenuation of peak viral burden were reduced.\(^{157}\)

- Compared with being unvaccinated, being vaccinated with two doses (of either Pfizer-BioNTech or Moderna) more than 3 months before infection was associated with lower odds of any adverse outcome. Infection with the Delta variant was independently associated with higher odds of experiencing any adverse outcome. Adverse outcomes included admission to the hospital, care in the intensive care unit, use of supplemental oxygen, use of high-flow oxygen, receipt of mechanical ventilation, and death.\(^{158}\)

- Vaccination with the Pfizer-BioNTech or Oxford-AstraZeneca vaccines were associated with reduced transmission. However, reductions in transmission of the delta variant were smaller than reductions in transmission of the alpha variant.\(^{159}\)

- Data collected during both the Alpha and Delta waves demonstrated an effectiveness of 73.6% and a 3.73-fold reduction in SARS-CoV-2 infection for people vaccinated with the J&J/Janssen COVID-19 Vaccine.\(^{160}\)

\(^{156}\) Karan Pattne et al, "Effectiveness of the BNT162b2 (Pfizer-BioNTech) and the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccines for reducing susceptibility to infection with the Delta variant (B.1.617.2) of SARS-CoV-2," *BMC Infect Dis* 22, no. 1 (March 2022):270. doi: 10.1186/s12879-022-07239-z

\(^{157}\) Poulwels, "Effect Delta variant"

\(^{158}\) Butt, "Severity Illness Delta Variant,"


54. The Omicron variant became dominant in both the world and Bulgaria in January 2022, and remains dominant as we enter the year 2023. Omicron has been associated with the rise of numerous mutations resulting in increased transmission, evasion of previous immunity, and reduced or lost effectiveness of therapeutics. Vaccinations became less effective against Omicron than they were for the Alpha or Delta. For example:

- Laboratory and human data have shown that three doses of BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) restored neutralization against Omicron, albeit a less robust response when compared to the Delta variant, and has demonstrated the importance of booster doses.

- Data from the American CDC found that during the rise of Omicron as the dominant variant, BNT162b2 (Pfizer-BioNTech) vaccine efficacy against COVID-19-associated emergency department and urgent care encounters after one, two and three doses to be 52%, 38%, and 82%, respectively. Vaccine efficacy

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164 Samuel Cheng et al, “Neutralizing antibodies against the SARS-CoV-2 Omicron BA.1 variant following homologous and heterologous CoronaVac or BNT162b2 vaccination,” *Nat. Med* 28, no.3 (March 2022): 486-489. doi:10.1038/s41591-022-01704-7


against COVID-19-associated hospitalizations was 81%, 57%, and 90% after one, two, and three doses respectively.\textsuperscript{173}

- Recent reviews have evaluated the performance of vaccines during the Omicron era. One outlined that the effectiveness of Pfizer-BioNTech, Moderna, and Oxford-AstraZeneca vaccines (all 2 doses) had a reduced efficacy against symptomatic infection from approximately 90% during Alpha and Delta waves, to 65%, 75%, and 59% during Omicron.\textsuperscript{174} The use of a booster dose demonstrated a vaccine efficacy of 68%, 74%, and 58%, respectively. Another review found no significant difference in vaccine booster efficacy against symptomatic infection between Pfizer-BioNTech, Moderna, Janssen, and Oxford-AstraZeneca; the average booster efficacy was 52.2%.\textsuperscript{175} Vaccine booster efficacy against Omicron-related severe disease, hospitalization or death remained high, with an average of 87.5%. There were no statistically significant differences of vaccine booster efficacy between three doses of the (same) mRNA vaccine, three doses of Oxford-AstraZeneca, or two doses of Janssen. Further, they found that this protection against severe disease and death was extended to both the general population and elderly.

55. Many public health experts feel that until the world is vaccinated, there will be ongoing emergence of new variants; similarly, if the world had been adequately vaccinated, dangerous and immune-evasive variants like Omicron would have been less likely to


\textsuperscript{174} Alam, “Insight into SARS-CoV-2.”

56. There is strong evidence that COVID-19 vaccines were particularly protective for elderly and medically vulnerable populations, especially during the Alpha and Delta waves.

57. COVID-19 vaccines are effective for people 65 years of age and older, and reduce the incidence of disease, symptomatic disease, hospitalization, and death. For example, elderly adults who completed 2 doses of either Pfizer/Corminaty or Moderna/Spikevax had a 94% reduced risk of COVID-19 related hospitalization. Aging causes immune function decline; additionally older adults tend to have more chronic diseases which can make them frail and more vulnerable to severe COVID-19. Subsequently, booster doses have been especially important for elderly people because additional doses have shown to boost antibody response and increase protection from the virus. Given that age is known

References:

184 Gavin Yamey et al, "It is not too late to achieve global covid-19 vaccine equity," BMJ 376 (March 2022):e070650. doi: https://doi.org/10.1136/bmj-2022-070650
187 Sara Hegg and Dorota Reilge, "COVID vaccination in older adults," Nature Microbiology 7 (July 2022):1106-1107. doi:10.1038/s41564-022-01166-0
to be such an important predictor of severe COVID-19, Bulgaria should have prioritized this population.

58. When COVID-19 vaccines became available in December 2020 and early 2021 (therefore before Omicron, and during the Alpha and subsequently Delta waves), there was existing evidence from tens of thousands of people in the form of various clinical trials which demonstrated safety and/or efficacy of the vaccines available in Bulgaria.190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208

207 Jordan Barrett et al, "Phase 1/2 trial of SARS-CoV-2 vaccine ChAdOx1 nCoV-19 with a booster dose induces multifunctional antibody responses," Nature medicine 27, no.2 (February 2021):279-288. doi: 10.1038/s41591-020-01179-4
208 Katie Ewer et al, "T cell and antibody responses induced by a single dose of ChAdOx1 nCoV-19 (AZD1222) vaccine in a phase 1/2 clinical trial," Nature medicine 27, no.2 (February 2021):270-278. doi: 10.1038/s41591-020-01194-5
59. Available COVID vaccines work in different ways but ultimately trigger our body to
develop immunity through generation of “memory” T-lymphocytes and B-lymphocytes that
will remember the virus and how to fight it.

60. The vaccines available in Bulgaria between December 2020 and June 2021 included:

*The vaccine known as Pfizer-BioNTech (BNT162b2) and is currently marketed as
Comirnaty:*

1. Examples of what was known at the time of vaccine delivery to Bulgaria:
   a) Vaccine efficacy in preventing symptomatic COVID-19 for people aged
      65 years and above was 94.7%, and 100% for those aged 75 years and
      above.\(^{209}\)

   b) A multinational, placebo-controlled, and observer-blinded RCT with
      43,448 people who received injections (21,720 with BNT162b2 and
      21,728 with placebo), demonstrated that a two-dose regimen conferred
      95% protection against COVID-19. The incidence of serious adverse
      events was low and similar between the groups.\(^{210}\)

2. Examples of what was known in 2021 during more early availability:
   a) Within 12,872 participants over the age of 70 years, a single dose of the
      BNT162b2 vaccine was found to be 60-70% effective at preventing
      symptomatic disease, and two doses were found to be 85-90% effective.
      Those who were vaccinated and went on to have symptoms had a 44% lower
      risk of being admitted to a hospital and a 51% lower risk of death
      compared with people who were unvaccinated.\(^{211}\)

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\(^{210}\) Polack, “Safety and Efficacy BNT162b2”

\(^{211}\) Jamie Lopez Bernal et al, “Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on covid-19 related
b) People aged over 80 years had an 80% lower risk of hospitalization for COVID-19 than those who were not vaccinated.\textsuperscript{212}

c) Data from a health registry (1,880,351 adults between ages 65-109 years, pooled data for Comirnaty and Spikevax) determined that mRNA vaccine effectiveness against COVID-19-related hospitalizations was 94% and 82% for those 65-79 and ≥ 80 years old, and 96% against COVID-related mortality.\textsuperscript{213}

3. Examples of what is known now:

a) A nationwide analysis in Finland between December 2020 and March 2022, and included 896,220 individuals aged 70 years or older, found that vaccine efficacy against COVID-19-related hospitalization was 93% and 85% at 14-90 and 91-180 days after the second dose. Vaccine efficacy increased to 95% 14-60 days after the third dose (booster). Protection against severe COVID-19 requiring ICU treatment was 98% and 92% at 14-90 and 91-180 days after the second and 98% at 14-60 days after the third dose.\textsuperscript{214}

b) A retrospective study with 400,136 people over the age of 60 found BNT162b2 to be 83% effective at preventing hospitalization, and 88-94% effective at preventing COVID-related death.\textsuperscript{215}

c) A study including 43,596 long term care facility residents with an average age of 83 years, found that vaccine efficacy from a two-dose


\textsuperscript{214} Ulrike Baum et al, "High vaccine effectiveness against severe COVID-19 in the elderly in Finland before and after the emergence of Omicron," BMC Infect Dis 22, no.1 (November 2022):816. doi:10.1186/s12879-022-07814-4

series was 81.2% for infection, 85.3% for COVID-related death, and 63.7% for all-cause mortality.\textsuperscript{216}

d) A systematic review using data through November 2021, demonstrated that Comirnaty compared to placebo: \textsuperscript{217}

(1) reduced the incidence of symptomatic COVID-19 with a vaccine efficacy of 97.84%, with a high grade of evidence
(2) reduced the incidence of severe or critical disease with a vaccine efficacy of 95.70%, with a high grade of evidence
(3) could not be compared for serious adverse events due to insufficient evidence mainly because the number of serious adverse events was low.

\textit{The vaccine known as the AstraZeneca COVID-19 Vaccine (ChAdOx1-SARS-CoV-2), and is currently marketed as Vaxzevria:}

1. Examples of what was known at the time of vaccine delivery to Bulgaria:
   a) Vaccine efficacy against symptomatic COVID for people aged 65 years and older was 83.5%.\textsuperscript{218}

   b) A pooled analysis from 4 blinded RCTs found that of 11,636 participants, the overall vaccine efficacy was 70.4%. Safety data from 74,341 person-months of follow-up after the first dose and 29,060 person-months of follow-up after two doses, confirmed an acceptable safety profile.\textsuperscript{219}

2. Examples of what was known in 2021 during more early availability:

\textsuperscript{216} Sivan Goldin et al, "BNT162b2 mRNA COVID-19 (Comirnaty) Vaccine Effectiveness in Elderly Patients Who Live in Long-Term Care Facilities: A Nationwide Cohort," Gerontology 68, no.12 (February 2022):1350-1357. doi:10.1159/000521899


\textsuperscript{219} Voysey, "Safety and efficacy ChAdOx1!"
a) Within 19,960 participants over the age of 70 who received one dose of ChAdOx1-S, there was a 37% reduced risk of emergency hospital admission. A single dose was about 60-75% effective against symptomatic disease.220

b) People aged over 80 years had an 80% lower risk of hospitalization for COVID-19 than those who were not vaccinated.221

c) Among people greater than 80 years of age, vaccine efficacy against symptomatic COVID-19 was 80.4% after only 1 dose.222

3. Examples of what is known now:

a) A retrospective study with 265,730 people over the age of 60 found ChAdOx1nCoV-19 to be 90.8% effective at preventing hospitalization, and 93.9% – 97.5% % effective at preventing death.223

b) A systematic review using data through November 2021, demonstrated that Vaxzevria compared to placebo:224

   (1) reduced the incidence of symptomatic COVID-19 with a vaccine efficacy of 70.23%, with a high grade of evidence

   (2) Resulted in little or no difference in serious adverse events

223 Arregocés-Castillo, "Effectiveness vaccines older adults," 242-252.
224 Graña, "Efficacy safety COVID-19 vaccines."
The vaccine known as the Moderna COVID-19 Vaccine (mRNA-1273), and is currently marketed as Spikevax:

1. Examples of what was known at the time of delivery to Bulgaria:
   a) An RCT/clinical trial was conducted at 99 centers across the United States and enrolled 30,420 people. The vaccine efficacy for preventing COVID-19 overall was 94.1% and 86.4% for people aged 65 years and greater. Aside from transient local and systemic reactions, no safety concerns were identified.\(^{225}\)

   b) Efficacy against symptomatic COVID-19 in people aged 65 or greater was 86.4%, and 100% for people aged 75 years of age and greater.\(^{226}\)

2. Example of what was known in 2021:
   a) Data from a health registry (1,880,351 adults between ages 65-109 years, pooled data for Comirnaty and Spikevax) determined that mRNA vaccine effectiveness against COVID-19-related hospitalizations was 94% and 82% for those 65–79 and \(\geq 80\) years old, and 96% against mortality.\(^{227}\)

3. Example of what is known now:
   a) A systematic review using data through November 2021, demonstrated that Spikevax compared to placebo:\(^{228}\)
      
      (1) reduced the incidence of symptomatic COVID-19 with a vaccine efficacy of 93.20%, with a high grade of evidence 
      (2) reduced the incidence of severe or critical disease with a vaccine efficacy of 98.20%, with a high grade of evidence 
      (3) resulted in little or no difference in serious adverse events

\(^{225}\) Baden, "Efficacy and Safety mRNA-1273"
\(^{227}\) Baltazar, "mRNA vaccine effectiveness"
\(^{228}\) Graña, "Efficacy safety COVID-19 vaccines."
The vaccine that has been known as the J&J/Janssen COVID-19 Vaccine (Ad26.COV2.S), and is currently marketed as Janssen or Jcovden:

1. Example of what was known at the time of delivery to Bulgaria:
   a) At 28 days post-vaccination, efficacy against symptomatic COVID-19 in the 65 years and older population was 82.4%, and 100% for people aged 75 years and above. Efficacy against severe COVID was 70.1% and 65.5%, respectively.

2. Example of what was known in 2021 when available in Bulgaria:
   a) A multinational, blinded, placebo-controlled RCT/clinical trial, where 19,630 SARS-CoV-2–negative participants were vaccinated and 19,691 received placebo, demonstrated that Ad26.COV2.S protected against moderate to severe critical Covid-19. Vaccine efficacy was higher against severe critical Covid-19 (76.7% - 85.4%). The incidence of serious adverse events was similar between the vaccine and placebo groups.

3. Examples of what is known now:
   a) A retrospective study with 64,997 people over the age of 60 found Ad26.COV2-S to be 60.9% effective at preventing hospitalization, and 85-95% effective at preventing death. Within age groups 70-79 years, it was 77.9% effective at preventing hospitalization.

   b) A systematic review using data through November 2021, demonstrated that Janssen/Jcovden compared to placebo:

   (1) reduced the incidence of symptomatic COVID-19 with a vaccine efficacy of 66.9%, with a high grade of evidence

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231 Arregocés-Castillo, "Effectiveness vaccines older adults," 242-252.  
232 Graña, "Efficacy safety COVID-19 vaccines."
(2) reduced the incidence of severe or critical disease with a vaccine efficacy of 76.3%, with a high grade of evidence
(3) resulted in little or no difference in serious adverse events

61. It is also known that medically and/or socially vulnerable people have been disproportionately impacted by COVID-19, and are more likely to die from the disease, and have lower COVID-19 vaccination rates.\textsuperscript{233, 234, 235, 226, 237, 238, 239, 240, 241, 242}

62. Dr. Hans Kluge, the regional director for WHO Europe, reminded the world that "protecting older people...is everyone's business," when he announced that 95% of COVID-19 fatalities on the continent had been people older than 60.\textsuperscript{243} In the United States, 75% of cumulative deaths have been in people over the age of 65.\textsuperscript{244} In fact, the differing case fatality rates between countries has been linked to the proportion of elderly people:

\textsuperscript{233} Clare Brown, Sean Young, and George Pro, "COVID-19 vaccination rates vary by community vulnerability: A county-level analysis," \textit{Vaccine} 39, no.31 (July 2021):4245-4249. doi:10.1016/j.vaccine.2021.06.038
\textsuperscript{238} Amaia Calderón-Larrañaga et al, "High excess mortality in areas with young and socially vulnerable populations during the COVID-19 outbreak in Stockholm Region, Sweden," \textit{BMJ Glob Health} 5, no.10 (October 2020):e003595. doi:10.1136/bmjgh-2020-003595
countries with more elders have higher case fatality rates because elderly people account for the majority of deaths.\textsuperscript{245}

63. COVID-19 vaccines have clearly saved and impacted many lives. For example:

- Between December 2020 and July 2021, The United States' Department of Health and Human Services estimated that COVID-19 vaccination was associated with prevention of over 25 million cases, 38 million hospitalizations, and 213,000 deaths, nationally.\textsuperscript{246}

- In England, between January 2021 and October 2021, unvaccinated people compared to vaccinated people (2 doses) had a 28 times higher mortality rate.\textsuperscript{247}

- Public Health England estimated that between January 2021 and September 5, 2021, COVID-19 vaccinations prevented 230,800 hospitalizations in people over age 45.\textsuperscript{248}

- In November 2021, The European Centre for Disease Prevention and Control (ECDC) and WHO Regional Office for Europe estimated that within 33 countries across the WHO European Region and among those aged 60 years and older, 470,000 lives had been saved due to COVID-19 vaccinations.\textsuperscript{249} The number of people whose health was impacted is certainly far higher as that estimate did not

\textsuperscript{245} Christian Hoffmann and Eva Wolf, "Older age groups and country-specific case fatality rates of COVID-19 in Europe, USA and Canada," Infection 49, no. 1 (February 2021), 111-116. doi:10.1007/s15010-020-01538-w


include data from people less than 60 years of age, or data from reduced transmission.

- Using data through November 2021, and across countries in the European Region who reported age-specific or age-aggregated data (Bulgaria does not), it was estimated that COVID-19 vaccination for older people saved 469,186 lives.  

- From December 2020 through December 2021, during the eras of Alpha and Delta variant predominance, 30,643,878 cases and 439,682 deaths associated with COVID-19 were reported across 48 states in the United States. A 10% improvement in vaccination coverage was associated with an 8% reduction in mortality rates and a 7% reduction in new infections.

- Between December 2020 and December 2021 COVID-19 vaccination was estimated to have directly prevented 14.4 million deaths globally. Estimates for an excess mortality measure for the same period of time was prevention of nearly 20 million deaths.

- Data from the United States’ Centers for Disease Control and Prevention (CDC) through August 2022, found that the risk of dying from COVID-19 among unvaccinated adults compared to adults in the same age group who completed a primary vaccination series was 3 times higher for adults aged 18–29 years, 5 times higher for adults aged 30–49 years, 6 times higher for adults aged 50–64 years, 9 times higher for adults aged 65–79 years, and 4 times higher for those aged ≥ 80 years.

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From December 2020 through November 2022, the COVID-19 vaccination program in the United States is estimated to have prevented more than 18.5 million hospitalizations and 3.2 million deaths. Without vaccination, there would have been nearly 120 million more COVID-19 infections. The vaccination program also saved the U.S. approximately $1.15 trillion in medical costs.\textsuperscript{254}

64. Furthermore, vaccination against COVID-19 has been associated with a reduced burden of Long COVID. The burden of Long COVID is not entirely known, but mounting data suggests it is and will remain significant.

65. A meta-analysis of 54 studies and 2 medical record databases totaling 1.2 million people who had symptomatic SARS-CoV-2 infection between March 2020 and January 2022, estimated that 6.2% of people experienced at least one long COVID symptom.\textsuperscript{255} An estimated 15.1% of people with Long COVID continued to experience symptoms at 12 months.

66. A systematic review, current through June 2022, which included 11 peer-reviewed studies and six preprint studies, used data from 17,256,654 people and suggested that vaccination was associated with reduced risks or odds of long-COVID, with preliminary evidence suggesting that two doses are more effective than one dose.\textsuperscript{256} Since this review, more reports have emerged suggesting the benefit of vaccination against Long COVID.\textsuperscript{257, 258}

\textsuperscript{258} Claire Hastie et al, "Outcomes among confirmed cases and a matched comparison group in the Long-COVID in Scotland study," Nat Commun 13, no.1 (October 2022):5663. doi:10.1038/s41467-022-33415-5
67. At this time in the United States, Long COVID is recognized as a disability under state and local government and public accommodations of the Americans with Disabilities Act, the Rehabilitation Act of 1973, and the Patient Protection and Affordable Care Act. 259

B. Vaccine Policies are Determined by States and Regional Bodies

68. The European Medicines Agency (EMA) continually monitors the safety and effectiveness of COVID-19 vaccines and works closely with the ECDC and the WHO. Despite the European Union (EU) sharing the same regulatory framework, each Member State is responsible for its own national vaccination campaign resulting in different implementation. 260, 261

69. Mortality rates and COVID-19 vaccine uptake have varied throughout the EU. One possible explanation includes the varying COVID-19 response measures. For example:

- a study reflected on the relationship between cumulative COVID-19 mortality and vaccine uptake. 262 The researchers found that after vaccine roll outs, countries with higher COVID-19 vaccination coverage were associated with improved (reduced) cumulative COVID-19 mortality; countries with low vaccination coverage were unlikely to show improvement in COVID-19 mortality. The researchers also found that by December 2021, Bulgaria was estimated to have 95% more COVID-19 deaths than expected. 263

263 Ibid
- a study analyzed data from 50 countries in the WHO European Region, in addition to data from the USA and Canada, and found that excess mortality was associated with reduced vaccination. They concluded that the degree of enforcement of government public health regulations was independently correlated to the excess mortality observed during 2020 and 2021 pandemic years, particularly in Eastern Europe.  

C. Vaccine Prioritization

70. In January 2021, The European Commission (EC) set a goal to vaccinate at least 80% of people over the age of 80 years and 80% of health and social care professionals in every EU/European Economic Area (EEA) country by March 2021.  

71. As the vaccines were scarce in the beginning, based on public health practices, lessons learned from previous health disasters, and mounting information and data on COVID-19, most countries and international organizations recommended vaccines be initially prioritized to vulnerable people and populations at high risk for severe disease. For example (non-exhaustive list):

- The World Health Organization (WHO):
  - In April 2020, the WHO Regional Director for Europe Dr. Hans Henri P. Kluge released a statement detailing that older adults were at a significantly increased risk of severe disease, and that "over 95% of these deaths occurred in those older than 60 years. More than 50% of all deaths were people aged 80 years or older." He also outlined that a large portion of deaths occurred in

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individuals with comorbid conditions, such as cardiovascular disease and diabetes.266

○ In May 2020, a Global Framework for equitable allocation of COVID-19 products was presented to member states and published.267 With a goal of "protecting public health..." they outline initial target groups for vaccine allocation: health and social care workers, high-risk adults such as the elderly and those with comorbid conditions, and an undefined "further target groups."

○ In June 2020, an updated Global Framework for equitable allocation and use of COVID-19 vaccines was presented to member states and published.268 With the goals of "reducing mortality and protecting health systems..." they outline prioritized populations for COVID-19 products: healthcare system workers, adults over age 65, and other high risk adults, defined as "adults between age 30-70 suffering from cardiovascular disease, cancer, diabetes, obesity or chronic respiratory disease," based on WHO data.

○ In July 2020, a policy brief on managing COVID-19 for people who require long-term care services was published.269 They discuss how people with chronic health conditions "experience difficulties in accessing essential health care services..." They elaborate that "residents of long-term care facilities are often facing higher risk, lower preventive measures and

inadequate resources to manage COVID-19. Older people, particularly those with underlying conditions who are more likely to develop severe COVID-19, make up a large proportion of those using long-term care services…” They call for immediate action to prevent infection and mitigate the impact of the COVID-19 pandemic among this population along with policy recommendations.

- In September 2020, a "final working version" of an "allocation mechanism" for COVID-19 was published.\textsuperscript{270} It recommends that target groups be defined based on "analysis of global epidemiological and scientific evidence..." and to use a "tier" group system. An example of a tier 1 group included frontline workers in health and social care settings, people over age 65 years, and people under age 65 who have underlying conditions that put them at a higher risk of death.

- The European Centre for Disease Prevention and Control (ECDC):
  - In July 2020, a technical report with guidance on the provision of support for medically and socially vulnerable populations in EU/EEA countries and the United Kingdom was published.\textsuperscript{271}
  - In October 2020, guidance for the introduction and prioritization of COVID-19 vaccinations was published. They proposed several target groups including individuals at risk of severe COVID-19, essential workers, all individuals above a certain age, and targeting groups with an increased risk of exposure.\textsuperscript{272}


In December 2020, strategies for vaccination prioritization in the EU/EEA was published, including the observation that "substantial reductions in mortality and pressure on the healthcare system could be achieved by the direct protection of high-risk groups," and "vaccination of healthcare workers is beneficial since it improves the resilience of the healthcare system."\(^{273}\)

In January 2021, a risk assessment was published and encouraged Member States to "accelerate...vaccination for high-risk groups, such as the elderly and healthcare workers," and elaborated that "...vaccination should be focused on protecting those most at risk..."\(^{274}\)

In March 2021, guidance was issued for COVID-19 vaccine challenges and good practice.\(^{275}\)

In April 2021, guidance for vaccination strategies was published.\(^{276}\) Public health goals included reduction of pressure on the healthcare system and reduction of severity and mortality. The ECDC reported that most deaths and hospitalizations occurred in older adults and people with comorbid conditions and stated that "if these groups were...protected against severe COVID-19, there would be a substantial decrease in bed occupancy and deaths and the pressure on the healthcare system would be significantly reduced."

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The United States Centers for Disease Control and Prevention (CDC):

- Starting June 2020, the Advisory Committee on Immunization Practices (ACIP) convened 10 public meetings to review evidence-based information pertaining to COVID-19 vaccines, including initial allocation of COVID-19 vaccine supplies. The COVID-19 Vaccines Work Group held 28 meetings to review data regarding vaccine candidates, COVID-19 surveillance, modeling of allocation scenarios, and vaccination program implementation issues. The Work Group also considered the relevant scientific literature, including ethical principles related to vaccine allocation in the setting of limited supply. These were published on the CDC website and remain available and open to the public.277,278,279

- On December 1, 2020, Phase 1a included health care personnel and long-term care facility residents. 280 On December 20, Phase 1b included persons aged ≥75 years and non–health care frontline essential workers. Phase 1c included persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b.

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In 2020, the United Nations (UN), Council of Europe, and the European Union also published guidance, including principles of equity, human rights, and ethical standards.  

D. Vaccination Allocation and Distribution

72. Throughout 2020, internationally societies released guidance on how to deploy vaccines ethically and equitably (non-exhaustive list):

- In March 2020, the United Nations Office of the High Commissioner for Human Rights, released a statement emphasizing human rights responsibilities, including that certain groups, such as older persons, those with disabilities, displaced persons, people in detention, among others, would need support and additional protective measures.

- In May 2020, the United Nations Sustainable Development Group released a policy brief detailing the impact of COVID-19 on older persons. They discussed the higher mortality and increased vulnerability of the elderly, and the need for social and health protections.

- In September 2020, The WHO released a values framework for the allocation and prioritization of vaccinations. This included priority groups for vaccination and

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286 "SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccines," World Health Organization, September 2020,
highlighted the additional risk to healthcare workers, older adults, and people in hard-to-reach population groups.

- In October 2020, the ECDC released a technical report discussing prioritization of vaccinations in the EU and the importance of ethical considerations.287 This included possible priority groups such as healthcare workers and the elderly.

- In January 2021, the Council of Europe published ethical, legal and practical considerations for member States, including for vaccine allocation.288

- The WHO published operational guidance on vaccine deployment, development of vaccination strategies, and uptake strategies in October 2020, January 2021, February 2021, and April 2021.289

73. Furthermore, many countries released guidance on how to deploy vaccines ethically and equitably, for example (non-exhaustive list):

- In October 2020, The Royal Society and British Academy released policy strategies detailing that vaccinations save lives, that vaccine deployment faces misinformation, and successful deployment would require significant communication with the public.290 They highlighted vulnerable groups including


people aged 65 years and older, people in crowded settings such as senior care facilities, and those with certain underlying medical conditions.

- In October 2020, the US National Academies of Sciences, Engineering and Medicine released a Framework for Equitable Allocation of COVID-19 Vaccines.\textsuperscript{291}

- In November 2020, The Australian Government published a Vaccination Policy plan.\textsuperscript{292} They outlined three priority groups: 1) those with increased risk of exposure including healthcare workers; 2) those with increased risk for severe disease including Aboriginal people and elders; and 3) those working in services critical to societal functioning.

E. The Case of Bulgaria

74. In early March 2020, Bulgaria confirmed the first documented case of COVID-19.\textsuperscript{293} In response, Bulgaria and the Council of Ministers declared a state of emergency.\textsuperscript{294} Throughout 2020, the Republic of Bulgaria reissued an emergency epidemic order, due to the "existing immediate danger to the life and health of citizens," and called on the Minister


76. Around the same time, Bulgaria's Governmental Cabinet approved the National Vaccination Plan Against COVID-19, which created five phases for the Bulgarian vaccine roll out.\footnote{Decision No. 418 of the Cabinet of Ministers of 2020 on the extension of the period of the emergency epidemic situation announced by the Presidential Decree No. 325 of May 14, 2020, extended by the Presidential Decree No. 378 of June 12, 2020, "Unified Information Portal, 2020, https://coronavirus.bg/bg/448. Accessed December 2022.} Briefly:

- Phase 1 included healthcare professionals
- Phase 2 included persons from social institutions, pedagogical specialists, and the staff of mink farms
- Phase 3 included employees of key state activities, without further elaboration of what these activities were
- Phase 4 included people aged 65 years and older, and persons with chronic diseases or who were immunocompromised
- Phase 5 was estimated to include other vulnerable people

\footnote{Decision No. 525 of the Cabinet of Ministers of 2020 to extend the period of the emergency epidemic situation announced by the Presidential Decree No. 325 of May 14, 2020, extended by the Presidential Decree No. 378, the Presidential Decree No. 418 and the Presidential Decree No. 482, "Unified Information Portal, 2020, https://coronavirus.bg/bg/498. Accessed December 2022.}


77. On December 26, 2020, the first shipment of vaccines arrived in Bulgaria (10,725 doses of Comirnaty/Pfizer mRNA vaccine). In January 2021, limited shipments of Spikevax/Moderna mRNA vaccine became available, while in February, Vaxzevria/AstraZeneca arrivals began. Between December 2020 and the end of March 2021, just over 852,000 doses were delivered. Janssen/J&J vaccine arrivals started in April 2021. Between December 2020 and the end of June 2021, just over 4,662,500 combined vaccine doses were delivered. This included 2,838,420 doses of Comirnaty, 1,183,200 doses of Vaxzevria, 488,400 doses of Spikevax, and 152,500 doses of Janssen. The Alpha variant was predominant in Bulgaria in January 2021, while the Delta variant became dominant in July 2021.

78. In February 2021, Bulgaria supplemented the National Vaccination Plan to expand phase 3 to include people involved in elections, for example the members of the Central Election Commission, and allow simultaneous vaccination of phase 2 and phase 3. Shortly thereafter, an additional amendment to the National Vaccination Plan was added to allow people who did not fall into phases 1-5 to be vaccinated if they desired and if vaccines were available. This created what has been referred to as "green corridors."

79. According to the Joint ECDC-WHO Regional Office surveillance website, there is no data from any period reported from Bulgaria on the number, rate or proportion of COVID-19 cases, deaths, or hospitalizations by age, comorbid condition, among others. This lack of more complete data or systematic reporting is concerning and a missed public health opportunity. A global pandemic requires a global response – an available and accessible

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data system is important for knowledge sharing, transparency, and contributes to preparedness and response mechanisms at both a local and international level.

80. Between December 2020 and the end of June 2021, and when compared to the rest of the EU, Bulgaria had, relative to its population size:\(^{309}\)
   - the highest COVID-19 case fatality rate
   - the 3rd highest number of confirmed COVID-19 deaths
   - the lowest amount of COVID-19 vaccine doses administered
   - the lowest number of people fully vaccinated (11.88% of the population)

81. The Bulgarian Ministry of Health has published a small amount of mortality data.\(^{310}\) In 2020, the average number of deaths from COVID-19 was 123 per 100,000 population. The number of people who died in the:
   - 60-64 age group was 210 per 100,000 people
   - 65-69 age group was 280 per 100,000 people
   - 70-74 age group was 384 per 100,000 people
   - 75-79 age group was 483 per 100,000 people
   - 80+ age group was 561 per 100,000 people

82. Data from the Open Data Portal, a Bulgarian governmental public data source reveals that:
   - between June 2020 and December 2020: 7,417 people died from COVID-19, of which 84% of deaths were in people over age 60.\(^{311}\)

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\(^{310}\) "Benefits of Vaccination," Ministry of Health, no date, last updated 2023, https://plusmen.bg/%D0%B2%D0%B0%D0%BA%D1%81%D0%B8%D0%BD%D0%B0%D1%86%D0%B8%D1%8F%D1%82%D0%B0%D1%82%D0%B5%D0%BC%D0%B8. Accessed January 2023.

• Between January 2021 and June 2021: 10,485 people died from COVID-10, of which over 86% were people over the age of 60.\textsuperscript{312}

• between June 2020 and December 2021, 30,474 people died from COVID-19, of which over 85% were people over the age of 60.\textsuperscript{313}

• in 2021, 23,057 people died from COVID-19. Approximately 3.5% of deaths occurred in vaccinated adults. It is not reported how many doses they had, but given that deaths recorded in vaccinated individuals was not reported until the end of April 2021, it is reasonable to guess that these may be adults who had completed a primary series.\textsuperscript{314,315}

83. Between December 2020 and the end of June 2021, the cumulative uptake of a complete (2 dose) COVID-19 vaccine in Bulgaria was:\textsuperscript{316}

• 32% of people in long-term care facilities
• 20.8% of healthcare workers
• 20.3% of people aged 60 years and older

84. Within the WHO European region between the same time frame (December 2020 and the end of June 2021), the cumulative uptake of a complete (2 dose) COVID-19 vaccine was:\textsuperscript{317}

• 67.6% of people in long-term care facilities (median uptake)
• 62.3% of healthcare workers (median uptake)
• 59.7% of people aged 60 years and older (median uptake)


\textsuperscript{313}"Ibid"


\textsuperscript{317}"Ibid"
85. As of January 10, 2023 there have been 1,293,491 confirmed SARS-CoV-2 infections, and 38,127 deaths in Bulgaria.\textsuperscript{318} There have been 26,309 confirmed cases in Medical Staff workers alone.\textsuperscript{319}

86. Demographical data from the Bulgarian National Centre for Infectious and Parasitic Diseases is available for approximately 87% (1,126,945) of the above officially confirmed and registered cases.\textsuperscript{320} Important statistics include:

- People above the age of 65 years accounted for 76.7% of all deaths in Bulgaria.
- Males between the ages of 65-74 years of age accounted for most deaths, while among women, the highest number of deaths occurred in the age group 75-84 years.
- The mortality rate overall was 3.2%. However, it was 15% for people aged 65-74 years, 22.7% for people aged 85-94 years, and 24.7% for people over 95 years of age.
- Only 12.78% of people infected had received at least one dose of a COVID-19 vaccine.
- Vaccination reduced the risk of death among those infected by approximately 59%.

87. As of December 14, 2022 a total of 14,434,990 vaccine doses have been distributed to Bulgaria, yet only 4,600,565 vaccine doses have been administered.\textsuperscript{321}

88. Poor vaccine uptake manifested early in the pandemic, persists to current times, and has contributed to SARS-CoV-2 infections and deaths in Bulgaria. Across the world, the downward trend of death rates has correlated with scientific progress, such as the roll out of therapeutics and interventions, including COVID-19 vaccines and the subsequent


\textsuperscript{320} Information obtained following a Freedom of Information request filed by the Bulgarian Helsinki Committee, Decision No. 32 / 12.12.2022 for providing access to public information, issued by Prof. Dr. Iva Hristova, PhD. Director of the National Centre for Infectious and Parasitic Diseases, pursuant to Art. 28(2), in conjunction with Art. 34 of the Access to Public Information Act (APIA).

progressive uptake of them. It is not a coincidence that deaths and case fatality rates were reduced in most parts of the world as vaccination uptake increased. It is impossible to ignore the correlation between negative outcomes and vaccination rates in Bulgaria. As of January 2023 (cumulative and relative to the population):

- **When Bulgaria is compared to the world (combined pooled data globally - a very macroscopic view), Bulgaria has:**
  - a higher amount of confirmed COVID-19 deaths per million people
  - a higher case fatality rate
  - a lower amount of COVID-19 vaccine doses administered per 100 people
  - a lower share of people fully vaccinated

- **When Bulgaria is compared to individual continents (Asia, Africa, Europe, North America, South America, Oceania, Australia), (combined pooled data within each continent only, data may therefore be more specific to that region – a macroscopic view), Bulgaria has:**
  - a higher amount of confirmed COVID-19 deaths per million people
  - a higher case fatality rate
  - a lower amount of COVID-19 vaccine doses administered per 100 people, with exception for Africa
  - a lower share of people fully vaccinated, with exception to Africa

- **When Bulgaria is compared to the European Union, Bulgaria has:**
  - the highest confirmed COVID-19 deaths per million people
  - the highest case fatality rate
  - a lower amount of COVID-19 vaccine doses administered per 100 people
  - a lower share of people fully vaccinated

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• When Bulgaria is compared to Eastern Europe (using the UN classification of regions, data available for: Belarus, Czechia, Hungary, Moldova, Poland, Romania, Slovakia, Ukraine), Bulgaria has: 325, 326
  ○ the highest confirmed COVID-19 deaths per million people
  ○ the highest case fatality rate
  ○ the highest excess mortality rate (data partially available)
  ○ the lowest amount of COVID-19 vaccine doses administered per 100 people
  ○ the lowest amount of people fully vaccinated

89. This burden of disease in Bulgaria was most likely avoidable if vaccination uptake had steadily increased.

90. As of December 11, 2022, 2,076,422 people in Bulgaria have completed a primary series, which is approximately 30% of the population. 327 Bulgaria has the lowest rate of primary series completion in the EU. 328 Besides Bulgaria, and Romania at 42%, the rest of the EU has upwards of 50% primary series completion, with 9 countries above 70% and 6 countries above 80%. 329 Bulgaria is also significantly behind other EU countries in uptake of the first and second booster doses. 330

91. When looking at the completion of the primary series of COVID of vaccination by age, through December 2022, Bulgaria also remains behind the EU. 331 Completion of a primary series among adults aged 60 years and older is above 90% for more than half of EU

330 Ibid.
countries; Bulgaria has the lowest primary series completion at 38.4% of adults 60 years and older.\textsuperscript{332}

92. A recent review and comparison of the COVID-19 healthcare responses in Bulgaria and neighboring countries highlighted pre-existing healthcare problems and how COVID-19 exacerbated them.\textsuperscript{333} For example, Bulgaria has an aging population, increasing demand for healthcare services with geographical imbalances of available services, a shortage of healthcare workers particularly in more rural areas, rising health care costs, and a growing burden of chronic diseases.\textsuperscript{334} Despite social insurance, the review found that about 15% of people in Bulgaria remain uninsured. They also discussed that many people in Southeastern Europe have low levels of trust in authorities due to widespread government corruption - which in turn is bound to impact the uptake of health advice and vaccinations. Taken together, these are examples of significant factors that Bulgaria needed to address in a public health campaign to bolster their COVID-19 response.

93. The severe impact of the pandemic in Bulgaria has already been attributed to a combination of demographics, uncontrolled viral transmission, misinformation, mistrust, a poorly prepared hospital system, and importantly, low vaccination uptake.\textsuperscript{335, 336}

94. Notably, from the start of vaccination in Bulgaria in December 2020, through the end of November 2022, there have only been 4,188 reports of adverse reactions, or 0.091% of the nearly 4.6 million COVID-19 vaccines administered.\textsuperscript{337}

\textsuperscript{332} Ibid
\textsuperscript{334} Ibid
\textsuperscript{335} Antoni Rangachev, Marinov GK, Georgi, and Mladen Mladenov, "The Impact and Progression of the COVID-19 Pandemic in Bulgaria in Its First Two Years," Vaccines 10, no.11 (November 2022):1901. doi:10.3390/vaccines10111901
\textsuperscript{337} "Of the nearly 4.6 million COVID-19 vaccines administered, there were 4,188 reports of adverse reactions -- or 0.091% of all vaccines administered," Unified Information Portal, November 24, 2022, https://coronavirus.bg/bg/news/3679. Accessed December 2022.
VI. Public Health Campaign and Communication regarding Covid-19 Vaccination

95. Health communication is an important and possibly the main component needed for cooperation during a public health emergency, infectious disease outbreak, or pandemic. Besides instructing local and national governments and health institutions on how to respond, and participating in international knowledge sharing, health communication is essential to establish and maintain trust with the general population.

96. Vaccine hesitancy, is defined as the reluctance or refusal to vaccinate despite the availability of vaccines, and has been named as one of the top threats to global health. A vaccines advisory group to WHO identified complacency, inconvenience in accessing vaccines, and lack of confidence as key reasons underlying hesitancy. The COVID-19 vaccines have proven to be safe and effective, but the belief that they are ineffective, unsafe and/or unnecessary remains pervasive among certain populations.

97. Vaccine hesitancy has been revived and worsened by the COVID-19 "infodemic." The WHO defines an infodemic as too much information including false or misleading information, in digital and physical environments, during a disease outbreak. They elaborate that it causes confusion and risk-taking behaviors that can harm health, leads to mistrust in health authorities, and undermines the public health response.

98. Structural factors, such as barriers to accessing vaccines or healthcare and socioeconomic disadvantages are also known to drive low vaccine confidence and uptake.

99. People who distrust healthcare workers, health systems, or governmental institutions are also more likely to be vaccine hesitant.

339 Ibid.
341 World Health Organization, "Infodemic"
342 ibid.
100. Eurobarometer is a polling instrument used by the European Commission, among others, to monitor public opinion in the EU. In May 2021, Eurobarometer conducted a survey titled “Attitudes on vaccination against COVID-19,” where they found that among Bulgarian responders:

- 23% reported they would never get vaccinated against COVID-19. The EU member state average was 9%.
- 40% believed that authorized COVID-19 vaccines in the EU were not safe. The EU average was 18%.
- Ranking of online social networks, websites, media, and people in the community for reliable COVID-19 vaccine related information was higher than the EU member state average.

101. Research from Gallup found that people in Eastern Europe are the least likely to believe that vaccines in general are safe and effective. In 2020, before COVID-19 vaccinations were available, a poll revealed that only 33% of Bulgarians were willing to receive a COVID-19 vaccine.

102. It is vital that public health and vaccination campaigns address the doubts that people have around safety and effectiveness, and pre-emptively address the harms of information overload, while working to build and maintain trust with the public.

103. Health authorities around the world discussed and advised on health communication as part of the COVID-19 response, and many provided resources. For example (non-exhaustive list):

A. The World Health Organization:
   - In January 2020, a guidance report on risk communication and community

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engagement was published. For example, the document states “One of the most important and effective interventions in public health response to any event is to proactively communicate…” and that health communication “…helps prevent…the spread of misinformation, builds trust in the response and increases the probability that health advice is followed…”

- In March 2020, an update on the above-named report on risk communication and community engagement, was provided.

- In June-July 2020, WHO held an Infodemiology Conference to address the overabundance of information, how to measure and control infodemics, and called for a coordinated response.

- In December 2020, a Global Risk Communication and Community Engagement Strategy was published. They call the COVID-19 pandemic an "information crisis," and discuss the need for health communication.

- In February 2021, a community assessment tool was published and designed to help national local health authorities assess community health needs and perceptions about health services during the COVID-19 pandemic.

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• In May 2021, a tool for health worker communication and vaccination workflow was published.\textsuperscript{351}

• In May 2021, guidance on critical actions for pandemic preparedness and response was published.\textsuperscript{352} This included a section on risk communication and infodemic management.

B. The European Centre for Disease Prevention and Control:

• In June 2020, a Rapid Risk Assessment report which included Risk Communication, outlining the importance and purpose of health communication.\textsuperscript{353}

• In February 2021, a risk assessment warned that "increasing levels of pandemic fatigue need to be properly addressed as a matter of urgency," and that public health authorities must understand community perceptions of the pandemic.\textsuperscript{354}

• In June 2021 a guidance report, factsheet, training package and presentation was published to provide "insights for national public health authorities into the factors behind the spread of vaccine misinformation...and capacities needed for responding to it..."\textsuperscript{355, 356}


C. The European Commission has included fighting disinformation as part of their Coronavirus response.357

D. The American CDC has had a variety of health communication toolkits and resources published and updated throughout the pandemic.358, 359, 360

E. In July 2020, the Organisation for Economic Co-operation and Development released a policy brief focusing on COVID-19, health communication, and disinformation.361

VII. Conclusion/Summary

104. COVID-19 has arguably become one of the deadliest and most catastrophic events in our lifetimes.

105. All people are susceptible to and capable of being infected with SARS-CoV-2.

106. COVID-19 can become a very serious multi-system disease, which can lead to, among other things, respiratory, heart and kidney failure, blood clots, neurological complications, secondary infections, and death. Older patients and patients with chronic underlying conditions are at a particularly high risk of severe disease and complications. The most

significant risk factor for severe disease or death from COVID-19 is age. Older patients have higher mortality rates compared to the younger population.

107. Among people who recover from the acute phase of COVID-19, there is a growing body of evidence demonstrating that many suffer prolonged symptoms or complications, often referred to as "Long COVID."

108. Since testing became available, more than 660,100,000 infections and more than 6,600,000 deaths have been reported worldwide. As of January 10, 2023, there have been 1,293,491 confirmed SARS-CoV-2 infections, and 38,127 deaths in Bulgaria.

109. The scientific literature and public health data from around the world have demonstrated that COVID-19 vaccines are very safe, effective, and that their benefits in reducing transmission and preventing severe disease and death extend to all ages - but particularly to older individuals.

110. Bulgaria has had a disproportionate amount of people die; elderly people in particular have been impacted. The severe impact of the COVID-19 pandemic in Bulgaria is related to low vaccination uptake. Across the world, the downward trend of death rates has correlated with scientific progress, namely COVID-19 vaccines and the progressive uptake of them. It is not a coincidence that deaths and case fatality rates were reduced in most parts of the world as vaccination uptake increased. It is impossible to ignore the correlation between negative outcomes and vaccination rates in Bulgaria. When compared to Eastern Europe, the European Union, other continents, and the world, Bulgaria has the highest COVID-19 deaths per million people, the highest case fatality rate, and the lowest or near lowest amount of COVID-19 vaccines administered per 100 people and share of people fully vaccinated. When compared to the European Union, Bulgaria has had a disproportionate amount of people die; elderly people in particular have been impacted. Bulgaria also has the lowest amount of COVID-19 vaccines administered.
111. Given well-established public health practices, expanding evidence for the effectiveness of COVID-19 vaccines in preventing death and severe disease, and clear statistical data demonstrating that certain people and communities were more likely to die from COVID, most countries’ vaccine rollouts prioritized high risk populations, namely those above the ages of 60-65 and people with underlying medical conditions.

112. It is likely that Bulgaria’s vaccine prioritization and related policies put hundreds of thousands of people at risk for death and disease and contributed to the relatively high burden of disease and death from COVID-19 in the country. It is apparent that these same policies failed to center basic human rights principles and equity for the most vulnerable and/or marginalized Bulgarian people. It is our further opinion that these groups, namely the elderly and those with vulnerable medical conditions and social circumstances, were denied their right to life, health, and safety, protection of the family, and the right to benefit and enjoy the highest attainable standard of health.

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